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Process Factors Influencing Informed Consent for Participation in Clinical Research

Thesis submitted in partial fulfilment of the requirements of the Doctor of Philosophy Degree, Northumbria University, Newcastle upon Tyne

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Declaration

I declare that the work contained in this thesis has not been submitted for any other award and that it is all my work. I also confirm that this work fully acknowledges the ideas, opinions and research of authors, being referenced within the thesis.

Ethical clearance for my research was granted by Northumbria University Faculty Research Ethics Committee on 10 September 2014 and by NRES Committee Yorkshire & Humber-Sheffield Research Ethics Committee on the 20th day of October 2014 (14/YH/1220).

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Abstract

Background

Nationally and internationally, evidence indicates that the process of informed consent for clinical research is not fulfilling the purpose for which it was intended, despite efforts by Research Ethics Committees (REC). The reason for this is unknown. Many studies have looked at the views of healthcare professionals on the process of informed consent for participation in clinical research but few focus on the views and overall experiences of real-life clinical research participants. There is a need therefore to gain more insight, particularly from service users' perspectives.

Methods & Analysis

Nineteen (19) clinical research participants were interviewed after having taken part in the process of informed consent for participation in clinical research studies. The interviews were conducted face-to-face individually in natural settings and were audio recorded with informed consent. Following verbatim transcription, constructive thematic analysis was conducted, and transcripts were coded to develop categories and themes. Themes were applied to discover theoretical concepts.

Findings

Four themes emerged from the data, namely: Trusting Interpersonal Relationships; Researcher Attributes; Study Information; and Personhood. The factors that influenced participants' decision making concerned the involvement of a trusted clinician and the timing of such involvement. The interpersonal attributes of the person seeking consent and how the participants perceived the relevance of the information being shared also influenced engagement and decision making. Other factors that encouraged research participation related to personal interests, the desire to do good and/or the hope for a cure. Perceived barriers to participation included intellectual limitations, lack of research awareness, social, physical, and demographic challenges, transportation, burden of illness, and interference with family life.

Conclusion

The findings suggest that the decision to sign up for research was influenced by a range of factors other than the content, size, or layout of written study information. There appears to be a conflict between the perspectives of real-life patients and those of policy makers in relation to the factors influencing decision making for clinical research.

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Chapter 1

Introduction & Background to Study

Introduction

The aim of this PhD research is to examine the process factors influencing informed consent for participation in clinical research. The need for an integrative and individualised approach to evidence generation was made apparent by the seemingly unparalleled complexity that exists at the frontline of ethical research practice (Symonds et al, 2012; Shannon-Dorcey & Drevdahl, 2011; Seely, 2010; Griffin et al, 2006; Green and Britten, 1998). There remains an unwelcome outcome whereby prospective clinical research participants sign up for clinical research with little or no understanding about the studies which they signed up for (Armstrong et al, 2012; Stryker et al, 2006). Eccles, Freemantle and Mason (1998) noted that practice guidance, such as ethical research guidelines, are valid only if they yield the health gains and expenses predicted for them; and that invalid guidelines, on the other hand, can lead to ineffective interventions that waste resources, or even do harm (Sandelowski, 2004). Such negative consequences have persisted and are undesirable in the process of informed consent for clinical research (Harvey & McInnes, 2015). Hence, the need to explore the process factors that may influence the outcome of the consent process in clinical research practice (Dickert, Eyal and Goldkind, 2017). Such relational insight may be of great benefit in the considerations for effective strategies to improve prospective clinical research participants' overall experiences of their care (Baranski et al, 2015; Staniszewska et al, 2014). It may also support researchers in the design, ethical conduct and recruitment stages of clinical research practice.

Additionally, clinical research participants' overall experiences of their care are important given that many trials often fail to recruit enough participants (Nilsen et al, 2013), an undesirable outcome in the utilisation of scientific evidence. Research that involves the

consumer is valuable not only for improving participants' experiences of the informed consent process, but also for enabling participants' involvement in the generation of scientific evidence, such as: on how a meaningful informed consent process might be achieved (Nilsen et al, 2013). This is recognised as an essential step towards reducing the evidence-practice and policy gap that has long endured in healthcare and clinical research (Grimshaw et al, 2012).

According to Ellis (2016 pg. 5) research implies the "structured and conscious application of scientific method to the exploration of an issue of interest in order to either better understand the issue or to establish new truths". One of the distinctive characteristics of a research study therefore is the identification of a problem or concern, to which additional insight or understanding is required. This chapter will give insight into the rationale for this research by providing some understanding of the history of ethical research within healthcare and the concept of informed consent in clinical research practice. Furthermore, the chapter will review the historical incidents that have led to the renewed emphasis on ethical research. It will also examine the regulatory and monitoring requirements that underpin the conduct of research in UK and international contexts, as well as from ethical and legal perspectives. The chapter will go on to consider the concept of informed consent being at the heart of ethical research and map out the essential elements of a valid informed consent. In doing so, it will explain the professional ethos that guides clinical researchers in monitoring and safeguarding the integrity of research outcomes, and of those who volunteer their lives to support and uphold clinical research across the globe. The chapter concludes with a 10-step-plan for evidence-based informed consent processes underpinned by current practice standards.

Background

The Nazi Doctors Experiments

1945 saw the liberation of war prisoners from Nazi medical abuses, where prisoners were treated as experimental animals with no regard for their autonomy or the principles of consent (Weindling, 2004). During World War Two, physicians and scientists from the German Air Force and other Nazi Institutions conducted a series of experiments using prisoners to test pharmaceuticals and to establish treatment for the good of the German military and occupation personnel (Weindling, 2006). The horrific and gruesome experiments took place at the German concentration camps and were not only perceived as war crimes, but were known to be influenced by racial discrimination, and therefore genetically and ethically undesirable (Mitscherlich and Mielke, 1949). The poison gas experiments received international condemnation not only because the inhumane, gruesome and deadly experiments were ethnically biased, but more so they were carried out on concentration camp prisoners without information or consent, making them crimes against humanity (Lou, 2000). Consequently, the Nazi doctors' experiments gave birth to a war of a different kind (Marks, 2006); a series of criminal trials ensued under the watch of an International Scientific Commission (ISC) and the monitoring of Nuremberg prosecutors (US military tribunals in Nuremberg) (Weindling, 2006). Using victims' testimonies, the review unmasked criminality and a chilling mass of documentation on euthanasia and sterilisation by German military medics, all in the name of science (Marks, 2006). International support for the condemnation of such medical abuses at any scale gave birth to the Nuremberg Code, which recommended a requirement for consent from experimental subjects (The Nuremberg Code, 1947). The Nuremberg code introduced a new framework for informed consent, which permeates modern medicine to this day, and will be discussed in greater detail under the regulatory and monitoring requirements sub-section later in this chapter.

The Tuskegee Syphilis Research

Following the Nazi atrocities, there were revelations about the Tuskegee syphilis study, which ran in the United States of America from 1932 until its public discovery in 1972 (Brandt, 1978). The Tuskegee Syphilis research was conducted by the United States Public Health Service (USPHS) to determine the natural course of untreated, latent syphilis (White, 2000). Its subjects were more than 400 men infected with syphilis, and a further 200 uninfected men who served as controls, all of men were of black minority ethnic origins (Brandt, 1978). The study continued despite the establishment of penicillin as an effective treatment for syphilis (White, 2000), with participants being denied effective treatment.

However, while the Tuskegee study brought about hope in the treatment and eradication of syphilis, the research subjects were prevented from benefiting from the research (Jones, 1981). In the interest of science, the USPHS denied treatment for the subjects at a time when the therapeutic option was available and the benefit-to-toxicity ratio in latent infections was unclear (Weindling, 2006). Despite the establishment of treatment in the 1940s, the subjects of the research were not offered treatment until the 1970s after the US Department of Health, Education and Welfare (HEW) had investigated the research (Jones, 1981). The investigation ruled that the malicious act of withholding treatment was responsible for the avoidable death of more than 100 research subjects (Lou, 2000). The deaths were ruled to be ethically unjustified given that they could easily have been prevented had the subjects been offered penicillin at the time that treatment had become available.

Like the Nazi doctors' experiment, the logic of non-treatment was rooted in the pervasiveness of a malicious and prejudicial nature among the medical researchers. There were ethical imperfections in the manner that they pursued science at the expense of the well-being of research subjects. Moreover, there were racial injustices in the creation and perpetuation of both studies (Mitscherlich and Mielke, 1949). It is noteworthy that although the outcry against the Nazi doctors' experiments surfaced before the revelations of the

Tuskegee study, the latter had been going on from 1932, prior to when the Nazi doctors' experiments were known to have occurred. Thus, elements of hypocrisy and ethical failings in research were detectable on both sides of the Atlantic. These historical events served to reinstate distrust of the medical and public health systems by members of the public, whose interests the systems were meant to protect.

Bristol Royal Inquiry and Alder Hey Hospital Inquiry, UK

More recent examples of ethically improper research exist in the United Kingdom. There was the Bristol Royal Infirmary Inquiry into children's heart surgery (Bristol Royal Infirmary, 1984-1995); and the Alder Hey Hospital Inquiry into the collection of babies' and children's organs (The Royal Liverpool Children's Inquiry Report, 2001). In 1998, an inquiry was set up to investigate the deaths of 29 babies who underwent heart surgery at the Bristol Royal Infirmary in the late 1980s and early 1990 (Bristol Royal Infirmary Inquiry, 2001). The Bristol Royal Infirmary Inquiry recounted that patients and their families had been left in the dark about the poor standard of care provided to their loved ones without adequate oversight by authorities (Bristol Royal Inquiry, 2001; Batty, 2001). The inquiry revealed far-reaching consequences about patients' rights and accountability in the health service, concluding that patients and the public should be more involved in decisions about their treatment and care, and that patients must be treated with respect and honesty, emphasising patients as the centre of the NHS (DH, 2002). Specifically, there was a call for 'a consent process which engages patients fully in decisions about their care' (DH, 2002). Relating to scientific research and the process of informed consent (or lack thereof), a different inquiry was conducted in the UK following revelations that three children's hospitals had been harvesting hearts, lungs and other organs from dead babies for purposes of scientific research without their parents' consent (DH, 2001b: the Royal Liverpool Children's Inquiry Report). The incidents occurred at the Liverpool's Alder Hey Hospital, where 2,080 organs were removed from 800 children, following post-mortems of children (Batty, 2001). It is documented that parents of deceased children were deceived into signing a fraudulent

consent form, without realising that by signing the consent form for a post-mortem, the hospital also held back a range of body parts belonging to the children. The motive for the illegal and unethical activities was said to be due to the sharing of children's organs with pharmaceutical companies for purposes of scientific research by a Dutch pathologist, Professor Dick van Velzen, between 1988-1995 (DH, 2001b; Batty, 2001; Hall, 2001). In response, the UK government and the British Medical Association (BMA) emphasised the need for fully informed consent for all activities involving human beings (DH, 2005; BMA, 2020), including human tissues before or after death (Hall, 2001; Human Tissue Authority (HTA), 2004). The Human Tissue Act 2004 regulates the removal, storage and use of any material that has come from a human body and requires that no human tissue can be removed for whatever purpose, including scientific research, without the consent of the person from whom the tissue came from, or from someone in a qualifying relationship (HTA, 2004). The recommendations heralded a new approach to consent and the initiation of new consent forms across the NHS (Hall, 2001; DH, 2001). There have since been further amendments in cases of organ transplantation as part of ongoing review of consent and public interests (HTA, 2017).

Ethical Frameworks for Clinical Research

The Nuremberg Code 1947

The above historical abuses highlight behaviours that had persisted, in some cases unchallenged, in the consciousness of scientific and/or medical supremacy (Spitz, 2005). Clearly, there was a need for a new way of thinking at a fundamental level, to ensure that research was ethical and just (Mahase, 2019; WMA, 2013; Gelling, 2011; Forster, 2001; Beecher, 1966). Professional self-interests were called out and shamed (Lacbucci, 2018). Medical paternalism could no longer be trusted or justified (Wells & Farthing, 2008; Hall, 2001). There was a change in perception, where patients and service users were seen as intelligent collaborators in decisions affecting their health and well-being (GMC, 2013),

rather than mere objects of research (Woodhead and Faulkner, 2008). In particular, the need to realize and seek permission through a process of informed consent from prospective research participants was recognised within the UK and internationally (GMC, 2013). Regulations started to emerge (The Nuremberg Code, 1947; Declaration of Helsinki, WMA 1964; Vollmann and Winau, 1996; Weindling, 2004). A change of terminology was also noted, moving from ‘subjects’ to ‘research participants’, especially within the social sciences, where qualitative enquiries dominate (Lincoln and Guba, 1985).

The Nuremberg Code of 1947 set forth the ethical basis of disclosure and unequivocal consent (The Nuremberg Code, 1947). The code was the product of extensive interrogations and ethical appraisals between the parties of the Nuremberg tribunal, which condemned in the name of science, any such coercive experimentation on human subjects (Weindling, 2006). Respect for humane and ethical research was considered paramount to justify experiments on human beings. The Nuremberg Code is widely accepted as the first manuscript to provide ethical standards for human research with a particular emphasis on informed consent from prospective research participants (The Nuremberg Code, 1947; Annas, 1992). However, there are debates on whether the code merits such accolade. Citing the Prussian directives, and the Nesser Case in 1891 and 1898 respectively, some critiques have argued that principles for consent may have existed before the Nuremberg tribunals (Vollmann and Winau, 1996; Ghooi, 2011). Nevertheless, the establishment of the Nuremberg Code provided explicit rules governing biomedical research on human beings. The code brought renewed emphasis onto the concepts of autonomy, beneficence and informed consent. The first of these principles emphasises the voluntary consent of the human subject as essential. It also brought about explicit rules with greater emphasis on the well-being of those taking part in clinical research. This responsibility was placed not only on the Principal Investigators (PI) but also on all those who engage in and direct the research process regardless of their role. The emphasis on voluntary consent will be explored in greater depth under the sub-heading ‘the concept of informed consent’.

The Declarations of Helsinki 1964

Subsequent to the Nuremberg Code of 1947, the World Medical Association (WMA) gathered for the first time in Helsinki, Finland in June 1964 to discuss and formulate an initial response to the renewed emphasis on ethical research. In their first response, and in solidarity with the Nuremberg Code, the WMA concurred that although the primary purpose of medical research was to generate new knowledge, such a goal should never take precedence over the rights and interests of human research subjects (WMA, 1964 – Declaration of Helsinki). Ultimately, they reinforced that the primary mission of the physician was to safeguard the health and well-being of people under their care (WMA, 1964). This meant that neither the need for diagnostic or therapeutic interventions nor the interests of science could take precedence over the physical or mental well-being of human subjects (The international Code of Ethics, 2009). Notably, there was emphasis on informed consent and the obligations of the physician researcher was prescribed (Principles 9-11, WMA 1964). Respect for prisoners and equality of treatment, including medical attention, was noted also in the Geneva Conventions (International Committee of the Red Cross, 2016).

Principles were agreed and declared, since referred to as the WMA 'Declarations of Helsinki' (WMA, 1964), consisting of twelve basic ethical research principles. However, there has been a number of amendments, and this now comprises of 37 ethical research guidelines following subsequent conventions (Helsinki, WMA 1964; Tokyo, WMA 1975; Italy, WMA 1983; Hong Kong, WMA, 1989; South Africa, WMA 1996; Edinburgh, WMA 2000; Washington, WMA 2002; Tokyo, WMA 2004; Korea, WMA 2008; and Brazil, WMA 2013). The latest version of the WMA Declarations of Helsinki was last updated at the assembly in Brazil in 2013.

The Belmont Report 1976

The Belmont Report reviews international frameworks and is one of the earlier foundations for ethical research conduct at international levels. Reacting to the Tuskegee revelations

(above), the US Congress gathered at the Smithsonian Institution's Belmont Conference Centre, to discuss and reset principles for the protection of human subjects in biomedical research at national levels (The National Commission for the Protection of Human Subjects in Biomedical and Behavioural Research, 1979). A report of these proceedings led to 'The Belmont Report', which provides an ethical framework for those involved in research in the United States. The report recognised and reinforced the philosophical principles of respect for persons, beneficence, and justice. While directed at those involved in research, its principles also relate to clinical care and are recognised worldwide (Cassell, 2012).

Although the Declarations of Helsinki (WMA, 1964), the Nuremberg Code of (1947) and the Belmont Report (NCPH, 1979) stipulate international bioethics guidelines and promote the exercise of caution and conscience in the conduct of bioethical research worldwide, the ethical codes were not implicated under any law nor are binding in any sense (Ghooi, 2011; Gillon, 1994). Therefore, physicians were merely guided by their professional and ethical obligations, or as their conscience led them.

Medico-Regulatory Frameworks for Clinical Research

The International Conference on Harmonisation (ICH) and the Good Clinical Practices (GCP) (ICH-GCP Guidelines)

The non-mandated system could not be sustained. To achieve high levels of quality assurance and compliance, there needed to be the promotion of agreed ethical codes beyond individual conscience or morality. Hence, at an international level, the establishment of regulatory authorities started to emerge. The International Conference on Harmonisation (ICH) gathering established a set of directives for the conduct of biomedical research on human subjects. Key directives includes the E6 (R1 and R2) Good Clinical Practice guidelines (GCP), initially finalised and published in 1996, with a subsequent

revision in November 2016 (GCP – ICH, 1996 and 2016: E6 R2); and the E8 General Consideration for Clinical Trials (ICH, 2019: E8 (R1)).

The GCP-ICH (1996) guidelines prescribe a set of responsibilities and expectations of all those involved in conducting research involving human beings, as well as their records, including the responsibilities of investigators, monitors, sponsors and research ethics committees (ICH-GCP, 1996). The goal of the ICH was to bring together various regulatory authorities, as well as the pharmaceutical industry and, through harmonisation, promote high standards of scientific and ethical research conduct and outcomes internationally. It now consists of 17 member countries and 32 observers (ICH, 2020) including Brazil, China, Canada, Singapore, Korea, The USA and the European Commission (EC). The ICH-GCP standards observe regular updates (ICH 2016; E6 (R2) and mimics the Declarations of Helsinki (WMA, 1964 & 2013) in the manner that it upholds ethical principles. In particular, the ICH-GCP guidelines emphasise informed consent from every subject prior to their participation in any clinical study (principle 9).

The European Commission Directives

In 2001, the European Commission targeted efforts towards the implementation of Good Clinical Practice (GCP) in the conduct of clinical trials on medicinal products for human use across its Member States. Its goal was to lay down a uniform rule and to provide common detailed guidelines that would enable the functioning of a harmonised application system in different Member States on issues relating to the conduct of research involving human subjects. On 4 April 2001 therefore, the European parliament and the Council of Member States agreed on the Clinical Trials Directive (Directive 2001/20/EC), which prescribed the laws, regulation and administrative provisions of the Member States with regards to the implementation of GCP in the conduct of clinical trials on medicinal products for human use. The directive established that the protection of human rights and the dignity of the human subjects must be protected in the conduct of clinical trials on investigational medicinal

products across its Member States. This included the ethical standards of ensuring that clinical research is not conducted unnecessarily; that GCP guidelines are observed; and that the safety and rights of research subjects are protected, including of individuals who may be deemed incapable of giving informed consent (EU Directive 2001/20/EC).

Significantly, the European Commission Directives of 2001/20/EC stipulate the monitoring of Good Clinical Research Practice Standards by way of laws, inspections and research ethics review committees. Having regard for the Nuremberg Code (1947) and the international statements of ethical principles for medical research (WMA, 1964), the European Commission adopted the principle of informed consent among other ethical research standards and amalgamated this into regulatory law (Directive 2001/20/EC of the European Parliament and of the council, 2001). In particular, the EU Directive 2001/20/EC meaningfully initiated provisions relating to the practical implementation of ethical review committees and competent authority approval procedures.

The EU Directive 2001/20/EC specified that before the start of a proposed study, an ethics review committee is required to give a favourable opinion (Article 9 (1) Directive 2001/20/EC) in order to enable an overview of the proposed study before human subjects should take part in it. The ethics review committee was given the responsibility of protecting the rights, dignity and well-being of all those taking part in clinical research and by so doing, hoped to restore public confidence in the conduct of scientific research.

In order to establish a reasoned opinion, the ethics committee considers specific aspects of an application for a proposed study including the relevance of the study, the study design, the protocol, quality of facilities, anticipated benefits of the study against potential risks, and whether conclusions are justifiable. Ethics committees are allowed a maximum of 60 days to return their opinions to the researcher after applications are submitted. For certain types of proposals, such as those involving genetic therapy, Ethics committees are permitted 90 days, potentially extendable by a further 90 days where additional documentation is

required before an opinion can be reached. Other areas relate to the range and format of documentation to be submitted in an application, especially the size and acceptable wording of study documents. Insurance and compensations issues are also examined.

In 2005, 2014 and 2017, and further to the EU Directive 2001/20/EC, additional clauses were added to the initial principles of the 2001/20/EC directives, and in specific cases repealed some sections of the former. Commission Directive 2005/28/EC of 8 April 2005 introduced detailed guidelines regarding the requirement for authorisation of the manufacturing or import of investigational medicinal products for human use, as well as emphasising the existing guidelines for good clinical practice. EU No 536/2014 of the European Parliament emphasised the robust and reliable use and management of patients' data. Most recently, on 24 March 2017, EU 2017/556 emphasised the practical procedures for inspections including the need for unannounced inspections (Article 8); collaboration guidelines between Member States (Article 19); and reinforcing the importance of data integrity and confidentiality standards (Article 14). At European level therefore, Directive 2001/20/EC of the European Parliament, Commission Directive 2005/28/EC, EU No 536/2014 and the recent EU 2017/556 provide the regulatory references, principles and detailed guidelines for Good Clinical Practice (GCP) among EC Member States. Ultimately, a duty was put on everyone involved in research with human participants, their organs, tissue or data, to act lawfully, with honesty and integrity, and in accordance with Good Clinical Practice guidelines (Declarations of Helsinki -WMA, 1964; Directive 2001/20/EC of the European Parliament and of the council, 2001). Sponsors and investigators were directed to consider all relevant codes of conduct and guidelines in commencing and conducting a clinical study.

It remains to be seen how Brexit will affect UK research governance in the future. It is anticipated that withdrawal from the EU may affect certain policy areas such as health and care workforce, medicines regulation, research and procurement (DHSC, 2017). The government and other agencies claim they will continue to work to achieve the best

outcome for health and social care and research and innovation (Department of Health and Social Care (DHSC), 2017). The Royal Society (2020) suggests that any new regulation post-Brexit must support access to new medicines, technologies and constructive collaborations by maintaining current regulation and governance and European Reference Networks. Whatever the future relationship between the UK and the EU, it is anticipated that Brexit will not be allowed to impact badly on UK science, as such damage may prove costly and difficult to rebuild (Royal Society, 2020). The following section reflects the current UK Research Governance Framework at national level.

UK Research Governance Framework

With the United Kingdom (UK) being part of the European Commission at the time, the UK Department of Health (DH) published its Research Governance Framework initially in the year 2001, with a second edition in 2005. In it, the DH outlined principles of good governance in health and social care research (DH, 2001 & 2005). Its goal was to restore public confidence in scientific research, as it made some bold and innovative, albeit controversial, initiatives. The UK government, through the Research Governance Framework, laid out the standards, responsibilities and accountabilities of all those involved in the conduct of Health and Social Care research (DH, 2005). Fundamentally, while it supported investment in research and was committed to making Britain the best place for research and innovation in healthcare, it recognised that the interests of research participants must come first (HRA, 2017; NRES, 2011; DH, 2005; WMA, 1964); and that the public has a right to expect high scientific, ethical and transparent decisions, with clear and robust monitoring arrangements in the conduct of health and social care research (DH, 2005). It emphasised that those responsible for health and social care research must ensure they take all reasonable steps to protect the dignity, rights, safety and well-being of research participants (DH, 2005).

Within the remits of ethical research practice and as stipulated by the European Directives (Directive 2001/20/EC of the European Parliament), the Research Governance Framework mandated all research involving patients, service users, care professionals or volunteers, or their organs, tissue or data, are reviewed by an independent Research Ethics Committee (REC) (DH, 2001). A favourable opinion must then be given before any research activity could be initiated (DH, 2005). All Health and Social Care research was required to meet the same general standards of governance regardless of research type, context or method. There was criticism by various stakeholders that the framework showed minimal consideration for the context and nature of research; and that procedures were stifling scientific research (Snooks et al, 2012; Knapp et al 2011; Fortun et al, 2008, Oliver, 2006; Stead et al, 2005; Cox, 2001).

The services monitored under the regulation included NHS healthcare services (UK-wide); Adult social care in England, Wales and NI; and Children's social care services in Wales & Northern Ireland (NRESS, 2011). Several other health and social care research arms were subject to the same regulation, and others were added to it over time.

UK Policy Framework for Health and Social Care Research 2017

In response to the difficulties reported by stakeholders regarding the UK Research Governance Framework (DH 2001 & 2005), and with a sense that the national Research Governance Framework merited a review, consultations led to the publication of renewed guidelines, the 'UK Policy Framework for Health and Social Care Research', which became effective in 2018, repealing the previous policy documents (HRA, 2017). The UK Policy Framework for Health and Social Care Research upheld most of the principles and guidelines from previous policies but sought to simplify governance and monitoring procedures. Like the RGF, it applies to all health and social care research, including interventional studies, and reinforces adequate consent and privacy safeguards for research participants (HRA, 2017). The UK Policy Framework for Health and Social Care

Research hopes to minimise ‘needless bureaucracy’ in the way it recognised that applying to do research needs to be simple and that getting a decision from ethical and governance bodies needs to be quick, with predictable timelines.

The UK Policy Framework reinforces the importance of ethical overview of scientific research conduct, but also recognises the need for a proportionate review of research proposals. Specifically, it encourages ethical consideration of individual research proposals be conducted in a manner that balances the risks of participation against the risk to the participant of not taking part in the research. On balance, the UK Policy Framework for Health and Social Care Research encourages a more straightforward approach to the initiation of scientific research (HRA, 2017) than was emphasised in previous policy documents.

UK Research Ethics Committees (REC)

To encourage that research be designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency (HRA, 2017 - Principle 5, The UK Policy Framework for Health and Social Care Research), Principle 9 of the policy framework mandates that a research project is started ‘only if a REC and any other relevant approval body have favourably reviewed the research proposal or protocol and related information, where their review is expected or required’ (HRA, 2017). To this effect, a proposed research study must undergo critical review by the REC and be given a favourable ethical opinion (and if the study is a trial of medicine, until there is clinical trial authorisation) before any aspect of the research study could take place (Gupta, 2013; DH 2005).

REC members consist of both lay and expert volunteers covering many disciplines, who review the ethical considerations of a given research proposal (HRA, 2020; DH, 2011). Upon the receipt of a review application, REC administrators conduct a quick initial assessment of the application to decide whether a face-to-face invitation is required or whether a non-face-to-face proportionate review (in the absence of the researcher) can be

conducted (HRA, 2017). Depending on the outcome of the initial assessment, the investigator(s) are invited to attend a REC meeting whereby the research application will be rigorously reviewed.

Specifically, informed consent is one of the most important aspects of research ethics reviews (Gupta, 2013; Tschudin, 2001). During a REC review meeting, researchers are required to provide well-presented and balanced information about health research at all levels (Moore and Donnely, 2018; Kirkbride, 2013; Stanley, 2012). The use of accessible/lay language when dealing with patients throughout the research process is emphasised (Smajdor et al, 2009). The process allows researchers the opportunity to clarify any uncertainties relating to the study proposal to enable the committee to form their opinion of the proposed research (Chaudhry et al, 2013). Overall, it is expected that consideration is given to the well-being of the human subject and this must take precedence over any other motives including the interests of science and society (WMA 2008). Although it remains to be seen how these expectations are adequately monitored at the front line (Anonymous, 2012), the task is to ensure that all research projects are conducted lawfully, with honesty and integrity, and in accordance with good clinical practice standards (GMC, 2010).

With the recognition that informed consent is at ‘the heart of ethical research’ (DH, 2005), the Research Governance Framework enforces that studies involving individuals must have ‘appropriate arrangements’ for obtaining consent. During ethics review, researchers will need to certify that relevant information would be provided in appropriate written or pictorial form and that the role and responsibilities of patients, carers or supporters is clearly explained and understood (DH, 2005). Similarly, the current UK Policy Framework for Health and Social Care Research (HRA, 2017 pg. 17) instructs that where consent is sought:

"Potential research participants should be provided, normally by the research team, with the information they need to help them decide whether they wish to take part in research or not and should be given reasonable time to reach their decision. The information should be provided in a suitable format. Unless otherwise justified (e.g. by feedback from public involvement), the information should include a concise explanation of relevant research evidence and research in progress that shows why the proposed research is justified; a permanent and accessible copy of any information sheet should normally be made available to all participants; and consent should be documented and available for inspection by relevant regulators".

Relating to information provision, the current policy framework (HRA, 2017 pg. 17) advocates that:

*"Proportionality should be applied to the provision of information to potential research participants. The more research deviates from established practice or otherwise detrimentally affects the balance between the anticipated risks and benefits, the greater the amount of information that needs to be provided to potential participants. By the same token, the closer the research is to standard practice, the less need there is to provide patients and service users with detailed and lengthy information"***.**

Professional Standards

The UK General Medical Council (GMC)

The General Medical Council (GMC) governs medical ethics in the United Kingdom. In alignment to the ethical research regulations and governance frameworks, the General Medical Council (GMC, 2013) and the UK Nursing and Midwifery Council (NMC, 2018a; RCN, 2011) issued detailed guidance requiring every professional to understand and follow good clinical practice in the context of international ethical research guidelines. The guidance documents made clear the role and responsibilities of doctors and nurses in

seeking and obtaining consent to clinical research (NMC, 2018a; GMC, 2013). In particular, the GMC, in the 67th principle of its 'Good Medical Practice' guidance, specifies that all doctors 'must act with honesty and integrity when designing, organising or carrying out research, and follow national research governance guidelines' (GMC, 2013 pg. 21). This highlights the importance attached to ethical research practice, and the process of informed consent. Healthcare professionals are required to comply with the law, governance arrangements and the codes of professional practice relating to ethical research (GMC, 2013; GMC, 2010).

The UK Nursing and Midwifery Council (NMC)

For nurses involved in the conduct of clinical research, gaining informed consent from research participants is reinforced as central to the research process and to the role of clinical research nurses (NMC, 2018a; RCN, 2015). Broadly speaking, the 21st century nurse is guided to make sure that he or she seeks and obtains 'properly informed consent and document it' before delivering care to patients (NMC, 2018a). To be proficient, 'the future nurse' must demonstrate the ability to 'use appropriate communication skills and strength-based approaches to support and enable people to make informed choices about their care…' (NMC 2018b, pg. 8). The NMC expects that nurses must always prioritise people and must put the interests of those under their care first (NMC, 2018a). Every nurse must seek, understand and base all healthcare decisions on people's needs and preferences, recognising and addressing any personal and external factors that may unduly influence a patient's decision or infringe on their autonomy (NMC, 2018b). Essentially, there is a professional commitment for nurses to act as an advocate for the vulnerable by encouraging and empowering people to share in decisions about their treatment and care; and to be respectful of a person's right to accept or refuse treatment (NMC, 2018a). In doing so, the NMC requires nurses to take reasonable care to 'treat people in a way that does not take advantage of their vulnerability or cause them upset or distress' (NMC, 2018a pg.18).

The NMC professional standards of practice for nurses applies to all registrants, both in research and clinical care. Nurses have long been required to function as patients' advocates (NMC, 2018; RCN, 2009; UKCC, 1996), meaning that a nurse will be judged by the manner in which she/he supports the dignity and welfare of those under her/his care, especially vulnerable patients, at a time when they may be anxious or in an unfamiliar environment. Furthermore, the Royal College of Nursing suggests that nurses must take the responsibility to ensure that the 'interests' of patients are advocated and protected (RCN, 2015). The onus is on nurses therefore to exercise professional competence and judgement in supporting potential participants during the process of informed consent for participation in clinical research.

In today's clinical research practice, the role of the clinical research nurse is diverse and ever extending (Suttling, 2019; Gibbs & Lowton, 2012). Fundamental to the role of the nurse in the recruitment of participants, is a valid informed consent process that stands up to the scrutiny of recognised ethical and legal frameworks. It is increasingly common for the task of gaining informed consent to be delegated to clinical research nurses, who in all accounts are required to practice to the same standard, regardless of hierarchy (Pereira, 2019). Doctors and nurses therefore have an overriding duty of care to treat patients with dignity and respect during the process of informed consent (NMC, 2018a; RCN, 2017; GMC, 2010; MacInnes, 1999; Amnesty International, 2009), and to obtain a freely given informed consent (WMA, 2013; Duncan, 2010; Leino-Kilpi et al, 2000; Brazier and Lobjoit, 1991). This duty is regardless of the context of care, whether clinical or research-specific (NMC, 2018a; GMC, 2013). All healthcare professionals involved in the conduct of informed consent have a duty to act with integrity, making sure that their knowledge and skills match the level of performance required of them. All healthcare professionals are expected to use professional judgement with their skills and experiences to effectively deliver dependable research (HRA, 2017; GMC, 2010; DH, 2005).

The following section examines the theoretical elements of a valid informed consent to establish principles of care, and the role of research staff in upholding research integrity during the process of acquiring informed consent.

The Theory of Informed Consent

Whether in clinical care or clinical research, informed consent is ingrained in the framework of professional codes of practice (RCN, 2019; NMC, 2018a; HRA, 2017; GMC, 2010, 2013 & 2008). Legally, denial of a person's right to an informed rational choice is taken as an act of slavery, or the act of treating an individual as a mere object or instrument (Dworkin, 1997). Therefore, to safeguard a person's capacity for rational deliberation and choice is to respect an individual's dignity (Benjamin and Curtis, 2010). In tending to the sick, nurses, doctors and other healthcare professionals deal with people who, because of their illness and vulnerability, depend on that professional's expertise and skills to support them through various dimensions of need (NMC, 2018a; GMC, 2008). In doing so, healthcare professionals are reminded to treat all human beings as ends in themselves, not merely as means to an end (Kant, 2004). As such, in clinical research particularly, the Declarations of Helsinki (WMA, 2013: principle 8) emphasise that "while the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects". Therefore, it is as much a duty for researchers to safeguard not only the health and well-being of clinical research participants, but the dignity, integrity, and right to self-determination of those volunteering for research, as it is in clinical care (WMA, 1964: Principle 9 Declarations of Helsinki). It goes without saying that before a person can be given treatment in clinical care or in clinical research, the healthcare professional must seek and obtain a valid informed consent from the patient.

In clinical research, the European Medicines Agency (EMA) (2016) and The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016: E6 (R2) define informed consent as a 'process by which a subject voluntarily

confirms his or her willingness to participate in a research study, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate'. The DH adds that for consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the interventions being proposed or, in the case of under-age persons or persons without capacity, someone who has the authority to do so (DH, 2009). Echoing this, the GMC policy document 'consent to research' states that a 'participant's consent is legally valid and professionally acceptable only if they have the capacity to decide whether to take part in the research, have been properly informed, and have agreed to participate without pressure or coercion' (GMC, 2013 p.8). Others have defined informed consent as an individual's autonomous authorisation of a medical intervention or of participation in research (Beauchamp, 2017). It can be understood therefore that a valid informed consent must satisfy certain standards of disclosure of adequate information; a capacity by the individual to demonstrate adequate knowledge of the information provided; and the free will of choice to make their own decision without pressure or duress (Medical Protection Society, 2018; HRA, 2017; WMA, 2013; DH, 2009; RCN, 2009). Figure 1 illustrates the fundamentals of a valid informed consent. Any deviation from this framework can amount to professional negligence (e.g., Montgomery v Lanarkshire Health Board, 2015; GMC, 2008). This emphasises the seriousness and overriding duty of healthcare professionals to support patients in making an informed decision in their care within the spheres of clinical care and clinical research.

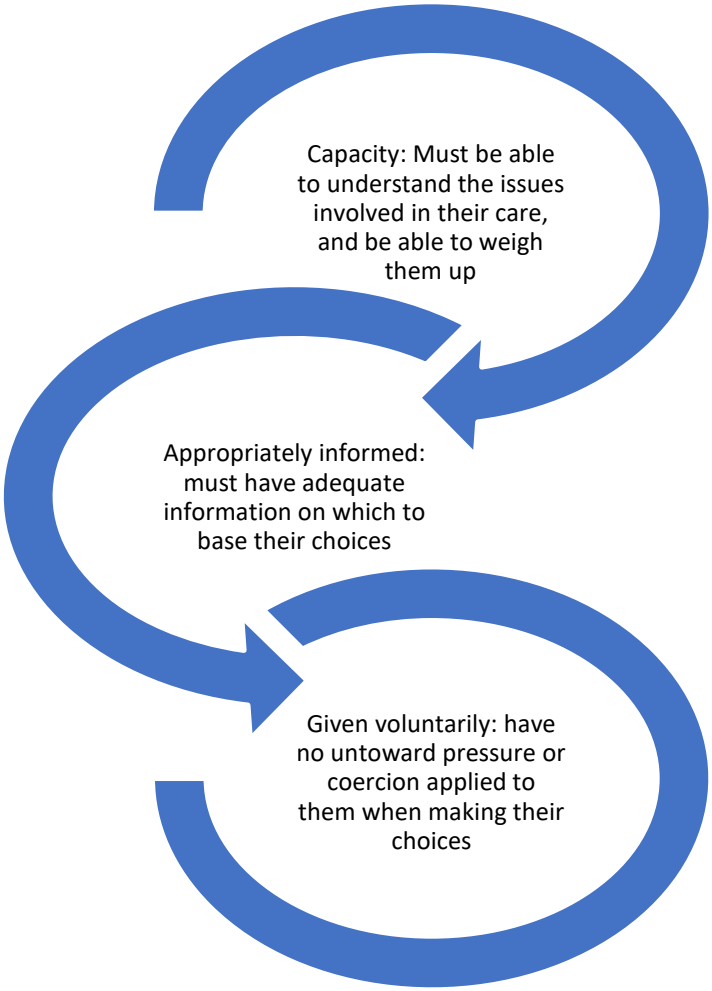


Figure 1 Fundamental elements of a valid informed consent

Capacity to consent: the patient must be competent

The Mental Capacity Act 2005 requires that informed consent is sought from a person who is deemed mentally competent to give consent (DH, 2005; Medical Protection Society, 2015). This means that a person is able to understand, believe, retain and weigh the necessary information, and to make their own decision to accept or refuse service, even if the decision appears irrational to others (GMC, 2008). On the other hand, 'a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment in the functioning of the mind or brain' (DH, 2017: Mental Capacity Act, 2005, Principle 2, as updated 2017). Hence, mental

capacity is a fluid concept in the sense that a person might be able to demonstrate mental capacity on a particular matter and at a particular time but might lack the mental capacity to process a more complex matter at the level required or at another time. It can also be that an impairment might fluctuate, in that it affects an individual depending on a range of other factors, including the nature of impairment (Nandra, Brockie and Hussain, 2020). For example, a patient might not have the mental capacity to make sense of information following an anaesthetic intervention, whereas the same person may be able to do so later if allowed enough time to recover from the effect of anaesthesia. Other examples where capacity may be temporarily impaired include: critically ill patients or those with loss of consciousness, hypoxia, pain, or alcohol (or other substance) intoxication (Nandra, Brockie and Hussain, 2020). A permanent impairment may necessitate a more elaborate assessment. In any case, the essential guidelines stipulate that a person must be assumed to have mental capacity unless it is established they lack capacity; a person must not be treated as unable to make a decision just because he or she appears to make an unwise or unpopular decision; every decision made on behalf a person lacking capacity must take into account the best interests of the person; and utmost care must be taken to minimise decisions that might impact on a person's right and freedom of action (Mental Capacity Act; 2005).

The fundamental freedoms set out in the UK Human Rights Act (1998) and the European Convention of Human Rights (ECHR) identified the right to have and express your own opinions as one of the fundamental human rights (Council of Europe, 1997; Human Rights Act 1998; European Convention of Human Rights Council of Europe, 1950: articles 9 & 10). It is therefore an internationally recognised priority that a person with mental capacity should be supported to make up their own mind, where they are able to do so. In the case of lack of capacity, there are guidelines on how to support such groups and individuals (see the GMC's ethical and legal guidance on consent for doctors, which can be applied to other healthcare professionals and the Mental Capacity 2005). This research focuses on

individuals who were considered capable of making their own decisions at the point that they were recruited to take part in clinical research.

Appropriately informed: sufficient disclosure of relevant information

According to the Medical Protection Society's guidance on consent, a person must be provided with enough information that will enable him or her to make a choice (Medical Protection Society, 2015). In relation to healthcare, the GMC stipulates that the patient must be given all information material to their decision, if doing so will not cause serious harm to the patient (GMC, 2008). Referring to material risk, the Medical Defence Union (MDU) (2018), citing the judgement in Montgomery v Lanarkshire Health Board (2015) UKSC 11, paragraph 87, explains that the test of material risk is judged by 'whether a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it'. The emphasis is noteworthy, as it signals a crucial shift in which what is meaningful is determined by the informational needs of patients (or of those in similar circumstances), instead of that determined by the profession. The 'duty to warn' was traditionally judged by the opinions of professional peers, those trained and practicing by the same standards as a clinician (Bolam v Friern Hospital Management Committee, 1957; Sideway v Board of Governors of the Bethlem Royal Hospital and others, 1985). However, a recent legal challenge by Montgomery v. Lanarkshire Health Board [Scotland] (2015) drew fresh attention to the concept of informed consent, overturning the previous decision and ruling instead in favour of patients' choices as opposed to the historical model of medical paternalism (Beauchamp & Childress, 2009; Komrad, 1983).

The Montgomery ruling is to be celebrated, as it agreed with the philosophical underpinning of this research, whereby the human agent is accepted as being capable of meaning making and worthy of self-determination (Lincoln and Guba, 1985). Practically, this implies that more effort needs to be made by anyone involved in the sharing and disclosure of

information to patients, especially by clinical research staff such as research nurses and all those involved in seeking informed consent from potential clinical research participants (Gibbs & Lowton, 2012). It requires that potential clinical research participants be supported to engage meaningfully in dialogue with research staff and that individuals be encouraged to express their choices and preferences for information disclosure. This research sets out to explore the views of clinical research participants on aspects of healthcare service, including the process of informed consent. This is to be encouraged, so that evidence can be generated on what is most important to patients, especially during information disclosure for clinical research. The current position recognises that no one, not even expert professionals, can decide what is right for another human being, as to be human is to be enabled to deliberate and make one's own choice, except for situations where the person is determined to lack capacity (Benjamin and Curtis, 2010; Mental Capacity Act, 2005).

Voluntariness without coercion

Freedom of expression (ECHR, 1950; Human Rights Act (1998), Article 10) is the third essential element for a valid consent (Medical Protection Society, 2015; HRA, 2017). A person must be able to give their consent freely, after having deliberated on the information provided to them and having the mental capacity to do so (Medical Protection Society, 2015). In enabling informed consent in health and clinical research, it is acknowledged that patients may be put under pressure by others to accept an investigation or treatment, or to take part in research (Pelto-Piri et al, 2019; Largent, 2017; BMC, 1995). To safeguard the rights and well-being of patients, it is required that healthcare professionals make efforts to support patients to consider all available options and enable patients to reach their own decisions (Mellado, 2016; Hardicre, 2014; Gupta, 2013; Kirby, 1983; The Belmont Report, 1979). In healthcare, voluntariness includes ensuring that patients are aware of their right to refuse treatment or to refuse participation in a proposed research study without repercussions (GMC, 2010; Nelson and Merz, 2002). The patient's decision or choice must then be respected without undue pressure on the patient either directly or subtly (Blitzer

and Sade, 2020; HRA, 2017). Thus, the Health Research Authority (HRA, 2017) in their guidance document on consent for research have added ‘a fair choice’ as the fourth of the fundamental ethical and legal principles underpinning a valid consent. Voluntary choice is one that is unrestrained by interference and unimpeded by another’s influence (Nelson and Merz, 2002), therefore ‘a fair choice’ can be taken as a component of voluntariness.

Philosophical foundations of informed consent

Autonomy

Ethically, the moral basis of consent is underpinned by the four principles of healthcare ethics, namely: autonomy, beneficence, non-maleficence, and justice (Casswell, 2012; Duncan, 2010; The Belmont Report, 1978). In the words of the Royal College of Nursing, ‘autonomy is the ability of an individual to make reasoned decisions about issues that affect them’ (2004 pg. 4). The principle of autonomy recognises that a person has the right to control his or her own life, so far as he or she possesses the capacity to think and reason, and the ability to action their thoughts (Duncan, 2010). Through the emphasis on freedom of choice, the informed consent process recognises the need for autonomy of action, and to do so without any form of restriction, in as much as an individual’s actions do not deliberately or inadvertently infringe on the autonomous right of others (ACOG, 2016). To respect a person is to respect their autonomy by seeking their wishes around decisions about their healthcare, and about their choices in healthcare research (RCN, 2009). Seeking informed consent before any clinical research procedure therefore respects a person’s moral right to bodily integrity and to self-determination, thereby supporting the patient’s freedom to make decisions on issues of his/her health, medical planning and care (ACOG, 2016).

Beneficence

The ethical principle of beneficence relates to a moral commitment by healthcare professionals to ensure they provide treatment that will benefit those under their care (Duncan, 2010). It is a moral obligation that links the concept of informed consent to the Hippocratic Oath, requiring that the clinician use his/her knowledge and expertise to benefit and help the sick, to the best of his/her ability (Green, 2017). Informed consent could therefore be seen as a reminder of these responsibilities to respect and safeguard the dignity and well-being of patients (Cassell, 2012). In the context of clinical research, McFarlane (2009) affirms that moral virtues ought to be lived out at all stages of the research process. The concept of informed consent requires clinical research participants to be treated with respect by ensuring that research staff do not deceive research participants as to the purpose of the study or its intended benefits (McFarlane, 2009; Benjamin and Curtis, 2010). The process of informed consent therefore needs to be respectful of the person and his or her individual circumstances, being attentive to the levels of risk of harm to the patient and ensuring that the expected benefit of the research outweighs the chances of harm to the patient (WMA, 2013).

Non-maleficence

Similarly, the principle of non-maleficence requires that healthcare professionals must not seek to harm their patients (Hawley, 2007). While the principle of beneficence requires that a healthcare professional actively seeks to do good in the best interest of his or her patient, the principle of non-maleficence requires the healthcare professional not only to avoid doing harm, but to also ensure he or she avoids the risk of harm to those under his/her care (Hawley, 2007). In medical care, Casswell (2012) compares the principle of non-maleficence to the principle of beneficence in terms of when doctors must manage scarce resources and so must consider the fates of different individuals if treated (doing good), and their fate if left untreated (avoiding the risk of harm).

Justice

The ethical principle of justice points to a fair and right action that assures equality with others (Hawley, 2007; Gelling, 1999). Justice does not mean that everyone could or should be treated as identical, or that every patient can be given the same medical treatment. Rather it encourages healthcare professionals to exercise due care in the manner they treat or care for individual patients (Growther & Smythe (2016). It considers that no patient should be disadvantaged in the quality of care they receive for reasons of socio-economic status, race, gender or religion (Hawley, 2007). Rather, treating people justly involves offering care that is appropriate to a patient's individual situation, depending on the patient's medical or social care needs, just as would be done for any patient, without discrimination or bias (Beauchamp, 2017). In research, the principle of justice obliges investigators to exercise due diligence at all stages of the research process. Specifically, the guidance for research provided by the GMC urges that clinical researchers 'must make sure that decisions at all stages of research, especially for recruitment, are free from discrimination and respect participants' equality and diversity. You should take all reasonable steps to make sure that people eligible to participate in a project are given equal access to take part and the opportunity to benefit from the research' (GMC, 2010: Principle 10). In clinical research therefore, justice could be demonstrated in the manner that researchers identify or recruit potential participants to ensure that no one is disadvantaged from taking part in research should they be eligible to do so (Hurd et al, 2017; Nilsen et al, 2013). On the other hand, the principle of justice may seek to protect vulnerable individuals from over-volunteering for research participation, to safeguard and protect vulnerable groups (GMC, 2010: Principle 17). To act justly, clinicians therefore need to be transparent, honest and open, avoiding unfair discrimination at all stages of the research process. This will include ensuring that the wishes, needs, decisions and preferences of potential research participants are respected without bias, regardless of age, gender or any other physical or social factors relating to the individual. Through such commitment to ethical practice and a

positive research culture (Wilkes and Jackson, 2013), the principle of justice can promote inclusivity and fairness.

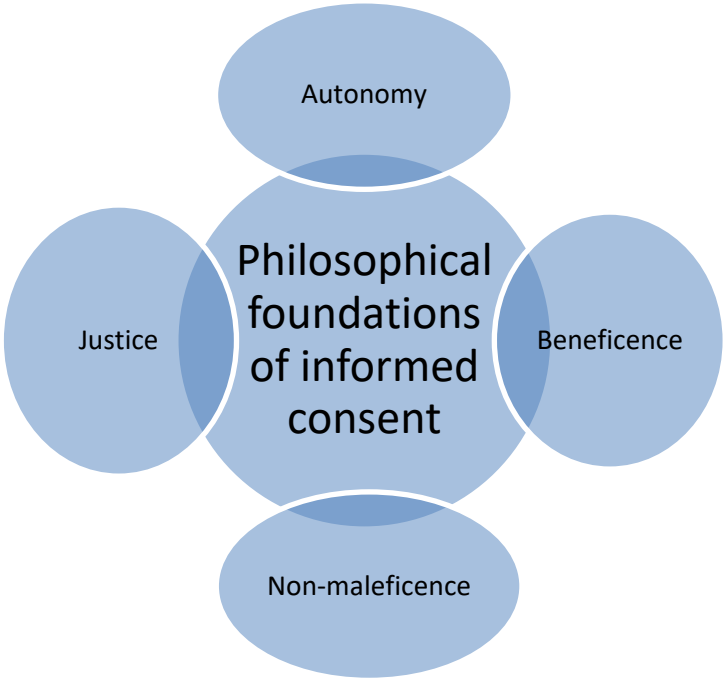


Figure 2 Philosophical foundations of informed consent

Steps for implementing effective informed consent processes in clinical research

So far, it can be seen that informed consent is multifaceted, comprising of intentionality, understanding and free will (Faden and Beauchamp, 1986). Hence, Savulescu and Momeyer (1997) warn against a rational belief of informed consent as merely an autonomous authorisation. It has been argued that clinicians have a duty of care not to abandon their patients to irrationality and rather, must support their patients to deliberate more effectively towards rational decision-making (GMC, 2008). Therefore, care should be taken to ensure that the patient is empowered to take part in the decision-making process for either medical procedures or clinical research, unless where there is a legal counsel of incompetence in place (DH, 2005b: Mental Capacity Act, 2005). The GMC (2008) recognises that ensuring decisions are made freely is largely down to the training and experience of the person taking consent. The requirement is that everyone involved in the

conduct of clinical research should be qualified by education, training and experience to perform his or her respective task (WMA, 1964, ICH-GCP principle 2.8).

Yet, for novice researchers new to clinical research and all those unfamiliar with the informed consent element of the research process, there is a scarcity of concise and accessible evidence-based information on an effective informed consent process with adults volunteering for clinical research. Conversations with professional colleagues and peers on the subject, combined with a review of healthcare literature revealed a gap in knowledge.

This section examines system theories and norms with regard to the process that need to be followed in the conduct of a valid informed consent process for participation in clinical research. To enhance credibility, the section draws upon available evidence from professional bodies, government and authoritative research on the subject, to provide a practical and accessible 10-step guide. The aim is to review and collate evidence-based strategies for achieving a valid informed consent process for participation in clinical research. Process refers to the steps that must be followed or a series of things that should happen in order to achieve an established outcome.

Step 1: Considerations for study review, approval & invitations:

The literature reviewed so far appears to suggest that the process of informed consent starts at the early stages of the research proposal. This is the stage when the researcher, having thought through the research process, prepares to enter negotiation with governance committees to obtain a favourable opinion from the relevant REC and institutions (DH, 2011; Macfarlane, 2009). REC reviews complement researchers' own consideration of the ethical issues and their involvement of service users (DH, 2011). At this stage, the researcher must consider carefully how best to inform potential participants about what taking part in the proposed study may mean for them, any anticipated risks, burdens or intrusions (HRA, 2019; DH, 2011; Rosse and Krebs,1999). For example, if written information is to be provided to potential participants, then the content, design, style,

and language of the consent documents ought to be user-friendly, person-centred, and mindful of the literacy level of the target population (RCN, 2019; Pick et al, 2014). Communicating scientific information to members of the public, often with limited literacy and possibly from diverse sociocultural backgrounds, can be challenging for all parties involved (Kadam, 2017; Cousin et al, 2013; Holmes et al, 2012). Yet, researchers are guided to make sure that decisions at all stages of research, especially for recruitment, are free from discrimination (GMC, 2013).

Consent documents usually include – but are not limited to – study invitation letters, the Participant Information Sheet (PIS) and the consent form (HRA, 2019). The HRA document 'Consent and Participant Information Guidance' proposes that researchers can consider a range of information media other than a written information sheet, including audio, video or online materials as appropriate (HRA, 2019). Their 104-page guidance document covers wider aspects of consent in adults, children, young people and adults lacking capacity, and considers UK-wide requirements. While the document does provide a comprehensive information on the considerations for study review and approval requirements, it is a lengthy read at a time of conflicting demands on a researcher. Hence this 10-step summary of the evidence will focus on adults with capacity to consent. There does not seem to be any published order as yet in the UK, on steps to seeking consent (DH, 2009).

Step 2: Consider how to approach potential research participants: by whom, when, how?

Another important part of the considerations for any governance submission and in the conduct of the informed consent process involves decisions on how to invite or signpost patients to ongoing studies. With regards to identifying and approaching potential clinical research participants, a HRA report (2015), as part of its consultations in the development of the recent UK Policy Framework for Health and Social Care Research (HRA, 2017), gave insight into the wishes of service users. According to the report, members of the public prefer that the main clinical staff responsible for patients' care should have the right to access patients' records for the purposes of clinical care and/or research. Hence, it is

undesirable for staff outside of the clinical team to have direct access to patient's data for whatever purpose, including for research purposes (HRA, 2015). Nonetheless, the position of the UK Policy Framework for Health and Social Care Research for almost all research conducted in the UK is that the person seeking consent must: understand the protocol and the implications it may have on the people involved; understand the alternatives that may be available to potential participants, including treatment alternatives; have the ability to communicate effectively with potential participants, including explaining complex scientific/medical concepts; and be able to support a decision of free will, avoiding undue influence (HRA, 2017). It went on to emphasise that informed consent must not be obtained under any form of duress or undue influence from health professionals, family or friends. Notwithstanding, the view of members of the public is that access to patients' data should be limited to NHS staff from the same institution in order to limit data sharing unless there is a clinical need to do so or where individual patients have otherwise given permissions ('consent to approach list') (HRA, 2015). This reinforces a preference for clinical staff to identify and invite potential patients to take part in relevant clinical research. In that regard however, there are concerns that patients may feel increased pressure to take part in the research when invited by their clinicians as it may be hard to say 'no' face-to-face to one's own doctor (HRA, 2015: Identifying and recruiting participants for health research). Ultimately, the Declaration of Helsinki (2013) recommendation is that physicians should be particularly cautious when seeking informed consent for clinical research if the potential participant is in a dependent relationship with the clinician, as the patient may agree to take part under duress (WMA, 2013, principle 10 as amended). They suggest that the process of informed consent for research should only involve staff who are not engaged in the proposed stud; and who are completely independent of an official relationship with the patients (WMA, 2013). Clearly, a dilemma exists, necessitating further clarifications in this regard.

Step 3: Consider location for conduct of consent, prioritising patient.

As with other elements of the research process, it is expected that issues concerning the location for the conduct of informed consent needs to be thought out at the development stage. Once the considerations for screening and identification of potential participants have taken place, and patients have expressed interest in taking part in the research, the next logical step is to meet with the individual in person to discuss the study information in a conducive environment; ensuring that the time and place are appropriate (RCN, 2017: RCN Principles of Consent). In doing so, a number of considerations are advocated. First, carrying out the procedure in locations and at times convenient to patients may encourage patient involvement (RCN, 2019). Second, patients must be given the time and space, as far as is reasonably practicable, to weigh up their options before arriving at a decision (Taylor, 2018). Third, it should be person-centred, to ensure that any persons whose involvement would help the participant decide are present (RCN, 2017). Ultimately, a person cannot be regarded as having been given practicable help and support to make a decision unless reasonable steps have been taken by the clinician or researcher to enable the patient to make a competent decision of their own (RCN, 2017). It is proposed therefore that care must be taken to find out from the patient where he or she may wish to discuss the study information, and any preference that the patient may have regarding the involvement of significant others in the informed consent process. The clinician or researcher should then take the patient's preference into consideration, being respectful of their wishes. The patient's view must be determined at various levels to add to the body of knowledge of where and how they prefer to be spoken to during the disclosure of study information for clinical research participation.

Step 4: Initiate, establish and maintain partnership with patient

When meeting with potential participants to seek consent for research, the RCN guidance is that research staff must set the scene for dialogue, at an appropriate location, and be prepared to actively promote patient involvement and engagement at every point in the research pathway, including priority setting during the process of informed consent (RCN,

2019). Establishing and maintaining partnership with the patient is one way of fostering trust between research participants and researchers (Perez-Merino, 2014), without which, the quality of research data may be jeopardised. The researcher needs to think about the important components of trust, and how a trusting relationship can be built, establishing rapport in what may be a very limited space of time (Pick et al, 2014). Without trust, patients may not be able to open up to the researcher in an honest manner, which could affect the quality of the data obtained. Since informed consent happens in the early stages of the research process, it is suggested that the researcher seeks to engage with potential research participants in a manner that is open and honest, giving accurate information and communicating with patients in a kind, considerate and respectful manner (GMC, 2010: Good practice in research). Fidelity and veracity are emphasised (Hawley, 2007). Fidelity involves an obligation to the fundamental principles of the informed consent process, and of the professional codes of conduct (as applicable), while veracity relates to the researcher's ability to maintain honesty and to refrain from deceitful acts (Hawley, 2007). The researcher needs to be able to show and sustain genuine interest by identifying the patient's priorities, attending sensitively to their concerns and avoiding a rigid attitude to truth telling, or rushing in with information before the patient is ready to receive it (Pick et al, 2014). This approach is best practice in considering the whole person; being respectful of the impact that the experience of illness may have on the person before proceeding to disclose study information. A person-centred approach to informed consent will serve to enhance voluntariness. The voluntariness of an individual may be affected by various factors such as intellectual and emotional maturity to make complex decisions; illness-related considerations; religious and cultural values; economic and care burden; and their relationship with the caregiver (Growther & Smythe, 2016; Gupta, 2013).

Step 5: Ensure adequate and accurate disclosure of study information, enabling active involvement.

The giving of adequate and accurate information is an essential component of the informed consent process (Kennedy, 2001). It is a crucial part of developing a patient-centred service

that is respectful of a patient's right to self-determination (Perez-Merino, 2014; Beauchamp and Childress, 2013). Without accurate and adequate information, patients will not be able to make an informed decision. As mentioned previously, the recent Supreme Court ruling in Great Britain sparked a new focus for a person-centred approach to information disclosure in both clinical practice and research (Montgomery v Lanarkshire Health Board, 2015). There has been a change of perspective, with emphasis on the adequacy of relevant information. More than ever, an attitude of openness, honesty, and provision of adequate information to patients is advocated (DH, 2002: Response to Bristol Inquiry; DH, 2005; GMC, 2008). In research practice, professional self-interest is unethical and must be avoided (Mahase, 2019; Beckford & Broome, 2006) likewise, medical paternalism is indefensible, especially in the disclosure of information (Montgomery v Lanarkshire, 2015; Hall, 2001; Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital, 1985; Bolam v Friern Management Committee, 1957). Instead, research participants are to be recognised as intelligent collaborators in decisions involving their body and life (Montgomery v Lanarkshire, 2015; GMC, 2008; Hall, 2001). Healthcare professionals and doctors no longer have the right to decide what the patient needs to hear and how that information should be presented without partnering with the patient (Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital, 1985). The current code of practice mandates healthcare professionals to be open and honest with participants and colleagues when sharing information about any investigation or intervention, and to answer a patient's questions honestly and as fully as possible (GMC, 2010: Principle 22; Montgomery v Lanarkshire, 2015).

The informed consent process should be one of meaningful information exchange between researchers and study participants (Pornpimon et al, 2017). Patients must be given enough information to enable them to make an informed decision (GMC, 2013). However, how much information to be disclosed should depend on individual circumstances, so needs to be tailored in a flexible manner to accommodate a person-centred approach to consent

(GMC, 2013; GMC, 2008). In clinical practice, the ethical recommendation is that the professional should discuss information with patients depending on their needs, wishes and priorities; their level of knowledge and understanding of their condition, prognosis and treatment options; the nature of their condition, the complexity of the treatment; and the nature and level of risk associated with the proposed investigations or treatment (GMC, 2008). In clinical research, understandably, it is common practice for consent forms to be pre-populated with certain vital information beforehand such as the nature of proposed investigation or intervention, itemised risks, benefits and alternatives (HRA, 2017). The UK Policy Framework for Health and Social Care Research recognises that consent needs to be person-centred and transactional and puts forward a set of information that should be discussed with potential clinical research participants. This includes: a clear statement that the proposed activity is research and not standard treatment; the condition or treatment under study; alternatives to participation; what will happen to participants during or after the study; the potential benefits or risks; any treatment that may be withheld (where applicable); sharing or dissemination of the research outcome to participants; randomisation and blinding details (where applicable); screening and exclusion criteria; involvement of the participant's GP; expenses and payments; impact on insurance; confidentiality matters; and various other elements (HRA, 2020). There is a need to understand more directly the sorts of information that real-life clinical research participants find useful in their decision-making. The experience and perspectives of real-life clinical research participants will support clinical researchers in achieving a patient-centred informed consent process. Patients are to be encouraged to make their own free decision as much as possible, though information cannot be forced on them, should the patient not wish to hear it (Appelbaum, Lidz and Klitzman, 2012).

Step 6: Appraise and establish mental capacity

The Mental Capacity Act (MCA) (2005) sets out a statutory framework for making treatment decisions for people who lack the capacity to make such decisions themselves; as well as the legal requirements for assessing whether a person lacks the capacity to decide. The

Medical Protection Society advises that the assessment of a person's capacity should be based on his/her ability to understand, retain, and weigh the information relevant to a particular decision; and the person must be able to communicate the decision (Medical Protection Society, 2015). In all circumstances however, the default position is to assume that all adults have capacity unless proven otherwise (MCA, 2005; Medical Protection Society, 2015), therefore deviation from the fundamentals of the Mental Capacity Act would only be necessary if there are reasons to suspect that the individual may lack capacity. In such situations, comprehension and freedom in consenting must be evaluated (Shafig and Malhotra, 2011; The American College of Obstetricians and Gynaecologists (ACOG), 2016). Comprehension as an element of the informed consent process (GMC, 2013; British Educational Research Association (BERA) (2011) can be assessed by checking the patient's awareness and understanding of his/her situation and other essential elements of the study information (Shafig and Malhotra, 2011; ACOG, 2016). This may involve using simple language and asking the patient to repeat what they understood in their own words (ACOG, 2016; Pasek, 2000), and checking the patient's understanding of their right to select a course other that what may be recommended (WMA, 2013; GMC, 2013).

Step 7: Allow time for deliberation, noting participant's right to refuse

The patient should be allowed as much time as he or she needs (Appelbaum, Lidz and Klitzman, 2012). Apart from an emergency situation, where a decision may need to be made quickly and where patients may have to be encouraged to accept a particular intervention to save a life (GMC, 2013; Gupta, 2013; Neff, 2008; Parvizi et al, 2008), the suggestion is that patients should be supported to deliberate on the information provided to them, and not be discouraged from asking questions (GMC, 2015; Maclean, 2009). Informed consent is considered a 'process' and not a one-off procedure (Medical Protection Agency, 2018; Santillan-Doherty, Cabral-Castaneda and Soto-Ramirez, 2003), so there should be no expectation that patients must give their permission when summoned to do so. Indeed, it is considered good practice to acknowledge to the patient that he/she can

take as much time as needed, with the reminder that he or she could accept or decline to consent (Maclean, 2009).

Comprehension (or understanding) and voluntariness have been considered as most fundamental when seeking informed consent from potential participants (GMC, 2013; ACOG, 2016). In recognition of the ethical and professional duties of care, healthcare professionals are guided to encourage and support potential research participants to an informed and voluntary decision about accepting or declining involvement in research or medical care (GMC, 2013). Communication and dialogue are therefore necessary for meaningful consent to be realised (Gomez-Zuniga et al, 2019; Cousin, Mast and Jaunin-Stalder, 2013; Brown et al, 2004). It is the responsibility of the research staff conducting the procedure to ensure they facilitate communication not only in individual relations with patients but also in accordance with ethical concepts of informed consent (WMA, 2013). The patient must be supported and allowed enough time to deliberate and determine the meaning of what he/she undergoes (European Medicines Agency (EMA), 2015). This might include the opportunity to discuss with significant or trusted others, such as family members or physicians. Time for deliberation may therefore be deemed as a pre-condition to a patient's capacity to understand and to consent (ACOG, 2016), so must not be taken for granted. The individual might also be allowed time away from the research staff or team, to minimise the degree to which the staff's values or opinions may influence the patient's decision. There appears to be limited evidence about the length of time that is required; rather, professionals are guided to give patients time to reflect, before and after they make a decision, especially when sharing complex information (GMC, 2010), which is often the case in research. In cases where a time limit is warranted for practical reasons, the patient needs to be advised in a considerate manner and informed of who they should contact if they have further questions (GMC, 2010).

Although not considered manipulation or coercion (Beauchamp, 2017), care needs to be taken that professional perspectives do not unduly influence a patient's voluntary decision

making, by ensuring that patients are allowed sufficient time to reflect on information provided before they should give their decision (ACOG, 2016). At present, there is no operative measure for verifying free consent in concrete instances (ACOG, 2016), therefore the onus is on the investigator to exercise due conscience in the manner he/she enables human freedom and, by extension, the integrity of scientific research outcomes.

Step 8: Document consent discussions & outcome

According to the ICH-GCP guideline, all clinical research information should be recorded, handled and stored in a way that allows accurate reporting, interpretation and verification of data (WMA, 2013 as amended, ICH-GCP principle 2.10). It is normal practice to sign a consent form as a way of documenting consent, which must then be filed within the patients' medical records (HRA, 2017; Lawton, Hallowell and Snowden et al, 2017; GMC, 2013). However, the legal understanding is that a signature on a consent form alone does not constitute a valid informed consent legally or ethically (Medical Protection Society, 2018). Rather, the best practice standard is to write down the essential elements of discussions with the patient after sharing all the necessary information with the patient (Medical Protection Society, 2018; Lawton, Hallowell and Snowden et al, 2017). For that reason, the consent document should not be pre-empted but should reflect the researcher's interaction with each patient, and is unique to each individual. It should capture the concerns expressed by each patient, the questions asked, the responses given and whether the patient was satisfied with the explanations before giving consent (Medical Protection Society, 2018). Hence, it may be said that verbal consent is just as valid as a signed consent form, providing it is witnessed (Medical Protection Society, 2018). In the words of the RCN, 'the validity of consent does not depend on the form in which it is given. Consent can be expressed in writing, verbally or non-verbally' (2017: pg.10). The default legal position, however, is to get written consent from participants if possible and to record the key elements of any discussion about their decision to take part in the research (GMC, 2013).

Step 9: Reassure and acknowledge consent as ongoing and ensure continuing permission

As stated previously, consent is a process that results from open dialogue with individual patients, and not merely the signing of a form (Medical Protection Society, 2018). Consent is deemed an ongoing process in the sense that it is considered a good and moral practice to inform participants if new knowledge emerges during the progress of a study, which may influence a participant's decision to withdraw, even after initial consent had been given (Gelling, 1999). In this regard, a research participant must be informed of their right to withdraw and be supported by ensuring that truth is communicated at every stage in the research process. Seeing informed consent as a process and not as an administrative exercise, Santillan-Dohery (2003) suggests that informed consent is no different in either clinical or research practice and must involve a meaningful engagement through continuous dialogue between healthcare professionals and the patient. The GMC's explanatory guidance for 'Good practice in research and consent to research' (2010) supports that the safety, dignity and wellbeing of participants must take precedence over the furtherance of knowledge, even where such ongoing dialogue might lead to withdrawal from study.

Step 10: Process and protect data, upholding research integrity

Various elements of the research process, including the process of informed consent involves access to patient's personal data, and is usually carried out with consent from the individuals concerned (ICH-GCP, 2019; The Belmont Report, 1979). 'Patients need to understand how information about them will be collected, stored and used, and how their confidentiality and privacy will be protected' (GMC, 2010 pg. 20). In that regard, the confidentiality of records that could identify research subjects should be protected, to respect research participants' privacy in accordance with data protection regulations (The Information Commissioner's Office, 2018; General Data Protection Regulations (GDPR); 2018). Two ways of protecting the personal data of research participants are: pseudonymisation and anonymisation (The Information Commissioner's Office (ICO) 2018; The General Data Protection Regulation (GDPR), 2018). Anonymisation refers to when a person's data is changed in such a way that their personal details are no longer identifiable

to others (ICO, 2018); whereas pseudonymisation is a lower level strategy that involves changing a person's name to ensure their privacy (ICO, 2018). When undertaken effectively, anonymised data is considered safer legally, given that the data subject is no longer identifiable (ICO, 2018). In the current climate of digital interactions and information rights, such as the Freedom of Information Act 2000, it is highly recommended that clinicians and researchers take adequate care to minimise accidental misuse of identifiable information relating to research participants (ICO, 2018), as this may leave an individual open to damage, distress or financial loss, as well as potential organisational damages (ICO, 2018).

To ensure safe handling of identifiable information during the process of informed consent, some of the good practice standards and practical measures include seeking consent for the disclosure of the data (GMC, 2017). In doing so, the professional needs to explain the possible consequences and any measure to lessen potential consequences of disclosure (ICO, 2018). Data must only be shared within closed communities where possible; and rigorous anonymisation measures must be adopted where any form of identification may breach data protection principles (ICO, 2018). Other measures may include redacting individuals' names from documents; blurring video footage to disguise faces; electronically disguising or re-recording audio material; and changing the details in a report, such as precise place names, dates etc. (ICO, 2018). Any planned measure for the safe processing and storage of participants' details may need to be discussed and agreed with each potential participant during the process of informed consent, even after organisational governance approvals have been obtained (BMA, 2020; GMC, 2017; Data Protection Act, 2018). However, individuals do not actually have the right to prevent the anonymisation of their personal data in the sense that effective anonymisation should not cause unwarranted damage or distress to data subjects, as that is the central aim of data anonymisation (ICO, 2018). Hence, it is a matter of ethical regard to inform potential research participants that their data may be anonymised, although legitimising the process of anonymisation by

seeking consent from individual data subjects is not a legal requirement (ICO, 2018). If after discussion of planned data protection measures, the potential participant has further questions or concerns, the researcher is guided to answer the patient's questions honestly, as far as practical and, as fully as the patient's needs require (GMC, 2017). Ultimately, it is important that patient understands the options open to them, and their right to refuse to take part in teaching or research should they not be satisfied with the planned arrangements (GMC, 2017).

Table 1 10-step plan to effective informed consent process

1.	**Consider ethical and methodological implications in readiness for REC review, approval and invitation process.**
2.	**Consider task allocation and delegation of duty - by whom, when, how?**
3.	**Consider conducive location for the conduct of consent, prioritising patient welfare.**
4.	**Initiate, establish and maintain partnership when meeting with patients.**
5.	**Ensure adequate and accurate disclosure of study information, enabling active involvement.**
6.	**Appraise & establish mental capacity.**
7.	**Allow time for deliberation, noting a participant's right to refuse.**
8.	**Document consent discussions & outcome.**
9.	**Reassure and acknowledge consent as ongoing, noting continuing permission.**
10.	**Process and protect data, upholding research integrity.**

Summary of chapter

To summarise, this chapter has explored ethical and legal guidelines for clinical research, rooted in historical incidents relating to unethical and illegal human experimentations since World War 2 (1939 – 1945). Evidence has shown that science is not without risk and there is a belief that patients, as autonomous human beings, must no longer be subjected to human experimentation without being truly made aware of the uses that will be made of

them. International and UK guidance has been reviewed to produce a 10-point overview, which guides the process towards upholding ethical standards in clinical research practice. There remains a goal to prevent ethical violations in the conduct of clinical research. This goal is as deep and important as ever in today's climate, where the current unprecedented global Covid-19 pandemic has threatened the reserve of even the most conscientious nations in the wilful pursuit for effective treatments. The predicament between ethical research and the advancement of scientific knowledge is currently so profound that the President of The United States of America, in a recent tweet, accused the U.S Food and Drug Administration (FDA) of slowing down vaccine production in the interests of research ethics, saying they were '…making it very difficult for drug companies to get people in order to test the vaccines and therapeutics'. The President alleges this slows down the development of coronavirus vaccines (Oppenheim, 2020, The Independent World News: 23.08.2020). Understandably, the observance of ethical research principles at real-life fronts remains complex. The next chapter will review the practical issues that have persisted in making ethical research and the informed consent process particularly problematic, highlighting what is known in the literature from both expert and patient positions.

Chapter 2

Literature Review

Introduction

Having discussed the background to the ethics of informed consent and the emergence of regulatory protocols in medical research practice in the previous chapter, this chapter presents what is known about the views of stakeholders on the practical implementation of ethical research protocols at grassroots level where it matters most. The various regulatory protocols protect the rights, safety, dignity and wellbeing of those who volunteer their time to participate in clinical research, and facilitate and promote ethical research for the benefit of the participants, science and society (British Medical Association (BMA), 2020; European Medicines Agency (EMA), 2017). This chapter identifies how the measures for ethical research practice are understood and implemented by those at the front line of ethical research practice. The chapter will identify gaps in the knowledge and determine the reasons for such gaps (Sandelowki and Barroso, 2003), in order to clearly defining the research objectives.

Literature search strategy

Medical research literature published between 2001 and 2020 was examined. 2001 marked the initial introduction of the UK Research Governance Framework (RGF) and a renewed emphasis on informed consent as the heart of ethical research (DH, 2001). The review was completed initially in 2013 at the early stages of this PhD, and was focused primarily on the literature published between 2001 and 2013. The search was subsequently repeated yearly to capture and keep abreast of emerging evidence. Search terms/phrases used were “consents” AND patients AND “information sheets” AND UK. It was anticipated that the terms ‘consent’ and ‘patients’ would bring up relevant literature on consent including clinical

and research literature, which allowed for more comprehensive screening of available evidence. Similarly, the phrase “patient information sheets” was anticipated to cover a more diverse range of literature than would be achieved if the search term was limited to “research participants’ information sheets”. This judgement was made following repeated searches with other terms such as ‘research ethics committees’ and ‘clinical research’, which either brought up irrelevant literature or unmanageable sources of information. The chosen phrases were successful in bringing up targeted and relevant sources. Databases searched included Web of Science (WOS), CINAHL, MEDLINE, and Cochrane Library. UK was included to target the ethical and regulatory context within the UK National Health Service (NHS). However, it must be emphasised that issues of ethical research conduct are of global significance (Ochieng et al, 2013; Munung, et al, 2016; Gammelgaard, Motensen and Rossel, 2004). Databases were selected for their subject specialism, although further searching was undertaken via manual review of reference lists within relevant hits and key professional and government policy documents as applicable. The findings of the review relate to ‘Expert concerns’ and ‘Patients’ concerns’. Table 2 outlines the search strategy.

Table 2 Literature search strategy

Database	Year	Search phrase	Search modes & filters	No. of search results
Web of Science	2001-20	Consents AND Patients AND Patient information sheets AND UK	Boolean/phrase; English Language; 2001-2020	18
Web of Science	2001-20	Consents AND Research ethics committees AND UK	Boolean/phrase; English Language; 2001-2020	88
Web Science	2001-20	Consents and clinical research AND UK	Boolean/phrase; English Language; 2001-2020	287
Medline (via ProQuest)	2001-20	Consents AND Patients AND Patient information sheets AND UK	Boolean/phrase; English Language; 2001-2020	21
Medline (via ProQuest)	2001-20	Consents AND Research ethics committees AND UK	Boolean/phrase English Language	186
Medline (via ProQuest)	2001-20	Consents AND clinical research AND UK	Boolean/phrase; English Language	426
CINAHL with Full Text	2001-20	Consents AND Patients AND Patient information sheets AND UK	Boolean/phrase; English Language; 2001-2020	1
CINAHL with Full Text	2001-20	Consents AND Research ethics committees AND UK	Boolean/phrase English language 2001 - 2020	28
CINAHL with Full Text	2001-20	Consents AND clinical research AND UK	Boolean/phrase; English language; 2001 - 2020	44
Cochrane Library	2001-20	Consents AND Patients AND Patient information sheets AND UK	Boolean/phrase; English Language; 2001-2020	81
Cochrane Library	2001-20	Consents AND Research Ethics Committee (in Title Abstract Keyword)	Boolean/phrase English language; 2001 - 2020	Central Trials database = 95 Cochrane reviews = 0 Editorials = 0
Cochrane Library	2001-20	Consents AND Clinical research AND UK (in Title Abstract Keyword)	Boolean/phrase; English language; 2001 - 2020	Central Register of Controlled Trials = 543 Cochrane reviews = 0 Editorials = 2

Existing knowledge

Chapter one explored the historical context underpinning research ethics. The fundamental goal of various frameworks for ethical research is to protect and safeguard the dignity and well-being of those who volunteer to advance scientific knowledge by offering to take part in clinical research. The underpinning principle is that healthcare research involving human beings or human tissues must conform to the generally accepted ethical and legal principles; the responsibility for this rests with the healthcare professionals conducting clinical research at every stage of the research process (WMA, 2013). For these reasons, Research Ethics Committees ensure that participants, funders, sponsors, employers, care organisations and healthcare professionals are provided with an independent opinion on the extent to which clinical research proposals comply with acceptable ethical and legal principles before a favourable opinion to proceed can be given (NRES, 2011; HRA, 2017). Research Ethics Committees seek to ensure that the process of informed consent, and more specifically the Patient Information Sheets, reflect all relevant aspects of ethical research legislation and that information will be explained adequately to potential research participants. The outcome for REC is to issue either a favourable opinion, a provisional opinion or an unfavourable opinion (NRES, 2011; HRA, 2017). Favourable opinion means that the research proposal is approved without need for modification and can proceed to initiate arrangements with hosting institutions; a provisional opinion means that amendments or further clarifications are required before the research proposal can progress; an unfavourable opinion means that the study did not meet ethical and legal standards, and should not go ahead (NRES, 2011). This is how RECs function as regulatory stewards for legal and ethical requirements at the development stage of a research proposal, enabling quality control (Kolstoe, 2019). With this in mind, the first literature theme identified is that RECs cause delays with research and are overly bureaucratic.

REC Reviews seen as bureaucratic and causing delays

While the need to ensure appropriate checks are conducted before research involving human participants can commence is well established (NRES, 2011; HRA, 2017; Office for Human Research Protections, 2016:The Belmont Report 1979; WMA, 2013), there have been longstanding concerns by various stakeholders about complicated processes and delays (Ennis and Wykes, 2016; Armstrong et al, 2012; Snooks et al, 2012; Knapp et al, 2011; Fortune et al, 2008; Hallowell et al, 2008; Robinson et al, 2007; Oliver, 2006; Stead et al, 2005; Cox, 2001). First, ethical research reviews continue to be seen by clinical researchers as a prolonged and painful process that many clinicians say hinders the start of meaningful research. In the words of Spence (2011: D6002), “The ethical approval process is endlessly bureaucratic and opaque and is subject to constant delays and redrafts. Many simply give up or never start”. This is despite recent and ongoing calls by the Royal College of Physicians (RCP) and the Care Quality Commission requesting that more clinicians need support to engage in clinical research (RCP, 2019; Care Quality Commission, 2018). The reason being that research-active organisations have better outcomes, either in healthcare practice or healthcare education practice, making research a key factor for service improvement (OECD, 2019; Care Quality Commission, 2018; Boaz, Hanney, Jones et al, 2015). Hence, barriers to the initiation of clinical research studies are seen to be serving a latent purpose, given that the outcome of no research is no evidence (Spence, 2011), impacting on health outcomes. There is clear need therefore for reform on how committees may better support clinicians wishing to embark on clinical research. This PhD aims to gain more insight into this and into the meaningful approaches as viewed by the service users who the system is meant to protect. Such insights will contribute towards the establishment of more wholesome endeavours in the initiation, development, review and implementation of ethical research practice, minimising the disinterest associated with research (Maben and King, 2019) and encouraging more clinicians to take up clinical research.

Stressful levels of administrative formatting and methodological revisions

Second, there are claims that the review of research proposals by research ethics committees provokes anxiety for committed researchers at the developmental stage of clinical research process (Kolstoe, 2019; Chaudhry et al, 2013). To many, the mention of informed consent may be met with a groan (Pasek, 2000). These concerns relate to the extra work and resources involved in the seemingly relentless ethical review process, which creates a heavy burden on researchers. For example, Chaudhry et al., in a multi-national web-based survey that included colleagues from Newcastle University, UK, sought to examine investigator experiences with ethics review processes and to characterise ethics review outcomes of trial applications. They report that 38% of those who took part in the study had negative experiences of the ethics review process of their research including delay in trial initiation, increased costs, compromised methodological quality and, more worryingly, compromised ability to recruit participants (Chaudhry et al, 2013). More recently, Butler et al. set out to analyse RECs' concerns, expectations and decisions for research applications by a given specialty research group in the UK. They reviewed REC meeting minutes, decision letters and researcher response letters involving 77 REC applications by Chief Investigators for National Institute of Health Research Portfolio studies. Of the 77 applications reviewed, 57 received requests for revisions at first review; with concerns commonly relating to participant information sheets, methodology, consent, recruitment or formatting of written study documents. The concern is that such high levels of formatting or administrative revisions, often including multiple versions of consent forms or participant information sheets, adds burden to the clinical research process and discourages even the most willing and committed clinical researchers (Butler, Vincent and Bluebond-Langner, 2020). Interestingly, Butler and colleagues' research revealed an apparent disconnect between what researchers feel is appropriate in terms of the process of informed consent, and what committees expect. More importantly, there seems to be little knowledge of what

real life research participants, the vital stakeholders of the clinical research process, feel about informed consent for research given that they are the end users of the processes.

These and other studies sought insight into committees' and expert opinions, however the views of service users at the end point of the continuum have not been adequately accounted for. Little research has been done at the grassroots and such knowledge is needed to appraise theoretical narratives and concerns (Spence, 2011). This is one of the gaps that this PhD research aims to fill, to gain a greater insight into consumer perspectives of the process of informed consent for participation in clinical research, especially at the grassroots level, where it should matter most. Spence (2011) identified that a radical approach to evidence generation is necessitated, stating that interesting research that changes day-to-day practice is often not large-scale experiments by notorious drug companies, but instead is focused, simple and wholesome questions that address grassroots concerns, as is the case with this pertinent PhD research.

A clear pattern of sustained anxiety is evident among clinical researchers, not only in the UK but internationally. Adams et al (2017) set out to review research proposals, notifications of outcomes to researchers and ethical concerns from research ethics committees. The study, published in the British Medical Council Medical Ethics Journal, reports that about two-thirds of the sample reviewed were required to improve their explanations of study procedures to participants, and 40% attracted comments on informed consent elements, including issues around risk and discomfort etc. Consequently, researchers were required to provide further clarifications, elaborate, revise or paraphrase elements of their informed consent documents (Adams et al, 2017). Adams and colleagues provide some international context around the global scale of the challenges facing those involved in research on human participants or human tissues. Yet it must be said that the activities of ethics committees are to be commended, after all, the Helsinki declaration makes it clear that the need for new knowledge must never take precedence over the health, dignity and well-being of those volunteering for research, and that the rights of

individuals must be protected even after they have agreed to take part in research (WMA, 2013). Instead, the challenge and focus remain on how to achieve meaningful engagement with all stakeholders, ensuring effective practice at the frontline, where it really matters. To address perceived challenges, there have been calls for standardised ethics review process guidelines, including education of ethics committees about distinct ethical concerns (Chaudhry et al, 2013). But it is the view of this research that in addition to experts' opinions, patients or service users are better placed to say what aspects of ethical research conduct matters to them. Greater insight from participants may inform future practice at various levels, especially for research ethics committees and researchers on the measures that matter to real life patients in the real world. Such knowledge may advance what is known and perhaps close some gaps in current knowledge, with regard to sustaining quality of RECs through distinct participant-centred considerations in the informed consent process for clinical research.

Unclear guidelines and inconsistency in REC opinions

Similar concerns exist about how and why clinicians could remain so unable to replicate the required ethical research standards expected of them. In their defence, it has been argued that clinical researchers do not always know what is expected of them by research ethics committees (Snooks et al, 2012). There have been claims of confusion due to the variations on how different committees interpret guidelines differently, both within national (Gale, Hyde and Modi, 2017; Snooks et al, 2012) and international research contexts (Waligora, 2012; Ross and Attanassoulis, 2014; Doorn et al, 2015). For example, in 2010, Snooks and colleagues responded to a call by the Academy of Medical Sciences regarding difficulties encountered by its members in starting medical research. They set out to examine the setting up of three research projects: a system research project, a drug trial study, and a public health intervention study. They reported difficulties and delays in navigating and gaining the appropriate approvals required to kick-start these valuable scientific studies (Snooks et al, 2012). Each study was said to be delayed by at least 12 months, causing

stress and additional costs of about 30-40% of the initial costing. Even with relatively positive REC outcomes, the inconsistency in the decision-making pattern by different RECs within the UK can be confusing for researchers (Gale, Hyde and Modi 2017). These experiences, in which three RECs rejected a valuable research proposal despite approval of the same study by other RECs at same period shows the daunting process that clinical researchers experience (Gale, Hyde and Modi, 2017). The evidence is overwhelming and goes to show that the difficulties in gaining ethical and governance approvals is of a historical nature, owing to complex and unclear guidance about processes between sites and UK countries (Gale, Hyde and Modi, 2017; Snooks et al, 2012). The variations in guidelines, procedures and requirements for REC submissions is not only limited to UK sites but are also apparent in multicentre research involving other European countries (Starmer et al, 2015). In their survey of 24 European hospitals participating in a multicentre postsurgical pain study, Starmer et al reported that written informed consent was mandatory at 12 hospitals, oral at 10 hospitals and not required at one hospital (Starmer et al, 2015). Therefore, time for approval of the studies ranged from less than 2 weeks to more than 2 months, with obvious financial implications (Starmer et al, 2015).

Apart from the anxiety and perceived burden of delays imposed by REC review processes, there seems an apparent lack of trust around the competence of RECs, with calls by clinical researchers for greater scrutiny and the establishment of transparency on the code of practice for ethics reviewers (Waligora, 2012). For instance, a research study by Buccini and colleagues in Australia investigated the published guidelines and policy statements of some local ethics research committees who had reviewed significant number of clinical study applications. They sought to determine the established protocols by which the RECs reviewed study applications. They found that formal readability standards had not been established nor applied by the RECs in question, and that evaluations of studies regarding readability of informed consent documents were conducted using informal rules (Buccini, Caputi and Jones, 2009). Such an approach to practice obviously raises concerns as to the

trustworthiness and dependability of REC judgments, given that decisions and recommendations might be influenced by subjective opinions rather than established protocols. There may be challenges for clinicians who might attempt to follow criteria from approved applications on similar studies but be met with inconsistency in REC opinions.

Another concern relates to arguments and disagreement over the evaluation and disclosure of risk during the process of informed consent in therapeutic research by RECs. While there appears to be a clear understanding of the role of the REC in providing ethical oversight to protect participants from risk, current ethical discussion among experts appears to reject a blanket requirement for risk disclosure or the need for an informed consent in all cases of clinical research (Goldstein et al, 2018; The Council for International Organisations of Medical Sciences (CIOMS), 2016). For example, in their recent review of literature, Goldstein et al (2018) identified that some clinical researchers do not agree that all clinical research studies should have to seek research ethics review or be required to disclose information regarding anticipated risks for participants. In particular, they argue that some clinical research studies often take place as an extension of clinical care, and often present less or the same risk as standard practice. In this regard, they assert that information need only be disclosed when research participation offers patients less benefit and greater risk than standard clinical care (Goldstein et al, 2018). Their findings support the claim that REC research oversight is thought to be burdensome and is seen as a practical impediment to the conduct of valuable research in the real world. It would seem therefore that some concerns remain. The experts argued that REC oversight should be streamlined, especially when risks to participants are considered minimal or on par with the risks from standard practice (Goldstein et al, 2018). Their suggestions relate to where study procedures are the same as those used routinely in standard practice or are part of usual care. Although these ideas may seem rational, there are calls for more debate and engagement with all stakeholders. It is the view of this PhD research that more insight is needed to determine the perspectives of real-life clinical research participants of their views on the process of

informed consent for research in the ways that it matter to them. Goldstein et al (2018) concluded that ethical research standards require the participation of all stakeholders in their design and conduct. Seeking the views of real-life clinical research participants in the real world of ethical research practice is an important step in the right direction, given that patients are an important stakeholder in 21st Century health service planning and delivery.

A bigger concern with the challenges of the ethics review process is the worry that such unprecedented burden on clinical researchers combined with drivers to improve patient outcomes may eventually cause clinicians to seek ways to avoid ethical scrutiny in the search for new knowledge and evidence. This was reflected in a case in the UK, where two senior consultant urologists at a UK NHS Trust conducted research without obtaining patients' permission or ethics committee approval (Dyer, 2016). The doctors were found by a tribunal to have acted misleadingly in preparing, conducting and disseminating a clinical trial without obtaining ethics or research & development approvals (Dyer, 2016).

Participants unable to recall study information

Despite the regulatory measures and the efforts put into ethical research review process, concerns remained that most research participants were unable to understand or recall essential information about the studies in which they agreed to take part (Samuel, Dheesa, Farsides et al, 2017; Dickert et al, 2015; Armstrong et al, 2012; Cohn et al, 2011; Falagas et al, 2009; Durand-Zaleski et al, 2008). Falagas and colleagues identified that only 54% of patients that took part in clinical research studies understood the purpose of the study they had taken part in; 50% did not understand the concept of randomisation even after they had taken part; only 47% were aware that clinical research was on a voluntary basis; 44% understood their right to withdraw from the study; 50% accepted risks without understanding the risks; and 57% understood the benefit of taking part (Falagas et al, 2009). There is a clear indication that the process of informed consent for participation in clinical research 'seems not to work' (Armstrong et al, 2012). Armstrong and colleagues

explored the enduring requirements for Participant Information Sheets (PIS), and the multiple functions of the PIS as it goes through the development process and use. They analysed written documentation from 13 applications for REC approval covering phase I, II and III trials in oncology. They also examined the outcomes of the study documents. They reported that research participants appeared to perceive study documents as little more than a prospectus and as a contract (Armstrong et al, 2012). They concluded that more research was needed to understand the complex factors influencing the process of informed consent, on realising that no simple technical fix is yet available (Armstrong et al, 2012).

Seeking to understand service-users' views with regards to involvement in research in a specialised context, Cook and Inglis (2012) conducted participatory research with seven men with learning disabilities in a care setting. Their research set out to explore how people with a learning disability make informed choices in relation to participation in research. They sought to identify and highlight the competencies of people with learning difficulties in terms of their ability to contribute to the development and conduct of scientific inquiries as research collaborators. The findings of their research identified huge variations in knowledge, context and understanding of research terminologies, and showed that study information is not always understood by those it was meant to inform. This happens even after studies have received a favourable ethical opinion by review committees. Their research, though specialised and not generalizable, indicates that formatting words and other technicalities does not seem to present a fix, especially when some participants confessed to not reading the participant information sheet at all. While Cook and Inglis's study involved a specialised group of people with learning disabilities, the individuals were said to possess full mental capacity, and were therefore deemed capable of comprehension and reasoning.

Difficult research terminologies

Cartwright et al (2011) examined the experiences of the parents of surviving and deceased infants of the process of informed consent for participation in clinical research. Parents were emotionally overwhelmed and expressed difficulty in fully comprehending what they were being asked to do, but they still went on to take part in the research. The research highlights the peculiar circumstances in which real-life research practice takes place, and which may not reflect the ideals of theoretical, ethical or regulatory concepts. The participants of the research were vulnerable and in an unfamiliar and complex healthcare environment. Most had limited knowledge of medical terminologies and struggled to comprehend research concepts and terminologies (Cartwright et al, 2011). It was said that the Participant Information Sheets were complex and difficult to understand.

Therapeutic misconception

In a different, but nevertheless worrying trend, Ponder and colleagues highlighted the issue of blurred boundaries between clinical care and clinical research during the process of informed consent for clinical research (Ponder et al, 2008). Their study recruited male participants with rare familial genetic disorders and their family members. The research was conducted in the UK and was approved by the London multi-centre Research Ethics Committee. Despite the research being of a high methodological standard and the study's adherence to approved guidelines for participant information sheets, participants were unable to recall their engagement in the informed consent process. They appeared to recall partially the information relating to research such as the study aims and objectives but did so with a mixed view that their involvement was of a clinical nature. These findings were similar to the account of Dickert et al (2015) who reported limited comprehension of study details by many participants. The participants believed their involvement in clinical research to be primarily of clinical or superior intervention. These studies highlight the complexity of information disclosure when dealing with potential clinical research participants, whereby

clinical research may be confused with clinical care, and which may influence patients' willingness to sign up for research. It was not clear whether the participants engaged in the consent procedure but remained confused, or whether they did not engage with the information provided to them at all. More in-depth outcome analysis of the nature of participants' engagements may have revealed the reasons why the participants lacked understanding of the clinical-research divide even after they had taken part in the informed consent process for research.

Complex research concepts

In what appears to be a decades-long pattern of negative outcomes in the process of informed consent for participation in clinical research, Stead et al. (2005) undertook a qualitative exploration of patients' understanding of the science of clinical trials. Using focus groups, the study explored how prospective trial participants interpret and understand the science of clinical trials and the participants' use of participant information sheets. The study was conducted in the UK with 27 patients living with diabetes. It reported that the participants lacked understanding of purpose and meaning of clinical research concepts, and that they found the language and use of words in the study information difficult and complex (Stead et al. 2005). It was a similar outcome with Richards et al (2002), whose findings suggests that research participants could not remember what the participant information sheet said. Some participants could not even remember seeing a participant information sheet. With such negative experiences, it remains to be understood how these participants make up their minds and able to give informed consent. The pattern of outcome is clear, but an account of the real-life process appears to be lacking from the available knowledge. Clearly, more insight is needed as to what goes on at the front line and how the procedure of consent for research is being implemented in the real world.

Lengthy and wordy written study documents

To gain further insight about the cause of these negative and unsustainable participant outcomes, Ennis and Wykes (2016) investigated whether the participant information sheet (PIS) characteristics are related to poorer readability. They reviewed 522 PISs from the UK National Institute for Health Research Clinical Research Network and assessed the readability standards. PISs were found to be longer and were far more complex than the recommended reading level of grade 6 for patient information sheets. Their findings also reported that the consent documents were heavily focused on medico-legal contents, which may have made the study information less user friendly. Similarly, Gillies et al (2014), in their attempt to investigate why trial participants fail to understand key components of trial processes or purpose of study, examined approved PISs. Their research reported that PISs did not meet expected standards for meaningful decision making, suggesting that poor quality of PISs may be responsible for the poor understanding of study information among the participants of the trials sampled. Their observation is not surprising, as it is well documented that some of the requirements for PISs and the informed consent documents are more often based on institutional requirement for researcher protection against regulatory bodies, than for participant benefit (Ahern, 2012; Armstrong et al, 2012; Martin, 2003). However, Ennis and Wykes (2016) noted that the perceived complexity of information documents did not present much of a barrier to patient involvement in the reviewed studies (Ennis and Wykes, 2016). In fact, they reported a high level of patient involvement and successful recruitment despite the complexity of written information. Written study information may not have played much of a role in the information sharing process with the participants, presuming that potential research participants would be less likely to read or understand complex written documents. Similarly, Knapp, Reynor and Silcock (2011) examined the effectiveness of PISs. Their research involved members of the public, not clinical research participants. Nevertheless, participants could not explain or show understanding of the PIS after they had read it. The study indicated that written study

information might not inform prospective research participants adequately. Although Knapp and colleagues recommended rewording and redesigning the study documents to improve readability, other studies have shown suboptimal engagement with written information documents by prospective research participants (Abhyankar, Summers and Bekker, 2016; Armstrong et al., 2012; Gillies et al., 2014).

Such evidence underscores the concerns by stakeholders that the focus on written study information during ethics committee reviews and research and development committees might be serving an impractical purpose. Approved documents remained complex to grassroots users, even after they had been approved by relevant NHS REC. Such an outcome is obviously undesirable because patients may be consenting for research without adequate understanding of the study, they are taking part in (Cartwright et al, 2011; Ponder et al., 2008). Research ethics committees may need to acknowledge these perspectives during the review process, especially regarding the process of informed consent for participation in clinical research. This research believes that one way of enhancing the body of knowledge is to seek to uncover the meaning that real life research participants attach to the process of informed consent for participation in clinical research. As the end users of the research ethics review process, their voice may hold the key to the measures that would be meaningful for a process that is fit for purpose. Following Ennis and Wykes (2016), this PhD research could yield greater insight into the factors that aided or influenced participants' decisions other than their reading (or not) of written study documents. By engaging more directly with service users on the process of informed consent for participation in clinical research, this PhD may extend the existing body of literature with greater insight into the meanings that social beings attribute to the process of informed consent. Such an insight would guide future practice by providing further knowledge of the aspects of care that affect patients' decisions during the process of informed consent for participation in clinical research. There could be a gain for research ethics committees and researchers alike, as such knowledge may allow for more targeted review process that

align better to participant contexts and values. Clearly, wider discussion is indicated beyond committee and researchers' audiences.

Mechanics of disclosure and poor utility of study information

Gobat et al (2018) questioned the public on their views regarding provision of information and consent to participate in a possible influenza pandemic study. Like this PhD, their goal was to gain the perspectives of the people 'that really matter' in the ethical considerations for clinical research participation. Their research employed a descriptive-interpretive methodology using a scenario-based approach. Despite its good intentions, the research fell short of the bold actions required to understand real-life situations (Guba and Lincoln, 1985). To achieve meaningful constructs, participants ought to be real-life patients capable of symbolising the realities of the burden of illness. On the other hand, involving real life patients in health service research can often be a challenging process, which may limit an investigator's motivation to willingly pursue such an inquiry. Nevertheless, there is an appetite for ethically robust research but with a simplified enrolment process (Gobat et al., 2018). The challenge remains how to determine real-life patients' values and priorities and conserve ethical research standards. Patients may be unlikely to participate in, or clinicians unwilling to involve their patients in research if they do not feel safe or protected (Jones and Semple, 2017). Collaboration and partnerships at all levels, including between research participants, research ethics committees and all those involved in the conduct of research is therefore crucial and needs to be encouraged (Morse, 2020).

In a rather practical research approach, Abhyankar, Summers and Bekker (2016) used a qualitative methodology to investigate the utility of consent information in supporting women's trial participation decisions. There was little evidence that the women thought through the written information provided to them, which had included the advantages and disadvantages of research participation. It was identified that the decision-making process for patients may not have followed the theoretical ideals of regulatory standards, in the

sense that the therapeutic service delivery context appeared to hinder the utilisation of study information. Their research provides some insight of a possible theoretical – practical divide, whereby written study information served little purpose in the decision-making process for the women who took part in the research. It provides further evidence that more needs to be done to gain insight into user perspectives, avoiding a narrow reliance on expert opinions, if the process of informed consent for clinical research is to achieve its vital purpose of sustainable ethical and scientific outcomes (Samuel et al., 2017).

More broadly, current healthcare polices advocate a collaborative approach with service users in all aspects of health service delivery (NHS England 2019: NHS Long Term Plan; Beech et al, 2019; NHIR, 2019; NHS England, 2017: NHS England Research Plan; NHS England, 2013: Research and Development Strategy). This emphasises the need for a genuine partnership between professionals and patients. It calls for a bottom-up approach whereby the expert knowledge of patients should be sought and be used to align regulations to patients' values and preferences. There appears a welcome move to support patients to contribute in making decisions about health care services, which will hopefully minimise barriers to implementation and outcome (NHS England, 2019). The Research and Development Framework advocates the inclusion of patients in setting priorities for research to the extent of participation in the design, delivery, and dissemination of research outcomes (NHS England, 2013; NHIR, 2019: INVOLVE).

It can be seen therefore that a focus on the views and perspectives of real-life patients on issues of ethical significance in the conduct of the informed consent process is a research question that is aligned in the right direction. Particularly, the National Institute for Health Research (NIHR) asserts that a core element of a progressive modern NHS is to encourage frontline NHS care professionals to engage in healthcare research (NIHR, 2019). They acknowledge that some of the best questions that generate meaningful outcomes relate to everyday frontline dilemmas that may not be realised by detached career researchers.

This research was borne out of the researcher's own frontline dilemmas. It was perceived that while there is a body of knowledge about the undesirable disagreements between experts and ethics committees, and some negative patient outcomes at the frontline, there appears to be a gap in knowledge as to how such unwelcome outcomes persist. As a clinical research nurse in an NHS Trust, I perceived that in the current climate of evidence-based practice, more insight was required to determine to what extent real life research participants engage in the process of informed consent for participation in clinical research. The objective is to explore whether the process of informed consent in current research encourages or discourages research participation, and whether it aids truly informed decision making. It seeks to explore the perspectives of real-life research participants, to discover which element of the informed consent process works, and any areas that do not work well according to patients' real-world perspectives. Using an open question approach, research participants had an avenue to reflect on the situations they had experienced regarding the process of informed consent, and to determine for themselves how and whether the process of informed consent is fit for purpose.

This research will distinctively add to the limited body of knowledge, to help support the education, development, and implementation of patient-centred informed consent processes. NHS England's Five Year Forward View supports that research of this sort is important in generating evidence that could be used to shape services and improve outcomes for patients, where research 'IMPACT' matter most (NHS England, 2014). Attaching such importance to this element of the research process demonstrates a need to investigate the views of those for which governance regulations serve, and to empirically examine why these regulations may not be fulfilling their intended purpose.

The proposition therefore is to go beyond theoretical observation and discussion of the doctrines of informed consent, to pull out intricate details about the thought processes, feelings, beliefs and personal experiences of clinical research participants in relation to the process of informed consent**.** This research will uncover the real-life issues of deep-seated

significance to research participants during the process of informed consent. The goal is to ascertain what the service users, patients and research participants really think about current research practice in relation to the various elements of the informed consent process, to identify to what extent current approaches meet the needs and preferences of end users. Findings about patients' possible interpretations of the process of informed consent are an essential step towards evidence generation for an informed consent process that is fit for its intended purpose. Where the consensus is that individuals have a right to the fulfilment of ethical and legal responsibilities by clinical researchers, then the process of informed consent for clinical research participation deserves a genuine evaluation of its use as it is lived in the real world.

Research aim:

The aim of this research is to explore service users' perspectives of the process of informed consent for participation in clinical research.

Research question

The research question is:

What is the perspective of service users of the informed consent process for clinical research participation?

Specific research questions will include:

1. What are the views and opinions of research participants on the process of informed consent for clinical research participation?

2. How do research participants describe their involvement in the process of informed consent for clinical research participation?

3. How have research participants constructed reality and meaning from their involvement in the informed consent process for clinical research participation?

4. What are the ‘information’ and ‘care’ needs of prospective research participants during the process of informed consent for clinical research participation?

5. How does the experience of approach and process of informed consent influence prospective research participants’ willingness to take part in clinical research?

To answer these questions, this research will engage a distinct constructivist methodology, underpinned by the Naturalistic Inquiry (NI) paradigm. As a research paradigm, NI supports an open-minded approach, allowing the researcher to enter real dialogue with research participants as human agents, while noting new revelations about the situation being studied (Guba, 1985; Denzin 1971). The following chapter will discuss the philosophical orientations of the NI paradigm, including the philosophical correlates and the procedural steps that will be applied to realise the goals of this research.

While effort is made to inform and debate the theoretical underpinning of this research, it is noted that there is nothing inherent in a method or a perspective that renders an approach useless – or unacceptable. Rather, this research acknowledges that it is the use to which the method is put, and the degree of rigor employed that determines its usefulness (Denzin, 1971). Nevertheless, Halcomb (2018) recommends that the philosophical underpinning of a research should have the potential to strengthen the research design and subsequently improve the quality of research outcomes. Such deliberation would also stimulate understanding of epistemological and methodological perspectives and their impact on the design, conduct and reporting of research outcomes (Halcomb, 2018). Kelly, Dowling, and Miller (2018) support that an understanding of paradigm development is necessary when planning a study, as it can shape the search for understanding. The next chapter presents an overview of the ontological, epistemological, and methodological perspectives guiding this research.

Chapter 3

Theoretical underpinning & methodology

Introduction

This chapter outlines the philosophical positioning that influenced the implementation of this research, by mapping out the various steps of the inquiry methods used (Rubin and Rubin, 2012). First, it will offer a reminder of the purpose of this research. Second, the Naturalistic Inquiry (NI) paradigm is presented as the worldview upon which this research was conceived. Through critical evaluation, the ontological, epistemological and methodological considerations that guides the decisions and actions in the planning and carrying out this research are described and justified. Constructivist methodology is the preferred methodological approach particularly due to its explicit alliance with the NI paradigm (Guba, 1990). By comparing the constructivist approach to alternative methodologies, this chapter will conclude with a resounding case for the use of constructivism in inquiries such as this. Constructivism will help bring to light the meanings that patients attach to healthcare policies and research, following their real-life experiences of having been consented into clinical research studies.

Philosophy has been defined as the questioning of fundamental concepts and the need to embrace meaningful understandings of a field (Burke, 2007). As highlighted earlier, the aim of a philosophical examination in the conduct of a scientific inquiry is to inform the research stance from the outset, in order that the context, conduct and subsequent outcome of the research may be appropriately appraised and utilised (Burke, 2007). It supports the researcher in the design and implementation of fieldwork by the adherence to established theoretical frameworks, and by so doing informs the practical implementation of the research (Halcomb, 2018).

To recap, the goal of this research is to enable clinical research participants to have the opportunity to describe their experiences of involvement in the process of informed consent for research, and to interpret for themselves the meanings that they attached to their experiences of the process. The intention is to explore the intrinsic and extrinsic behaviours that research participants perceive to be significant in helping them decide whether to participate in a clinical research study. In view of the research goal, the components of the NI paradigm best reflect the researcher's positioning because of the desire to explore how participants construct meaning and because the phenomenon under investigation can only be researched in a real-life setting (Erlandson et al, 1993).

Research paradigm

Paradigms of inquiry relate to the theoretical frameworks that inform the steps taken in the facilitation and management of a scientific inquiry (Guba, 1990; Guba and Lincoln, 1982). Guba and Lincoln (1982 pg. 233) define paradigm as "axiomatic systems characterised by essentially by their differing sets of assumptions about the phenomenon into which they are designed to inquire". Erciyes (2020) discusses paradigm as the philosophical stance of the researcher that shows how his/her inquiry is designed in the research process. Representing a philosophical stance, paradigms predict the set of overarching and interconnecting assumptions about the nature of reality as perceived by the inquirer (Guba and Lincoln, 1981). To put it simply, paradigm implies a set of common beliefs and agreements within a discipline (Kuhn, 1962). Through paradigms therefore, a researcher's assumptions about a phenomenon into which they are designed to inquire can be predicted (Lincoln and Guba, 1982).

Hence, an awareness of a researchers' philosophical stance is useful in the appraisal and utilisation of research outcomes, as it allows for an inference about the nature and context of the research reports and findings (Cresswell and Poth, 2018; Burke, 2007). For this reason, one of the critical requirements when planning or utilising research evidence is to

establish which paradigm and subsequently which methodology or strategy was employed in answering the research question (Welford, Murphy and Casey, 2011). To do so involves consideration of the ontological standpoints of the research, in other words, the stance towards the nature of reality (Cresswell and Poth, 2018). It must also consider the epistemological principles, i.e. how the researcher knows what he or she claims to know, as well as ethics, i.e. relating to the role of values in the research conduct; rhetoric, i.e. the language of research; and the methods used in the research process (Cresswell and Poth, 2018). Therefore, the decisions about methods as the steps to an inquiry are secondary to considerations about a researcher's worldview or paradigms of inquiry. Interestingly, Guba and Lincoln (1994) clarified that the terms 'qualitative' and 'quantitative' approaches to inquiry, that are often confusingly implied as paradigm, should rather refer to descriptions of types of methods that may be used for specific research questions. These terms have therefore been avoided in the context of the discussions so far. The following discussion explores the philosophical positioning of the NI paradigm, which also signifies the constructivist's perspective, with both terms often used interchangeably (Guba, 1990; Guba and Lincoln, 1985).

Naturalistic Inquiry (NI)

An open-minded analysis of various worldviews was conducted to fully appraise the different knowledge generation frameworks and the different perspectives that exist. After a careful analysis of relevant literature, the NI paradigm (Lincoln and Guba, 1985) was shown to reflect the fundamental philosophical underpinning of the research objectives. Unlike the positivist paradigm that governs the natural sciences (Rubin and Rubin, 2012), NI acknowledges the limit of theoretical rules and policies and recognises the varying biases that compound human reasoning (Lincoln and Guba, 1985). It supports that regarding patients views of reality as ignorant or misguided and attempting to persuade them to follow

law-like practices has had limited value in the negotiations required to achieve good clinical outcomes (NICE, 2011; Green and Britten, 1998;). The belief is that patients and the public need to be placed at the centre of healthcare research, policy and service (Stocks et al 2015; Nilsen et al, 2013; Coulter and Collins, 2011). Failing to incorporate patients' views and perspectives has resulted in policy and clinical shortcomings, not just within the NHS but worldwide, especially as it relates to healthcare policies and services (Ocloo and Matthew, 2016). In a systematic literature review by Ocloo and Matthews (2016), it was found that involving patients and the public at every stage of healthcare policy and service allowed patients to work in partnership with professionals and policymakers, and by so doing, influenced healthcare service delivery for a greater outcome. While uncertainty continues to exist as to how best to involve service users in healthcare and health research, it is believed that patients' perspectives, who are experts by the virtue of their unique experiences of living through medical conditions and the healthcare system, are important contributors in leading the way for a shared decision making in healthcare policy and service (Coulter and Collins, 2011).

The NI paradigm is both a research philosophy and an innovative research methodology (Appleton and King, 1997). The paradigm uses the constructivist framework to gain a slice of 'real life' insight in the context of 'real life' situations (Lincoln and Guba, 1985). It considers that realities cannot be understood in isolation but must reflect the reasoning and context of the human experiences, which interact with values and varying unique concerns (Guba, 1978). It considers how people behave when absorbed in genuine life situations in the natural setting (Frey, Botan and Kreps, 1999), but also the interpretations and meanings that influence human actions in real life situations. Hence, it goes beyond the observing, retelling or describing of events, towards reasoning, meaning making and knowledge generation (Denzin, 1971). Therefore, the paradigm of NI came into play for this research. It seemed vital to engage in a methodology that supports the unpicking of the meanings that research participants make of the informed consent process for research. This is given that

the consent process is a time bound and distinct encounter that usually takes place behind closed doors with a lone clinician and a patient in a peculiar context. It was therefore important that research participants are enabled through social construction of their experiences to unpick and make meanings out of their situations (Denzin, 1971), rather than merely retelling their experiences.

Naturalistic perspectives of reality: Ontological considerations

Guba (1978), citing Wolf and Tymitz (1977), explained that the goal of NI is to present "slice of life" episodes documented through natural language and representing as closely as possible how people feel, what they know, how they know it, and what their concerns, beliefs, perceptions and understanding are". NI supports that reality or perception of the world is dependent on the meanings that people attach to life events, situations or processes (Rubin and Rubin, 2012). A focus on actions and effects (Ellis, 2014) therefore would not fully explain the intentions that lead to behaviours, as reality constantly changes and can only be understood through a proper 'view' of people's lenses since the lens affects what people see and how they interpret what they find (Rubin and Rubin, 2012). Reality therefore is not fixed but filtered through the lens of the individual at a point in time. This is contrary to the positivists' stance that the world has an existence independent of our perception of it, or some sort of universal reality (Cresswell, 2014).

In comparing competing philosophies, Lincoln and Guba (2000) highlighted other world views, including positivism, post-positivism, critical theory, constructivism, and some participatory approaches. Of these, and as already discussed, positivists views reality as totally independent of humanity (Park et al, 2020; Kelly, Dowling and Miller, 2018; Clarke, 1998), claiming that the world has an existence independent of our perception of it. In other words, reality is deemed to be separate from the individual who observes it, implying a dualistic perspective (Park et al, 2020; Weber, 2004, Clarke, 1998). They suggest that reality is fixed, factual and universal, and should be observable by the senses (Park et al,

2020; Cresswell, 2014; Rubin and Rubin, 2012). The other paradigm, post-positivism (often referred to as critical realism) (Cresswell, 2014; Erciyes, 2020), considers reality from a critical perspective, accepting that there may be no absolute truth (Kelly, Dowling and Miller, 2018), and proposing that the human intellectual mechanism is insufficient to totally make sense of reality on its own (Guba and Lincoln, 1994). Instead, post-positivists suggest that humans could understand reality though only imperfectly and probabilistically, a position countered by the NI paradigm (Guba and Lincoln, 1994). So post-positivism denotes that human agency may only be capable of partially estimated truth, rather than an absolute truth as in the case of positivism (Kelly, Dowling & Miller, 2018; Guba and Lincoln, 1994). In comparison to the NI paradigm, post-positivists reject that reality should be context-bound, arguing that such reality would be imperfect since human perspective, in their belief, is deemed inaccurate and imperfect (Welford et al, 2011). Clearly, such a position could not be adopted within research such as this, which seeks to realise the perspectives of clinical research participants and the meaning that they attach to their experiences.

Following on from positivism and post-positivism is the interpretivist paradigm. The interpretivist paradigm is often used interchangeably with the NI paradigm (Ryan, 2018), though subtle differences exist (Kelly, Dowling and Miller, 2018). Ontologically, the interpretivist understands that human beings are unique. They also recognise that there can be many constructions of reality, as 'social facts' or lived experience is unique to each individual due to the lens through which they view the world and the cultural/societal influences that may influence that view (Welford et al, 2011). In other words, interpretivists recognise that a persons' perception of reality is dependent on the persons' interpretation of the world around him/her, and that the decisions and/or actions a person takes may be influenced by such perceptions and interpretations (Weber, 2004). For that reason, there is no unequivocal or foundational way to explain reality given the subjective states of individuals (Guba, 1990; Guba, 1978). In other words, the interpretivist ontological position

is that of multiple realities underpinned by lived experiences and societal influences on a group of people (Kelly, Dowling and Miller, 2018; Welford et al, 2011). The focus of inquiry is therefore studied through the eyes of the people that experience the situation, acknowledging specific contexts and respecting multiple realities (Welford, Murphy, and Casey, 2011).

Similarly, the constructivist philosophy, which is often aligned to the interpretivist paradigm (Kelly, Dowling, and Miller, 2018) but is rather a component of the NI paradigm (Lincoln and Guba, 1985; Guba, 1990; Guba, 1978), holds a unique stance to reality. Its stance goes beyond societal influences on a group of people and seeks to understand the unique experiences of each person as an individual (Kelly, Dowling, and Miller, 2018; Crotty, 1998). This unique stance explains the subtle difference between another term, constructionism, and the constructivist philosophy, with the latter linked to the NI paradigm, and being the favoured methodology for this research (Rubin and Rubin, 2012). While constructionism seeks to explore societal influences that underpin interpretivists' philosophy, constructivism explores the way in which everyone sees and interprets the world around them (Guba, 1990). Crotty (1998) provides further clarity by suggesting that constructivism emphasises the mind and the construction of meaning, whereas constructionism identifies the collective generation of meaning. The significance of these explanations is drawn upon later in this thesis as it identifies why constructivism is the methodology of choice for this research.

The interpretivist philosophy accepts that the studying and understanding various perspectives of a group can be done through questioning and by listening to the affirmations between human agencies (Mack et al., 2018; 2010; Burke, 2007).

Clearly the process of informed consent for research by its nature is unique to each individual and depends on the meanings that each individual attach to their involvement in clinical research. It may not particularly depend on the 'quantity' or 'volume' of information

being provided to prospective research participants. The current infrastructures have not achieved the required purpose of meaningful and informed decisions by prospective clinical research participants. Over the decades, literature points to plenty of anger, anxiety, distrust and disagreement, but no apparent growth in knowledge.

In seeking understanding, this research perceives that meaningful consent may not be achieved in isolation without a match between theory and reality. To fill the gap and given that consent is conducted on an individual basis, there is a need therefore to engage with real-life research participants at individual levels to advance empirical and personal insights. A significant point being that the ideology of law-like controls (Cresswell, 2014; Barker, 2013) over human reasoning (Crotty, 1998) have only served to impede the advancement of the foundations upon which the process of informed consent was originally conceived. The notion is that individual patients can determine for themselves the factors that play a role in their decision to be involved in a given clinical research study. It may be that such factors are reflections of some established theoretical assumptions, commonly accepted views of healthcare research or assumed set of expectations in the clinician-patient relationship. Whatever is thought regarding perceptions of reality, the impulse is to seek plurality of thoughts, insights and alternatives from participants (Guba, 1978). Such knowledge is required to enhance our understanding of the decision-making processes of actual clinical research participants in the real-world context of contemporary healthcare delivery.

This ontological stance reflects the NI paradigm. First, the nonconforming characters of the NI paradigm support that what we can know or understand is interpreted through human reasoning, not merely senses (Guba, 1978), and that it may not always be observable as is advocated by positivism and/or realism (Park, Konge and Artino, 2020). Naturalistic Inquirers agree that reality is socially constructed and subjectively interpreted (Erlandson, et al., 1993), which means that reality is relative and in the eye of the beholder. Worth or value are unique to the individual (Guba and Lincoln, 1994). No intellectual, professional or

organisational institution can determine worth or value without consideration for the perspective of the service users. We have been unable to predict for sure what the nature of reality is, as it relates to the meaning that real life clinical research participants attach to the process of informed consent for clinical research (Armstrong et al, 2012; Ponder et al, 2008; Richards et al, 2002). It is important therefore that we inquire what the patient or service user sees as significant to them, and what we know would play a part in their compliance with or use of healthcare policies and services.

As with NI principles, the onus is to advance knowledge through the exploration of research participants' views and concepts, rather than to use a top-down approach to the informed consent process (Halcomb, 2018). This is contrary to the goal of theory testing, which positivist researchers seek to achieve through numerous refinements, replication, and eliminations until they accomplish an alternative or preferred explanation (Park, 2020; Ryan, 2018; Streubert and Carpenter, 2011). Although a naturalistic inquirer is guided by a research question or aim from the outset, as with other forms of inquiries, this research is not dictated by an *a priori* construct or theory; rather theory or constructs will advance from within the data by an inductive process (Ellis, 2014; Guba, 1978). This is an additional reason why NI lends itself to the focus of this research. Whatever truth may exist requires the consideration of the views and opinions of research participants in a manner that allows them to express their views and perspectives as it matters to them, rather than a received view or law-like rule (Streubert and Carpenter, 2011). Therefore, unlike previous studies that focused on the views of healthcare professionals on the process of informed consent for participation in clinical research (Snooks et al, 2012; Hallowell et al, 2008; Harris and Dyson, 2001; Jenkins et al, 1999), this research acknowledges that reality ought to be sought and viewed from the lens of the service users themselves. The ontological underpinning of this research therefore allows it to understand not only the ways that individuals come to know what they value, but also how what they come to value is created or validated (Streubert and Carpenter, 2011).

Naturalistic perspectives of knowledge: epistemological considerations

With regard to the epistemological underpinning of this research, enough has already been said that indicates a subjective stance about the nature of truth (Ryan, 2018: Erciyes, 2020). Epistemology questions the relationship between the knower and the known (Denzin and Lincoln, 1994; Welford, Murphy and Casey, 2011). This enlightens the research process and can include arguments for objectivism, subjectivism and others (Ryan, 2018), which relate to how we know what we know (Streubert and Carpenter, 2011).

In that regard, and in line with the NI paradigm, in this research, the inquirer and the respondents can use a common vocabulary to interact and positively influence one another in the meaning making process of constructing knowledge (Erlandson et al., 1993). Guba and Lincoln support that knowledge can be created through the interaction of inquirer and participant, rather than the positivist's stance that knowledge may only be discovered through objective observation (Guba and Lincoln, 1994). The role of the inquirer is therefore as a human instrument that is capable of socially interacting with other human social agents, rather than as a scientific instrument used to describe and predict patterns (Bunniss and Kelly, 2010). From the naturalist perspective, the view of knowledge is that there are possible influences on an individual's perception of the world and how they see and interpret it. The perceived notion is that no one else has the right to dispute a persons' view of their world (Guba and Lincoln, 1994). The place of the inquirer therefore is to seek to understand the meaning that persons attach to their world and to accept the multiple realities that exist (Streubert and Carpenter, 2011). Guba and Lincoln (1994) explained that such an epistemological assertion of the truth requires the researcher to be respectful of the views of the researched as credible knowledge without the need to want to prove its truthfulness. For that reason, the epistemological position of the NI paradigm is criticised as being basic, given that such knowledge is not provable, and so not taken as a universal truth (Bunniss and Kelly, 2010). Yet that is what makes NI relevant and valuable in the study of human decisions and behaviours. Human beings and the meaning they attach to

their world are simply valued and respected, without the need or desire to want to disprove an individual's view of their world. Participants' accounts are accepted simply on faith, with no pursuit to establish their ultimate truthfulness (Lincoln and Guba, 1994). The knowledge gained by NI is not intended to be generalised (Denzin, 1971) but can give insight in dealings with people in similar circumstances, where relatable (Guba, 1978).

Lincoln and Guba (1982) perceived this as a strength of the NI paradigm. They argue that it will be impossible for the human instrument to abandon its own humanness in the pursuit of unrealistic objectivity, and that to do so could be ethically undesirable. This research concurs, given that the researcher is a former clinical research nurse with an abundance of experience in the language and context of clinical research practice, so to claim an abstract position may be impossible, unethical and uncomfortable. For instance, a participant may start to engage with the researcher on a human or professional level during interactions in the field. In such a situation, Clarke (2006) recommends that it may be unrealistic or unethical to ignore the participant's advancement carelessly or insensitively to fulfil a researcher's agenda. Clarke (2006) recounted her own experience of ethical dialogue in her dealings with human research participants, where building rapport with human research participants was recognised as an important part of the naturalistic interview process. To do otherwise would have risked harmful effects on the psychosocial wellbeing of research participants during their involvement in research (Clarke, 2006). Instead, a two-way reciprocal interaction process is recommended - the gathering and giving of information as the interview dialogue detects (Clarke, 2006). In doing so, the researcher is encouraged to bracket or put aside prior experience of the field to ensure that participants' voices are heard without undue influence (Guba, 1978). It must also be acknowledged however that objectivity has its place in certain fields of research, such as the hard and life sciences, where laboratory experiments are the preferred approach, and in which non-living objects of inquiry cannot be said to be under the influence of any interpersonal distractions (Dash 2005; Duffy, 1985). However, meaningful social and behavioural research outcomes can be

achieved through engagement in research approaches that support active participation of the researcher in the construction of knowledge within established boundaries (Bunniss and Kelly, 2010). Bunniss and Kelly (2010) assert that there is no one superior or perfect research approach but instead, all research paradigms can be valid when used sensibly, in context, to answer appropriate research questions. It is recognised that because positivist methodologies have reigned for decades, the naturalistic paradigm may be less familiar to most career researchers in certain fields of study, with NI having only recently emerged in social/behavioural research (Guba and Lincoln, 1982; Lincoln and Guba, 1985; Guba and Lincoln, 1989b; Guba, 1990).

In this study, it is the researcher's ability and attributes as a former clinical research nurse that distinguished NI as a suitable approach. NI supports the researcher to function as a 'smart' instrument, and to utilise prior experiences productively throughout the research process. Through interactivity, the researcher can guide respondents to make meanings out of situations and to interpret data in collaboration with the data source (Guba and Lincoln, 1989b). The researcher advances knowledge by exploring how people describe and justify their actions. It is through such deeper explanation that the researcher can penetrate beyond the worlds of a participant's experience to determine the forces that shape and influence behaviour (Denzin, 1971). Hence, the inquirer-respondent relationship is that of co-construction of knowledge throughout the research process (Denzin, 1971). The epistemological position of the naturalistic inquirer is therefore context-bound and subjectively valued, with the researcher recognised as part of the research process (Streubert and Carpenter, 2011). The focus of this inquiry is to achieve wholesome and relevant insights of the multiple realities that exist to compound research participants' reasoning with regards to the process of informed consent for research. The gap in existing knowledge is that no one understands why ethical and regulatory measures have remained unable to effect meaningful informed decisions by research participants. By engaging an appropriate methodology, this research is expected to yield rich data that gives insights into

the human cognitive processes influencing participants' actions and decisions during the informed consent process.

Some critics of NI believe such a stance could potentially predispose the inquiry to bias (Park, Konge and Artino, 2020), and this is not entirely unreasonable. However, Weber (2004) argued that even the objects of positivists' research cannot truly be said to be independent, given the manipulation that goes on in the process of testing and measuring artefacts or theories. Such manipulation could also affect the behaviours and qualities of the objects being tested or measured (Weber, 2004). So even in positivist research, the concept of independence or objectivity remains questionable. Instead, the naturalistic inquirer openly accepts that the researcher and the researched can both make sense of meanings together, and by so doing inevitably influence one another. The researcher and the researched are acknowledged to be interdependent. Concerns about trustworthiness of naturalistic research are countered by taking a systematic and meticulous approach at every stage of the research process. The steps to trustworthiness are essential components of the naturalistic tradition and are embedded at all stages of the research design and conduct. The fundamentals of trustworthiness in NI will be reflected upon in the methodology and methods sections that follows.

Methodological assumptions

While research paradigms refer to worldviews, traditions, belief systems or a framework of a set of philosophies (Seely, 2010; Lincoln and Guba, 1985, Guba and Lincoln, 1994), methodology relates to the methods/approaches or procedures that will be used to achieve the research objectives (Kumar, 2019). Methodology details how the inquirer will go about finding out what is knowable (Guba, 1990, pg. 18). Although paradigms do not necessarily imply methodologies (Kumar, 2019; Lincoln, 1990 pg. 78), in most cases, research methodology is underpinned by a framework of a set of philosophies and reflects techniques that have been tested and are trusted by experts to produce dependable

research outcomes within a discipline (Kumar, 2019). It details how each philosophical principle may be put into practice in the actual conduct of the research. In other words, research methodology spells out 'the doing plan' of every stage in the research process, providing definitions and justifications for the intended actions (Lincoln and Guba, 1985). Dobbert (1990) refers to the concept of methodology as a 'study of methods, a study in which we lay bare our choices of method and define the way these choices fit our research problem'.

It must be acknowledged that 'instead of methods being important, the problem is most important, and researchers use all approaches to understand the problem' (Cresswell and Poth, 2018; Denzin, 1971). Nevertheless, an understanding of philosophical traditions is essential for demystifying and making sense of the theories that underpin scientific research, and the rationales for the choices made (Kelly, Dowling and Millar, 2018; Welford, Murphy and Casey, 2012; Bunniss and Kelly, 2010; Polly, 2006; Guba and Lincoln, 1982). Osborne (1996) asserts that failing to consider how scientists come to 'know' runs the risk of developing learners who may not value knowledge as rational. The question of how we go about finding out that which it is believed can be known is therefore an important aspect of evidence generation.

The methodology of constructivist (naturalistic) inquiry

This research will be guided by the constructivist methodology. But before progressing, it may be useful to clarify further that the terms NI and constructivism are used synonymously to convey the same assumptions or approaches to inquiry (Guba and Lincoln, 1994). There is little difference, if any, in their application, especially within NI traditions (Guba and Lincoln, 1994; Guba, 1990). In fact, Lincoln and Guba's inquisition about the nature of knowledge and ways of knowing brought about the emergence of the NI paradigm (Guba, 1978; Lincoln and Guba, 1985). They explain that the use of the different terms is for

symbolic reasons and does not necessarily connote dissimilarities in meaning or application (Guba and Lincoln, 1994; Lincoln and Guba, 1985; Guba and Lincoln, 1981).

Guba and Lincoln recount that the use of the term 'constructivism' emerged in response to critics in an attempt to expand their revolutionary transformations as human inquirers (Guba and Lincoln, 1994; Lincoln, 1990; Guba, 1978). In 'Competing Paradigms in Qualitative Research' (1994), Guba and Lincoln say "we acknowledge at once our own commitment to constructivism (which we earlier called "naturalistic inquiry: Lincoln and Guba, 1985" (Guba and Lincoln, 1994 pg. 105). They urged that this be considered in future discussions about alternative research paradigms. Other investigators have since been inspired to use the term 'Naturalistic Inquiry' when engaged in dialogues about research traditions (McInnes et al, 2017; Guba and Lincoln, 1989b; Guba and Lincoln, 1981), and constructivism as a research methodology (Barkin, 2014; Appleton and King, 1997; Guba and Lincoln, 1994; Erlandson et al., 1993; Guba, 1990). The mandate, whatever the terminology, is salient on what the researcher does and the choices they make in the design and conduct of research (Lincoln and Guba, 1985). This research has adopted the use of the term 'Naturalistic Inquiry to refer to its philosophical worldview or paradigm (Lincoln and Guba, 1985), while the term 'constructivism' represents the methodologies or paths guiding the practical conduct of this research (Guba, 1990; Schwandt, 1990).

Constructivist methodology engages in the process of knowing and the mental activity that is involved in it (Andrew, Pedersen, and McEvoy, 2011). It provides the scope to construct a comprehensive and contextual understanding of a phenomenon (McInnes et al., 2017). It guides human beings to make meaning about their environment or experiences through interactions that yield to constructs (Andrew, Pederson and McEvoy, 2011). From an epistemological perspective, constructivist methodology examines how people know what they know and what meaning people place on their knowledge (Kelly, Dowling and Miller, 2018). This is achieved when an individual engages in interactions through which they are supported to express their own views with the focused goal of constructing or shaping new

ideas using natural language (Lincoln and Guba, 1985). In this way, constructivist research attempts to rationally understand the world through the lens of those experiencing it. The focus is on ‘why’, rather than ‘what’, ‘when’ or ‘how’ (Allen, 2008), along with the acknowledgement that reality is a product of human intelligence interacting with experience in the real world (Andrew, Pederson and McEvoy, 2011).

The constructivist approach was particularly fitting for this research, which aims to bridge the gap between theoretical perspectives and the service consumer perspectives of the informed consent element of the research process. It is assumed that the complex and challenging situation regarding consent outcomes cannot be understood as a whole, based on expert opinions alone. Rather, the views of those experiencing it is crucial to the understanding of the whole picture. In this research, the participants’ views are taken to be the ‘missing part’ in the existing knowledge to date.

Within healthcare and clinical research, Seely (2010) states that the pursuit of knowledge is married to the utility of knowledge. Bridging the gap between the discovery process of knowledge and its bedside application would therefore seem to require an integrative and individualised approach, with patients as constituents of the research process. Participants’ perceptions and interpretations, which are the hallmark of the constructivist methodology (Guba, 1970; Bunniss and Kelly, 2010), it is hoped would provide greater knowledge and understanding of the component parts missing from the process of informed consent for research. Given the known limitations of current knowledge, a constructivist approach seemed complementary and fundamental to improving insights by engaging common interdisciplinary and patient-centred language in the research process (Guba, 1990). The focus on theoretical perspectives and the engagement of professional opinions alone are yet to lead to effective informed process outcomes, those being informed decisions.

Other methodologies were considered within the naturalistic paradigm for this research, including ethnography and phenomenology. However, it was thought that ethnography,

which provides information about organisational or cultural behaviours (Streubert and Carpenter, 2011), would not have been fitting for this research, which aims to provide in-depth interpretations of the individual perspectives of the participants. Muecke, (1994 pg. 192) explained that the objective of ethnographic methodology is to 'define the structure of culture, rather than to describe a people and their social interaction, emotions, and materials'. As the focus of this research was not to study or describe the culture that exists in the clinical research setting, ethnography was therefore not considered appropriate. Given that this research involved real-life patients experiencing real life situations, there was also the concern that ethnographic methodology may have been too intrusive and burdensome for patients, and on those providing care, given that the researcher would have to spend more time in the field constantly observing and making sense of behaviours (Streubert and Carpenter, 2011). It was thought that such constant observation could get in the way of patient care in an already busy clinical environment.

Phenomenology explores the lived experiences of phenomena such as health and illness (Whitehead and Ferguson, 2020; Plager,1994). Like constructivist methodology, phenomenology focuses on the interpretation and description of people's experiences (Ryan, 2018), however the exploration of meaning is taken to be embedded through 'felt' aspects of experience (Wilson, 2015). As such, it is geared towards exploring people's moods, sensations and emotions, thereby pursuing an affective analytical framework (Wilson, 2015). According to Goulding (1999 pg. 863), phenomenology aims to 'describe and clarify the essential structure of the lived world of conscious experience by reflexively meditating on the origins of experience'. A notable difference is that, unlike constructivism, phenomenology seeks to describe and interpret knowledge through focusing on thoughts, feelings, moods, sensations and emotions (Wilson, 2015), whereas constructivist research engages beyond feelings to interact with human intelligence (Guba, 1990). In other words, constructivist methodology enables reality to be pursued through the construct of the human mind (Andrew, Penderson and McEvoy, 2011). Therefore, more than having

participants merely recount their feelings, the constructivist researcher engages with the participants to generate knowledge as they collaborate to make meaning throughout the research. In comparison, phenomenological research focuses solely on affective accounts of lived experiences and appears to ignore individual biographies, social norms or attitudes, only recognising such elements if they emerge but without actively pursuing them (Wilson, 2015).

Recognising reality as the product of human intelligence and a belief that human beings can unpick the real world beyond feelings of 'here and now', constructivist methodology naturally lent its hand to the focus of this research. This research set out to provide real-life clinical research participants the opportunity to open up about how they decided, but also why they decided to consent, or not, to participating in research. It is only by such deep-rooted engagement that this research can truly extend conversations beyond what is known, to highlight that which may yet be uncovered.

Setting the strategy

Truth values: pluralistic relativist ontology, multiple, intangible, socially constructed and often conflicting realities.

About truth values and ways of knowing, the constructivist methodology recognises that reality is relative to circumstances and exists in multiple forms (McInnes, Peters & Bonney et al. 2017; Guba & Lincoln, 1994; Lincoln & Guba, 1985). The belief is that reality has no universal or timeless value but is valid only in the circumstances or context of the group or individual (Kumar, 2019; McInnes, Peters & Bonney et al. 2017; Appleton & King, 1997). So what can be known will depend on the perspectives of those experiencing the phenomenon under investigation; and their interpretations of it (Streubert & Carpenter, 2011; Appleton and King, 2002).

This notion that reality may be perceived differently by different individuals is referred to as relativism (Green and Britten, 1998; Guba and Lincoln, 1994), which is supported by the

constructivist methodology. Relativism assumes that truth values can be multiple, apprehendable and could uncover conflicting social realities that are the products of human intellect (Appleton and King, 2002; Guba and Lincoln, 1994). This research concurs, as it aims to gain new knowledge by engaging with real-life clinical research participants to explore their perspectives and the interpretations they attach to their individual circumstances. Guba (1990) supports that openness to relativism is key to the continuing search for meaningful and relevant constructions, asserting that realities can be "multiple, socially constructed and often conflicting" and exist uniquely in peoples' minds (Guba 1990 p.72). This contrasts with an ordered, immutable or predictive view of truth (Welford, Murphy and Casey, 2011; Cresswell, 2014; Osborne, 1996). Put simply, individuals are taken to know the truth in their unique circumstances, so it follows that uncovering such truth requires personal engagement with the individuals.

Ways of knowing: relationship of knower to known

Epistemologically, constructivist methodology supports the use of the inquirer as an instrument for generating knowledge through interaction and in doing so, both the researched and the researcher are considered inseparable (Appleton and King, 1997; Lincoln and Guba, 1985). To know, the researcher sustains a process of interaction and discussion with research participants (Appleton and King, 2002). The researcher seeks for mutual shaping through description and interpretations and must therefore approach the phenomenon or object of inquiry with an open mind (Lincoln and Guba, 1985; Guba, 1978). By immersing herself with as open a mind as possible, utilising aesthetic skills (Streubert and Carpenter, 2011), the researcher can permit impressions to be formed and emerge from the researched to enhance understanding. Such a methodological approach is believed to yield authentic and meaningful discoveries, providing unique opportunities to uncover new knowledge (Lincoln and Guba, 1985). By engaging in meaningful interactions with respondents and by being adaptable and flexible (Appleton and King, 2002), the human instrument can bring about new insights (Lincoln and Guba, 1985). In this research,

this was considered pivotal given that the researcher is a former clinical research nurse with an abundance of relational skills and an understanding of the context of care. In this context, it was considered that the nullification of such capabilities for whatever gain or value (context-free, subjectivity, prediction and control), would make a bad trade-off.

Setting

Methodologically, constructivism demands that the inquiry is conducted in natural contexts, to capture realities holistically (Lincoln, 1990). Such a context will enhance the comfort of respondents in their natural setting (McInnes et al, 2017). In that regard, the decision was made to conduct research interviews in the natural environment in which consent would normally take place. This will include private clinic rooms within hospital settings or at participants' homes, depending on individual preferences and convenience. Such natural settings will support rich data by allowing more natural conversations with participants in comfortable environments, enabling open and honest interactions (Lee, 2006).

Data collection technique

The constructivist methodology supports interaction between the investigator and the respondents (Lincoln and Guba, 1985). Interactions between the researcher and the respondents enables the researcher to pursue knowledge on the go within reasonable limits, enabling some grounds for persuasive probing (Lincoln and Guba, 1985). This research will utilise a variety of open-ended questioning techniques with the aim of discovering a wholesome perspective of real-life clinical research participants' views on the consent process for research. Polly (2006) refers to this as exploratory in nature, suggesting that an exploratory research design is appropriate when little is known about a phenomenon, so as to allow for open dialogue with no fixed or pre-determined questions or agenda. Kumar (2019) adds that exploratory research is 'when a study is undertaken with the objective of either exploring an area where little is known or of investigating the possibilities of undertaking a particular research study'. With little known about clinical

research participants' overall experiences of their care in relation to the process of informed consent and their perceptions and interpretations of the process, an exploratory approach seems fitting. In this research, data will be collected using a flexible approach such as open or semi-structured interview questions. It is encouraged that interview data collection will need to be supported by audio and video recordings for fidelity purposes (Lincoln and Guba, 1985), with consent. Other tools that could be considered in naturalistic inquiries include participant observation, focus group interviews, field notes, and documentary evidence, depending on the objective of the research (Appleton and King, 1997; Lincoln and Guba, 1985). The hope is to engage in semi-structured face-to-face individual interviews with participants.

Data analysis: mutual shaping & co-construction of knowledge

Constructivist methodology explores the patient's possible interpretations of his/her world and of his/her experience using the inductive mode of discovery (Guba, 1978 p.190). The goal of constructivist data analysis is therefore to discover reality by exploring meanings, intentions and purposes through natural relationships (Mills, Bonner and Francis, 2006). Marshall and Rossman (2016) assert that constructivist research is required to uncover what people believe to be true in their unique circumstances (with an understanding that there is no absolute truth). This is achieved with a focus on the data, whereby the researcher sieves through to look for instances where natural relationships can be observed (Guba, 1978). The unique discoveries that emerge can be reported authentically by providing 'thick descriptions' that illustrate both data and context (Lincoln and Guba 1985, p.125).

Having a subjectivist epistemology, constructivist methodology recognises that the researcher cannot understand the data from a purely objective stance. Instead, the researcher engages with the data with the hope of simplifying the complexity found in the data (Levers, 2013). To do so, the ontological and epistemological dimensions merge

together by the way that the researcher is external to the views of the researched, yet internal to the emergence through the interpretation and meaning making process (Levers, 2013). So, the researched through data, and the researcher through involvement in the meaning making process participates in co-construction of knowledge towards theory building.

Constructivist data analysis involves interaction between the researcher and the researched (Smith, 1990). It is an exercise that occurs in a dynamic, intuitive, continual, systematic and transparent process through thinking and theorising (Lincoln & Guba, 1985; Streubert & Carpenter, 2011). Constructivist methodology is therefore interactive and subjectivist in nature (Smith, 1990). Analysis starts at the very first interaction with the researched and continues as data emerges until the end of the research (Appleton and King, 1997). In doing so, the researcher commits fully to a structured analytic process in order to gain a wholesome understanding of the data. Analysis is engaged through reading, intuiting, analysing, synthesising, and reporting of the discoveries (Streubert & Carpenter, 2011). The meticulous process yields in-depth discoveries and is seen as a meaningful process of evidence generation (McInnes et al, 2017).

In this manner, the constructivist methodology differs from some other qualitative research approaches in the way that it encourages a detailed exploration of patterns and influences. For example, unlike ethnography, constructionism is concerned with societal influences on communities (Shorter and Gergen, 1994). Constructivism supports in-depth transactional engagement with the researched at individual levels personally through discourse (Osborne, 1996). This is achieved through the negotiation of meaning during interview interactions and the subsequent interpretation of data with the sources from which the data was drawn until a consensus is gained (Guba and Lincoln, 1985). For the constructivist researcher therefore, hermeneutic and dialectical skills are essential as the researcher must utilise the skills & art of understanding to be able to identify the significance of human actions, utterances, products and intuitions throughout the research process (McInnes et al,

2017; Streubert & Carpenter, 2011) . In doing so, the goal of constructivist data analysis is to interpret, explore, and discover new concepts, constructs, theories, frameworks or models.

Unlike some other qualitative and/or quantitative methodologies such as ethnography or surveys, whereby researchers may seek to remain ultimately distinct and objective (Pope and Allen, 2019), constructivism reaches beyond the superficial grasp of utterances to construct essence and meaning. The researcher can use the intuitive knowledge of a field to inform and guide the inquiry process (Appleton and King, 1997). This is considered a strong element in the choice of constructivist methodology, given that the researcher is a former clinical research nurse. Indeed, it would be impossible to attempt to claim that the researcher can fully put aside knowledge of the phenomena being investigated in order to approach the data with no preconceptions (Dowling, 2006). Instead, the researcher can seek to relate her knowledge of the phenomena to understand the respondents' allegiances (Appleton and King, 2002). Such transaction supports a sequenced pattern of flow from a naturalistic real-life perspective (Lincoln and Guba, 1985). Also, given that the respondents are aware that the researcher is a former clinical research nurse, it would be unnatural to pretend a distant stance, which would jeopardise data quality. If dutifully implemented, Appleton and King (1997) suggest that a constructivist methodology will make an invaluable contribution in the progression of a fruitful NI (Appleton and King, 1997).

Goodness or quality criteria

The constructivist methodology is no less concerned about quality than is the conventional researcher, although quality may be measured using different terminologies (Lincoln and Guba, 1985). Denzin (1971) conveyed that the naturalistic researcher must address the question of replication and whether the research process can be built upon by others. The recommendation is to maintain transparent processes that allow the reader to assess and

confirm the trustworthiness of the research outcome (Healy and Perry, 2000; Krauss, 2005; Osbourne, 1996; Lincoln and Guba, 1985)

In that regard, Guba (1978) explained that both conventional and naturalistic inquirers strive for quality, but the meaning they each ascribe to the concept is quite different. Highlighting the differences in terminology, trustworthiness is the term used within NI with regard to issues of quality, as opposed to the term 'rigor', applied within positivist paradigms (Guba, 1990; Lincoln and Guba, 1985). Within NI, quality appraisal or trustworthiness is measured by the 'credibility' of the research findings, the 'dependability' of the instrument of research, the means by which data was collected, 'confirmability', implying an auditable pattern of conduct in the research process, and 'transferability', the extent to which the knowledge may be transferred in similar contexts (Lincoln and Guba, 1985, p. 289). These terms parallel the standard criteria of validity, external validity, reliability and objectivity respectively, in comparison to positivist research traditions (Guba, 1990). The observance of each of these constructivist criteria will be discussed in more detail in the methods chapter. In the meantime, for context, some brief discussion is provided below:

Credibility

Some of the basic considerations for credibility relate to the degree to which the constructed realities that exist in the minds of the research participants are resembled in the knowledge produced (Erlandson, Harris, Skipper and Allen, 1993). Credibility of research is judged by depth of meaning and richness of understanding (Streubert and Carpenter, 2011). Fundamental to the issue of credibility is the researcher's ability to manage the potential biases and influences that could impact on data, whilst ensuring richness of meaning and understanding (Appleton and Kings, 1997). The strategies that enhance richness of meaning and understanding include prolonged engagement in the field and persistent observations (Lincoln and Guba, 1985). Persistent observation is applied by consistently pursuing interpretations in different ways, both during field work and during

processing of data (Lincoln and Guba, 1985). The purpose of prolonged engagement is to allow the researcher to immerse themself in the data in order to gain a deeper understanding of what the data conveys (Streubert and Carpenter, 2011).

Where possible, triangulation is also encouraged, as it promotes the credibility of the research outcome. Triangulation implies using two or more approaches to research a question (Heale and Forbes, 2013). It relates to the assumption that adopting two or more different approaches to answer the same question may yield to more rigorous outcomes, thereby enhancing the credibility of the research findings (Duffy, 1985). Within constructivist methodology, this may include the way that the population is sampled; using multiple data sources; or a variety of methods in studying a single phenomenon (Krauss, 2005). The goal of triangulation is to capture more diverse views and give more perspectives on the phenomenon being investigated.

Another useful way of enhancing depth of meaning is by providing contextual insights through referential adequacy materials, which also enable the reader to determine where evidence may be transferable (Erlandson et al., 1993). Other measures include peer debriefing and 'member check'. Peer debriefing is achieved by reviewing interpretations with relevant others who may provide feedback and suggestions to guide the research process (Collins and Onwuegbuzie, Johnson and Frels, 2013; Lincoln and Guba, 1985). Member checks involves the verification of findings with research participants after they have taken part in the research; both data and interpretations are reviewed by the research participants before dissemination (Hadi and Closs, 2016; Lincoln and Guba, 1985. These measures provide alternative approaches for enhancing the truth level, which is equivalent to the internal validity measures in the positivist paradigm (Lincoln and Guba, 1985).

Transferability

The goal of constructivist research is not to realise generalizable data but to elicit individual constructions that will be refined hermeneutically, and compared and contrasted

dialectically with the aim of generating constructions on which there may be substantial consensus (Guba, 1990 pg. 27). Some critics have argued that the findings from such a relativist approach would be of limited use given that knowledge based on individual reality or truth cannot be generalised (Kumar, 2019; Bunnis and Kelly, 2010; Osborne, 2006). But Appleton and King (1997) point out that the findings of a constructive research, though not intended to be generalizable, can be transferable in cases where people hold similar views about the nature of realities within and across social groups. As highlighted earlier, the intent is to provide rich descriptions of the research context and settings so that readers can determine for themselves the transferability of the research outcomes in relevant contexts (McInnes et al, 2017; Guba and Lincoln, 1982, Lincoln and Guba, 1985), summarised as 'Good data are obtained by getting inside the worlds of others (Marshall, 1990 pg. 192).

Dependability

A credible research outcome should also be deemed to be dependable and no extra test should be required for checking its dependability (Lincoln and Guba, 1985). However, there are obvious differences in the two goodness criteria (although overlap exist). It can be understood that the credibility criterion relates to the truth value of the research data, whereas the dependability criterion is linked to the degree of consistency; the degree to which the research could be reproduced given the same circumstances. Dependability refers to the degree of accuracy and consistency of the research process, and whether any variance can be trackable (Erlandson et al., 1993, Guba, 1981).

To encourage a dependable research outcome, the researcher is guided to maintain an auditable trail and to ensure frequent ongoing communication at milestones with other members of the research team (Lincoln and Guba, 1985). In doing so, and by following a transparent process in the inquiry, Lincoln and Guba (1985 pg.102) declared that "it is only reasonable to assert that the investigator's judgement can be relied upon to the extent that he or she interacts with the phenomenon over time".

Confirmability

Confirmability is somewhat related to dependability. It refers to the degree by which an auditor may confirm the process and product of the inquiry; whereby process refers to the steps of the inquiry and products refer to the data, findings, interpretations and recommendations; these being the end-products of scientific research (Lincoln and Guba, 1985). Confirmability is fundamental as it determines to what extent the research findings could be verified by an external checker and to what extent users of research might consider the findings to be authentic and trustworthy (Lincoln and Guba, 1985). In many ways therefore to be confirmable is to be dependable (Guba, 1990).

Measures that enhance confirmability are understandably similar to those of dependability and include appropriate audit trail linkages to sampling strategy (appropriateness of inclusion/exclusion criteria), raw data, interview notes and document entries (Lincoln and Guba, 1985). There should also be an audit trail that explains the logic of interpretations, which may consider the analytic techniques, appropriateness of category labels, quality of interpretations, and recognitions of alternative interpretations (Lincoln and Guba, 1985). Ultimately, confirmability measures would allow an external checker to determine and confirm that the data and interpretations of the study emerged from the raw data and that the constructions were not the outcome of a biased process or of the researcher's personal constructions (McInnes et al, 2017; Lincoln and Guba, 1985).

Ethics

In all research, regardless of the methodology or philosophical beliefs, it is important that the wellbeing of human research participants is safeguarded at every stage of the research process. Marshall and Rossman (2016) remind us that the researcher must be careful about the sensitivity of those being researched to ensure that ethical standards are maintained, and that human dignity is not infringed upon. Some of the main principles that guide ethical research conduct include that the research must first set an answerable

question or objectives and, importantly, the question must be of social and/or clinical value (National Institute of Health (NIH), 2016). The outcome of the research must also provide answers to the questions or generate further questions in a manner that generates new knowledge or confirms existing knowledge (Emanuel, Wendler and Grady, 2000). For a research outcome to be scientifically valid, the participants must be selected fairly with considerations for the ratio of risk to benefit, ensuring a balanced rationale (NIH, 2016). Before any research could be initiated with human participants, the researcher must ensure that the study has undergone research ethics scrutiny and has been given a favourable opinion where applicable (HRA, 2017). Each prospective research participant must also be given all the relevant study information to enable them to reach an informed decision (Emanuel; Wendler and Grady, 2000). During fieldwork, while involved in research with human participants, the legacy of the Nuremberg Code and the principles of the Helsinki declaration must be observed and upheld at all stages (Nuremberg Code, 1947; WMA, 2013). Ultimately, MacFarlane (2009) emphasises that the ethical researcher is one that is courageous, respectful, resolute, sincere, humble, and reflexive. Chapter Four (Methods) gives an in-depth discussion of the steps taken to safeguard the dignity and wellbeing of the participants that took part in this research. Guided by the conditions of the Research Ethics Committee approval (page 114), the researcher carefully considered measures around access (118 -121), recruitment (121 – 123), data collection (125-128), data analysis (129), and in the risk assessments for researcher/participant safety during the field work (128-129).

Statement of researcher reflexivity in philosophical underpinning

The conceptualisation phase of this research provided the opportunity for ongoing reflection on how the researcher's values and professional experiences have affected the positioning of this research. Palaganias et al (2017) state that the journey of how a qualitative

researcher shapes and is shaped by the research process is fundamental to the discovery and understanding of personal and methodological concerns towards learning and growth. The goal of reflexivity is to enable the researcher to recognise their own values and to allow others to examine the views of the researcher (Birks et al, 2014; Jotun, Mcghee and Marland, 2009). From a philosophical perspective, the underpinning ethos of this research is an appreciation of the real world as it exists (ontology). From the researchers' professional stance, it was recognised that the theoretical rules with regard to the process of informed consent for research were often met with resistance by those for whom the service was meant to protect. This realisation from a professional perspective guided the researcher towards a methodology of inquiry that could support an examination of views and perspectives of those that may be impacted by the system. So, the research aim, and choice of methodology can be said to have been intuitively influenced by the researcher's experiences as a former research nurse.

The research field of nursing places more value on the human agency compared to the more rule-like approaches to knowledge generation associated with biomedical research. This is not to say that nurses do not engage in quantitative research. However, this research was determined to provide a rigorous account of the service users' perspectives of the process of informed consent as it is experienced in the real world, in order to advance meaningful knowledge. To the researcher, there is the belief that no one is better placed to determine the worth or value of an experience than those that experience it (constructivism). About informed consent, a lot has been written about the views of professionals but very little about the views of the research participants. In many cases, patients have continued to be the objects of research rather than partakers of it (Carson, Hinton and Kurinczuk, 2018). Such an ideology ran contrary to the researcher's professional ethos (NMC, 2018).

Intuitively, a gap was perceived between principles and the practice of research ethics in the real-world context of busy clinical environments. Real life practice appeared to present

constant challenges and dilemmas. The dilemmas brought curiosity that led to this research journey. The search for stability within the scientific research platforms that the researcher worked in, amid medical professors, intensified. The need to enquire was apparent, but there was uncertainty about how best to go about finding out that which should be known. The struggle within resulted from a perceived shift in paradigm. Petty, Thomson and Stew (2012) acknowledged that the types of knowledge one recognises and values in practice is influenced by ones' own professional artistry and values. It was apparent that the propositional nature of knowledge derived from theories had begun to make less sense when there was a mismatch with reality. Finally, the decision was made to put the researcher's curiosity to some greater use. The outcome led to the start of this research.

Reading about research traditions and the decisions that followed yielded interesting and engaging discussions with the supervisory team. The options for methodology seemed endless and the decision appeared complex. Literature review highlighted several worldviews and methodologies, often with very small but significant differences. Among the initial contenders were phenomenology, realist evaluation and constructivist methodology. Although most initially appeared compatible (Barkin, 2014), constructivist methodology eventually stood out due to its support of unique perspectives and multiple realities.

The search for understanding of the theories about knowledge generation and the anxiety that it causes for novice researchers is not always documented in published literature. It is intellectually challenging, and each methodological philosophy is not always clear cut (Halcomb, 2018; Welford, Murphy and Casey, 2012; Mack, 2010; Duffy, 1985). The definitions of each concept often occurred in ways that made it difficult to differentiate each principle between and across the others (Crossan, 2017; Ellis, 2014; Dash, 2005). Goulding (1999 pg. 862) acknowledged this when she stated that 'to engage in methodological understanding is to enter into a quagmire of contradictions and conflicting philosophies, within as well as across paradigms'. The limited discussion in published literature about beginners' experiences points to a lack of self-consciousness in the research process. For

a novice researcher, to simply identify and select the most appropriate methodology is challenging enough without the requirement to cross-reference unclearly defined methodological borders.

Summary of chapter

The philosophical underpinning of this research is compliant with the NI paradigm (Lincoln and Guba, 1985), also referred to as constructivist inquiry (Lincoln and Guba, 2000). The constructivist research process operates on the belief that multiple constructions of reality exist, as reality is relative and unique to everyone (Lincoln and Guba, 1985; Lincoln and Guba, 2000). By adopting the constructivist methodology, this research acknowledges that all people do not experience the world in the same way and that any such attempt to control, manipulate or impose universal or law-like rules in the conduct of informed consent for clinical research may be futile. In seeking a holistic and in-depth understanding, this research will instead engage in dynamic relationships with the researched in an attempt to explore contextual realities and their impact on decision making for research. Regarding trustworthiness and the authenticity of the design statements of this research, Marshall and Rossman (2016) summarise that the essentials of good and quality constructivist research are judged by an explicated research process. Spelling out the research process in detail allows the audience to judge for themselves whether the research process and outcome can be trusted. Second, the researchers' assumptions are to be clearly stated as that enables the audience to appraise the research against personal biases. Third, the researcher must avoid value judgements both in data collection and in analysis. This is to ensure that the views expressed in the research reflect the views of the respondents. Fourth, there ought to be abundant evidence from raw data that shows a link between the presented findings and the real world. This is enabled by presenting data that are readable and accessible, and can include texts, graphics, models, charts and figures (Marshall and

Rossman, 2016). Further, the researcher must be tolerant of ambiguity and willing to pursue alternative explanations where indicated. Finally, data is to be preserved and be made available for reanalysis should the need arise. The next chapter presents the actual steps taken in the conduct of this research.

Chapter 4

Methods

Introduction

This chapter discusses the steps followed to realise this enquiry. The basic tenant of this research was to provide an insight into the research participants' understanding as it relates to the process of informed consent for clinical research. Note therefore that the product of this research was not to measure understanding, rather to set out to explore views and generate insight. To this effect, the research implemented an exploratory research design guided by the constructivist-NI framework. Data was gathered using semi-structured individual face-to-face interviews with clinical research participants in the natural setting. Bryman (2016) described research design as an outline of the various criteria that the researcher followed in the generation of research evidence, while method details the actual steps and procedures carried out to yield the research outcome. This chapter therefore appraises the procedural steps implemented in order to uphold the ethical and methodological values that underpinned this research.

The focus and context of the study necessitated specific measures concerning choices for accessible population, sampling design, participating research sites, the retrieval of the actual samples and issues with sample size. Measures were implemented to overcome gatekeepers' gearshifts, including the challenges in navigating access through NHS departmental frontiers, clinicians, research team leads and other signatories. Engagements during data collection by way of individual face-to-face semi-structured recorded interviews and the analysis of data followed guidance from Lincoln and Guba (1985, pg. 336 – 356), Tesch (1990, pg. 142 – 145), Erlandson et al (1993, pg.111 – 122), Harding (2013) and

Wutich and Ryan (2016). The chapter concludes with an evaluation of the various approaches taken to enhance rigour and the trustworthiness of the research findings.

Accessible population

Population refers to all possible participants or items that could be included in a sample (Gerrish and Lacey, 2010). The population of interest for this research was patients that had been recruited and/or who had taken part in a clinical research study. The study sought to recruit actual patients that were diagnosed with a medical condition and that had been cared for within the NHS, and for whom as a consequence of their ill health, had taken part in a clinical research study within the acute care setting. More precisely, the individuals ought to have experienced ill health personally, so relatives or family members of the patients were not targeted. Also, although clinical research does involve healthy volunteers in certain research studies such as randomised controlled trials or other studies that often require family members of patients for screening purposes, this study excluded healthy volunteers, as the intention was to capture the views of actual patients. It was thought that the complexity and dilemma of deciding to take part in clinical research as part of a treatment option might be uniquely placed for the individuals that are personally involved in it. The thought was that the process of informed consent could hold different meanings particularly to patients for whom the liberty of choice and freewill may not always seem plausible in the face of limited treatment options. Such manifold reality may not be associated with healthy volunteers or other categories of clinical research participants. Hence, certain elements of the informed consent process for clinical research may not be perceived equally by healthy volunteers, as may be the case for the actual patients involved in clinical research. This informs the focus of this research on actual patients in order to capture the unique lenses of patients' experiences and the interpretations, thinking and beliefs that guide their perception of the consent process for clinical research.

Furthermore, the research sought to recruit adult patients with capacity to consent and an ability to engage in the meaning making process by constructing their own version of reality from the consent process. Children under 16 and adults lacking capacity were therefore not targeted as it was thought that such patients might not have been able to engage at the deep level of meaning making or construction of meanings required within the constructivist-naturalistic framework.

To narrow the population to a manageable focus, four NHS Foundation Trusts located in the North East of England were identified. The Trusts were selected due to the obvious geographical benefits of convenience, as well as for their active engagement in clinical research studies within the acute care setting. Three of the four NHS trusts subsequently supported the study and served as Participants Identification Centres (PIC) by identifying and allowing access for the recruitment of potential participants within their organisations.

Purposive sampling strategy

As with the constructivist-NI paradigm, the choice of sampling for this research was purposive (Lincoln and Guba, 1985), which enabled the researcher to target research active Trusts and units that allowed for the collection of rich data (Cresswell and Poth, 2018; Patton, 2015). Sampling was carefully thought out to allow for the selection of participants that would provide rich and relevant insight on the real issues that impact on patients. Burns and Groves (2017) highlighted that the sampling technique used in a research study is critical to the credibility and utilization of the research findings. A purposive sampling approach relates to the selection from a target population the individuals with the greatest potential that will allow for depth and richness of data (McInnes, Peters & Bonney et al, 2017). To capture real-life issues, this research recruited patients with varied medical diagnoses from a range of clinical research platforms. With that in mind, the researcher engaged in discussions with organisational R&D departments to identify suitable investigators for subsequent negotiations. The researcher then met with supportive investigators and lead research nurses who helped determine that patients suffering from

long term conditions such as those from cancer units, cardiovascular units, orthopaedics units, gastroenterology units, and from women's health were appropriately placed to participate in the study. It was considered that the unique positions of individuals living with an enduring medical diagnosis would encourage a deep and authentic insight into the diverse realities that may compound decision making in the real world.

With the support of research nurses, potential participants were identified and screened before being targeted for study invitations and recruitment. Purposive sampling was applied in the sense that prior decisions were made on the location, types of hospital setting, specialties and patient categories that were targeted to participate in this research (Morse, 2020; Coyne, 1996). In line with the NI orientation, typical and divergent data was aided during the interview discourse by the way that the researcher probed, in her function as a human instrument, for further insight where necessary (Denzin, 1971). Specifically, participants were supported to provide in-depth explanations of both typical and divergent patterns of reasoning and meaning making during interviews. The approaches taken increased the range and depth of data and maximised the researcher's ability to identify emerging themes with due consideration for contextual and diversified normalities (Erlandson et al, 1993). This is an important tenet in constructivist-NI, whereby sampling is governed by the researcher's insight into what is relevant to the study.

Sample size

19 participants took part in this research, offering deep insight into the real issues that impacted on participants' decision making for clinical research. As with naturalistic inquiries, this research is centred on the theoretical assumptions that 'the whole is greater than the sum' when human experiences, interpretations and understanding of reality is concerned. To produce depth and richness, the goal was to generate a sample that will provide valuable insight, particularly from the missing voices in the deliberations on the process of informed consent in the available literature. Therefore, sample size was of less importance than it might be with other approaches. In relation to sample size when using a purposive

sampling strategy, the basic rule according to Paton (1990) is that there are no rules for sample size. Focus is on ‘quality’ rather than ‘quantity’, and on information richness rather than information volume (Erlandson et al, 1993). In some previous naturalistic research, it has been possible to conduct naturalistic inquiries with fewer than 8 participants (Barrett, 2005; Veltri, 2010; Williams, 2005) and as many as 44 participants (Sogoric et al, 2004). Although rare, a sample size of 110 participants has been recorded (Belk, Sherry and Wallendorf, 1988). Focusing on a relatively small number of participants enables the researcher to concentrate and discover an in depth understanding of the needs, interests, thoughts, perceptions, impressions, feelings, views, behaviours, values, opinions, conceptions, experiences and meanings from the patient’s world (Coyne, 1996). These are the central tenets of this research, which can only be achieved effectively with a relatively small sample size.

Others suggest that a key determinant of sample size in qualitative research relates to the point in the data collection and analysis process where the results from new data collections start to appear redundant, meaning that no new finding emerges (Morse and Clark, 2019). This is particularly applicable in grounded theory research designs, where data saturation is considered when additional interviews or data are not believed to add new information to the dataset (Appleton and King, 1997). However, Van-Rijnsoever (2017) and Josselson and Lieblich (2003) cautioned against the utilization of the saturation concept in research such as constructivist-NI as each individual experience and perspective is uniquely placed. It is argued that each individual participant may potentially have something unique to contribute to an inquiry from his or her unique perspective, so saturation of data may never truly be realized as each new participant could potentially reveal new findings (Van-Rijnsoever, 2017). Instead, the focus in constructivist-NI is to select an appropriate sample that provides quality data by the breadth and depth of the transactions. Morse and Clark (2019) offered a guide of 10 participants as a reasonable estimate in NI but preferably more. Considerations about sample size are an important

element in the planning and conduct of scientific inquiry as they enable users of research to make judgements on the quality and appropriateness of the research process and outcomes (Morse, 2020; Sandelowski, 1995; Morse, 1991).

Actual sample

The sample is the selected group of people or elements included in a research study (Burns and Groves, 2017). This study recruited 19 patients that had been involved in the informed consent process for clinical research. This included five (5) participants from cancer research, five (5) participants from cardiology research, one (1) participant from orthopaedics research, four (4) participants from endocrinology research and three (3) participants from gynaecology research. Two other potential participants could not take part in the study ('screen fails'). The first expressed that she was involved in numerous other studies at the point of recruitment, so it was reasonable to support her to withdraw from participation in this research. The second did not appear to have good memory of past events, so was excluded on grounds of memory lapse as judged by the researcher. Although it can be easy to overlook issues concerning participants' wellbeing, the researcher, as a former clinical research nurse, was duly attentive and sensitive to the fundamental principles of ethical research practice. Irrespective of the desire to advance the study recruitment targets, the principles of beneficence, non-maleficence and professional integrity underpinned all decisions and actions.

The researcher was satisfied with the varied disease representation in this research as this was typical of the set of individuals that makes up real-life clinical research participation. It signals the group of patients that are most often the subject of health research, such as those with challenging and life-threatening diagnoses. For example, cancer is a disease that threatens life, with limited treatment options in the standard treatment pathways. This means that patients are often faced with dilemmas and lack freedom of choice in their treatment plans, necessitating involvement in clinical research as an alternative pathway for treatment (Berrios, James, and Raraigh *et al*., 2018). Similarly, cardiovascular diseases and

their related pathophysiology can present patients with life threatening realities, and participation in relevant research studies may be perceived as an unavoidable pathway to improve their wellbeing. Cardiovascular diseases such as advanced coronary artery diseases and other abnormalities can be immediately life threatening, unlike some other chronic conditions. Comorbidities can activate and present patients with varied realities, which may not be associated with less troubling clinical abnormalities. Table 3 summarises the actual sample that was recruited to take part in the study.

Table 3 Actual sample

Pseudonym	Age	Gender	Ethnicity	Marital status	Occupation	Medical history
Mathar_1	69	Female	White British	Widow	Retired	Endocrinology
Winnie_2	66	Female	White British	Widow	Retired	Endocrinology
Peter_3	59	Male	White British	Married	Businessman	Cardiac
Mary_4	85	Female	White British	Widow	Retired	Endocrinology
Silas_5	48	Male	White British	Married	Self-employed	Cardiac
Naomi_6	63	Female	White British	Married	Hospital governance board member	Endocrinology
John_7	70	Male	White British	Widower	Retired	Cardiac
Ron_8	67	Male	White British	Married	Retired	Cancer
Don_9	65	Male	White British	Married	Retired	Cancer
Ivanka_10	65	Female	White British	Married	Retired	Cardiac
Hannah_11	64	Female	White British	Widow	Retired	Endocrinology
Eric_12	67	Male	White British	Married	Retired	Cardiac
Maggie_13	58	Female	White British	Married	Unemployed	Orthopaedic
Nicolas_14	69	Male	White British	Married	Retired (Policeman)	Cancer
Simon_15	58	Male	White British	Married	Employed	Cardiac
Andrew_16	67	Male	White British	Married	Retired	Cardiac
Stephen_17	39	Male	White British	Single	Employed (NHS)	Cancer
Philip_18	50	Male	White British	Married	Employed (scientist)	Cancer
Jude_19	66	Male	White British	Widower	Retired	COPD

Ethics review submissions

With the decision to sample across four NHS Foundation Trusts and with the focus on NHS patients, this research was submitted for ethical opinions from the Higher Education Institution (HEI), and the NHS Research Ethics Committee (REC). It is a governance requirement that any research involving NHS patients or staff must undergo NHS Research Ethics Review, whose focus is to oversee that a research plan is ethical, feasible and does

not expose potential participants to avoidable harm (HRA, 2017; NRESS, 2011). The HEI Faculty Research Ethics Committee (FREC) reviewed and approved the study on condition of some minor ethical recommendations for the initial draft of the protocol. These requirements were duly attended to and a final FREC approval was granted by Chair's action after which the study proceeded for the NHS Ethics Review submission.

A submission was made for NHS REC review via the Integrated Research Application System (IRAS) as required, (NRES, 2018; NRES, 2011). The application was submitted to a regional NHS REC for a proportionate review via IRAS. A submission for a proportionate REC review is considered when a research plan does not indicate substantial material ethical issues and it is usually an accelerated ethical review process (HRA, 2018). It is shorter than full Research Ethics Committee review meeting, where the researcher is required to attend in person to discuss a study. This study therefore was deemed low risk and was accepted for the proportionate review process.

As with the FREC review, an initial feedback with a favourable opinion was received with minor recommendations to the protocol. A meticulous effort was made to address the NHS REC recommendations successfully. Finally, a favourable REC opinion recommending the conduct of the study in the NHS was granted. Altogether a total of 16 study documents were reviewed and approved by the NHS REC Panel within a three-week period from the initial submission on the 7th of October to the final decision letter of a favourable opinion without further conditions on the 31st of October. The speed of the NHS ethics review process was admirable, considering the historical delays associated with the NHS REC review processes (Petrova and Barclay, 2019; Hallowell et al, 2008; Hearnshaw, 2004).

Institutional Research and Development Reviews

Following the favourable opinion by an NHS REC committee, the study subsequently underwent organisational Research and Development (R&D) reviews at the four NHS Foundation Trusts. However, securing organisational R&D approvals proved daunting at

some organisations. Applications to the four Trusts took place between November 2014 and June 2015. As highlighted by Thompson and France (2010), there were substantial variations in R&D application procedures. The effectiveness of the research governance personnel was also beyond the expected standards. One of the aims of the Research Governance Framework in the UK is to streamline the governance approval process in order to support a more effective and efficient governance review structure across all fronts (DH, 2005 & 2001). The IRAS application system was one of the initiatives aimed at streamlining the process by the way of an integrated research application system (HRA, 2017; NRES, 2011). However, the experience of this research found a different story. It looked as if the Framework and related initiatives were disregarded or misinterpreted. Each organisation required several study documents to be directly provided to them and in most cases the requirements and procedures were peculiar to each. This meant that the researcher observed different procedures in the R&D submissions across the four NHS sites. The length of time for processing the applications also caused delays that unavoidably hampered the starting and progression of the research.

One of the organisations declined to support the study with no reason given. This is notwithstanding that a few of its senior clinicians had expressed interest and willingness to support this study. One could only assume that the research and development department, as the institutional frontier for research, may have been uncomfortable with the focus of the inquiry. Difficulties in initiating a methodological focused research from within institutional committees for studies that 'research the researchers' is well documented. Mckenzie et al. (2010), recounting their experiences researching the researchers, pointed to some ethical, methodological, and practical challenges in accessing a 'difficult to research' community. This is although methodological research studies usually have minimal or no discomfort to the potential participants and with great potential for public and professional benefit. An awareness of the views of research participants on the process of informed consent, for example, is a vital step in determining the effectiveness and adequacy of the ethical and

methodological principles guiding clinical research. Such awareness points to a need for a larger inquiry or for training and/or policy reforms at various levels of governance. Further, any ineffectiveness in methodological approaches, such as the process of informed consent, can impact on both the research product/publications, and more importantly the evidence-based guidelines on which real life clinical decisions are based. The researcher had hoped therefore that this methodological focused research would have been embraced by all the potential beneficiaries, especially the R&D research community, and clinicians and patients alike.

A second Trust displayed some relative reluctance or inefficiency in the length of time (6 months) it took to respond and process its R&D application (November 2014 - May 2015). However, the researcher is mindful that research and development departments are required to consider more specifically the practical logistics of supporting a study at their institutions. This is notwithstanding any scientific benefit that a study may yield. Scientific considerations are usually undertaken by the Research Ethics Committees; the practical elements in the review process, such as staff support and facilities, are usually scrutinised rigorously by the institutional R&D departments (Al-Shahi, 2005). These may have been credible reasons for the refusal of any research study. In this case however, the institution concerned is known to support academic research projects with a reasonable infrastructure in place, being a teaching hospital itself. A notable difference could have been the focus of this inquiry, which may have been misinterpreted as policing the institutions' clinical research practice. It is well-documented that the biomedical research community are often reluctant to allow for outside scrutiny of their practice in their conduct of clinical research (McKenzie et al, 2010). Stamer *et al* (2015) in their investigations of ethical research practices across Europe reported a jaw-dropping variation in ethical research practices relating to informed consent. In their survey of some European hospitals, it was reported that only about 25 to 30% of the institutions surveyed provided information to participants on details such as risks/benefits of participation etc. It is easy to see therefore how some

institutions may be uneasy for a researcher to explore their practice of such an important element at the heart of ethical research.

These real-life challenges of accessing a difficult to research community mandated the researcher to adapt the research plan substantially from the initial plan of action. The initial research plan had incorporated an observational element in the informed consent process for clinical research. However, it was feared that may have been too intrusive and impractical in a busy clinical research unit. Some research staff may not have been amenable to being 'watched' while they performed this crucial process. Any such reluctance might have hampered recruitment to the study, which by extension could have undermined the success of this research. These were some of the painstaking considerations that point to a bigger picture of all the hindrances and limits to the initiation of meaningful and valuable research in NHS institutions.

Two other NHS Trusts were very proactive and efficient in their procedures and processes. In the end, three of the four NHS Trusts granted approval and supported this research as Participant Identification Centres (PIC). The success with relevant governance approvals at the local level was the outcome of a tedious process, indicating the degree of resilience required of researchers daring to conduct research that may involve recruitment from or within NHS organisations, including patients and/or members of the NHS workforce.

Navigating for access to participants through clinical research teams

Following the necessary site-specific governance approvals, the next stage involved a significant level of networking with various research staff including clinicians, departmental research leads and frontline clinical research staff. Negotiations ensued with the practical arrangements relating to the identification, screening, and distribution of study invitations to potential research participants. The researcher sought and engaged in several meetings with key members of staff at each of the participating NHS sites. Networking involved both email and telephone correspondence, and subsequent face-to-face meetings with staff. As

anticipated, this stage proved challenging and demanding but was vital to the realization of the research study. In certain units, a significant degree of resistance was encountered. It appeared that some local networks and units found the need for mediation to protect a perceived sense of partnership in their organisational cultures. Wenger (2010) talked about communities of practice and the challenges of operationalizing from the peripherals in situations where the community feels the need to guide their incumbent indulgences. The concept of “communities of practice” relates to a group of people who share a concern or a passion for something they do (Wenger, 2010; Wenger, 1998; Wenger, 1996). The community may hold their connections and relationships with one another closely and may naturally fight off a perceived predator that appears to threaten their domain (Wenger, 2010). To overcome the challenges, the researcher utilised insider knowledge of the community and sought to build and develop effective working relationships with frontline staff. Initially, some research staff appeared to sustain self-consciousness by a repertoire of tricks to deter the researcher. However, persistence by the way of regular emails, phone calls and face-to-face drop-in meetings proved successful in navigating the essential departmental frontiers. It was the good working relationships with the clinical research leads and the frontline research staff that paved the way for the screening and identification of the potential research participants. The researcher practically engaged to sustain a presence over a 9-month period during the data collection stage (March – December 2015). Meetings were held periodically with the research teams to touch base and maintain momentum, without which the recruitment could have easily stalled prematurely. Occasional email prompts were also sent to the responsible clinicians whenever recruitment appeared to drizzle, a possible indication that staff may not have been distributing the invitation packs as proactively as they might.

That said, an encouraging number of clinical research staff were very supportive from the outset as they considered this research a topical and important study that is meaningful for both research staff and clinical research participants. The importance of this research was

thoroughly valued by some clinicians, who praised the scientific merits of the research protocol and committed to support the study. However, it was also evident that despite the layers of merited approvals, some staff appeared underestimate the scientific contributions of methodological research on the practical applications of ethical theory, especially exploring practical judgement of the views of patients. It may have been challenging for some staff to appreciate the worth and scientific merits of research that did not directly impact on clinical outcomes.

For this reason, efforts were made to design the study so that all the responsibility was on myself as the researcher, to minimise the duty on the clinical research staff. The initial plan was for all the research-specific activities to be completed by the academic researcher. The researcher, an experienced former clinical research nurse, was familiar with the dynamics of the clinical research environment and thus planned to undertake the screening and identification of potential research participants given appropriate access permissions. The intention had been to approach and distribute the study invitations directly within the departments after conducting a pre-screening of the potential participants alongside staff. This may have enabled a more collegial approach in the recruitment process. However, a condition of the governance approvals required that the study was first introduced to potential research participants by members of the clinical research team. NHS REC required that the responsible clinician or a delegated member of the clinical research team identify, screen, and introduce the research to the potential clinical research participants, including the distribution of study invitation packs. This was deemed necessary to observe ethical boundaries and safeguard the privacy and interests of patients. The academic researcher was therefore prohibited from direct contact with the potential research participants until after the patients had considered the study invitations independently. Such a measure, although well-meant, did present some challenges in the recruitment process. As discussed below, the bureaucratic process appeared excessive given that the academic researcher was a fully trained clinical research nurse who had recently left practice at the

time of recruitment. It also resulted in significant delays in the speed of recruitment as discussed, especially given that the research is an academic programme with pre-determined time limit on the length of engagement for the research. This inevitably contributed significantly to delays in the recruitment phase of the research.

The recruitment process - locating the sample and the process of informed consent

The recruitment process evolved in three stages; the distribution of study invitations by the responsible clinicians; a response from interested potential participants by return of the self-addressed envelopes included in the invitation packs; and the completion of a full informed consent process by the academic researcher, leading to enrolments in the study.

Stage one involved the introduction of the study to potential research participants by the responsible NHS clinicians/clinical investigator. This occurred after the patients had been involved in an informed consent process for a clinical research study. Study invitations for this academic research were initiated within weeks 1-2 of a patient's involvement in the informed consent process and/or upon their enrolment on a clinical research study. All the potential participants eligible for inclusion into this study were invited to take part in the study by the way of an invitation pack (see appendices 01, 02, 03 and 04). The invitations were initiated by the way of a very brief introduction by the responsible clinician or members of the clinical research team. The study invitation packs contained invitation leaflets, participant information sheets and the contact details for the academic researcher. The individuals interested in the study were advised to contact the academic researcher by telephone for further information on involvement. The patients also had the option of contacting the researcher by returning a self- addressed pre-paid envelope, which was included in the study invitation packs (see appendix 02).

In the second stage, the academic researcher responded to the interested research participants who replied. A follow-up contact was established via a telephone call to the individuals within a 2-3-week period of their involvement in an informed consent process for

a clinical research study. The goal of the telephone conversation was for the researcher to introduce herself to the potential participants and to establish if they remained willing to be involved in the academic study. Information was also discussed regarding the informed consent process for participation in this study. Opportunities were provided to answer any questions that the participants may have had in preparation for and, prior to, a face-to-face meeting with the researcher.

The third stage involved the actual enrolment of the participants into the study by the completing a full informed consent process. This took place during a face-to-face meeting with the potential participant at a place of their choosing. Here, the researcher discussed the participant information sheet (appendix 03) thoroughly and reiterated all elements that had previously been discussed over the telephone. A further opportunity was provided to clarify any concerns, before obtaining consent both verbally and by way of a signed consent form (appendix 04). The informed consent process was an ongoing process throughout the participants' involvement in the study. The participants' right to withdraw at any point up to study closure without having to give any reason was reiterated. Contacts were provided to the participants should they need to contact the research team for any reason. See Figure 3 below for summary of the screening and recruitment flowchart.

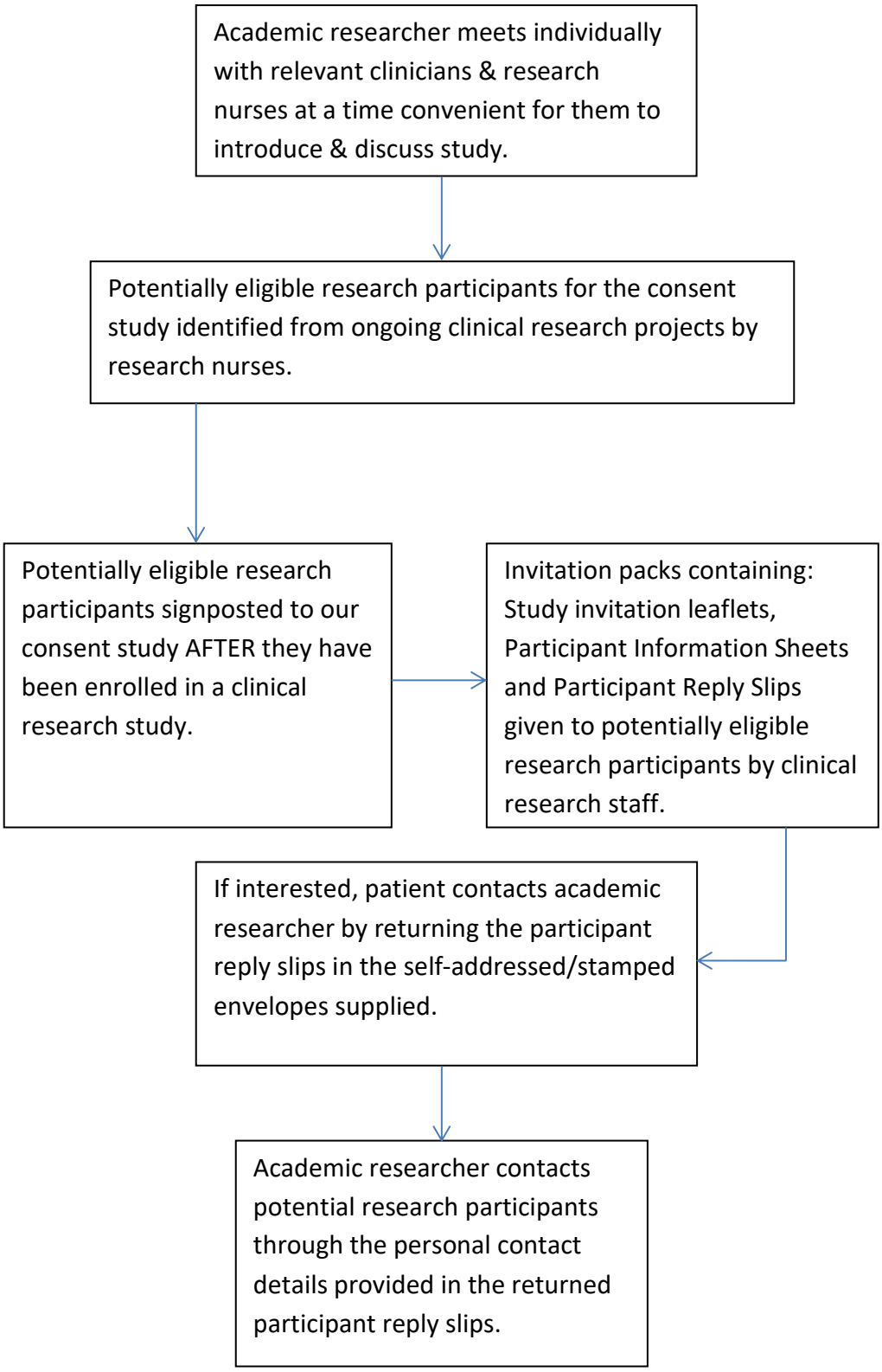


Figure 3 Screening & Recruitment Flowchart

Setting

Data collection took place in a variety of locations all of which were natural settings. This included quiet and private places within the hospital units, including cancer day units, out-patient clinics, meeting rooms, and in some cases patients' homes. The choice of setting was predominantly decided by the patient and in most cases reflected the natural setting in which the initial clinical research study had taken place. Duffy (1985) and Lee (2006) cautioned that the environment for naturalistic research methodology cannot be controlled or manipulated in same way as the environment of objects in the hard sciences. Human participants as social beings are conditioned to thrive in natural settings. Any artificial attempt to alter the natural setting of the phenomenon being studied, may blind the research outcome (Duffy, 1985). It is common for clinical studies to be designed and conducted at the patients' convenience in order to minimise any foreseeable burden on potential research participants. This was an important element in the ethical review considerations where committee members sought reassurance that patients would not to be subjected to avoidable discomfort during their involvement in the research. With that in mind, and in accordance with the logic of constructivist-NI paradigm, decisions on the venues were left to patients where possible.

There were benefits of conducting the research within the field in the natural setting, but there were also some challenges. Notably, the natural settings were useful in enabling the participants to be at ease without undue anxiety or pressure. The setting enabled space and time for all involved to reflect and interact freely without intrusions or distractions. The participants were encouraged to discuss their views and opinions more openly in privacy, without any perceived undue influence by others, such as clinicians, amid the hustle of clinical activities. Participants that chose their homes as the setting were privileged to be able to retrieve and refer to certain study documentation such as the participant information sheets. It was also interesting to observe that some participants opted to involve their significant others in the conversations, especially those that chose their home for the

research setting. The home setting proved a relaxing atmosphere as opposed to hospital wards, which are often associated with challenging personal circumstances. The neutrality of the natural setting shifted the balance of power to the participants, which fostered open and free dialogue during the interviews. On one occasion, this was manifested when a participant expressed his disapproval with a contradiction in the information that he received during the informed consent process for the clinical research he had participated in. Such dialogue might otherwise have been stifled in a less neutral environment. This demonstrated the usefulness of open dialogue without such stringent control of the objects of inquiry.

Privacy enabled the researcher to maximally engage in attentive listening and be alert to both verbal and non-verbal communication clues, which is often challenging in busy clinical environments, such as at the bedside on the wards. The natural setting therefore added strength to the outcome of the research findings as the participants were supported to reveal issues with deep-rooted significance to them. For those that selected a hospital venue, the flexibility was useful to them as most already had scheduled hospital visits as part of their clinical research procedures and treatments. In all cases, inconvenience was minimal for all the participants that took part in this study.

Data collection method: Individual face-to-face semi-structured interviews

Data was collected through individual face-to-face semi-structured interviews. According to Kvale and Brinkman (2015), a research interview is a conversation that has a structure and a purpose. It goes beyond the spontaneous exchange of views to a careful questioning and listening approach with the purpose of obtaining thoroughly tested knowledge (Kvale and Brickman, 2015). Although there are alternative interview strategies, such as structured and unstructured approaches (Gillham, 2000), the semi-structured interview technique was preferred as it enabled the researcher to focus the inquiry while allowing participants the ability to direct the inquiry process. Semi-structured interviews support the use of a flexible semi-structured interview guide, containing a scheme of questions to be explored, which

helps to keep the interview focused on the central topic of inquiry (Rubin and Rubin, 2012). This interview approach is recommended for healthcare research such as the one proposed in this study, which utilises face-to-face individual conversation and that requires extended responses on a single occasion (DeJonckheer and Vaughn, 2018). Comprehensive depth of meaning was achieved using prompts from the interview guide and follow-up questions to moderate and redirect the interview discussion on the central topic while enabling the participants to express their opinions openly and systematically (Rubin and Rubin, 2012). The semi-structured interview guide used in this research was made up of open questions, which served as a start point but allowed the participant to extend the conversation and to express their views. The guide was developed by the researcher and reviewed by the principal supervisor. The final draft was subsequently piloted with selected postgraduate peers, who provided added scrutiny, having themselves participated in clinical research previously themselves. See appendix 05 for the semi-structured interview guide and the sample of open questions.

Before data collection, a period of two weeks was allowed from the time of the participants' involvement in the clinical research study to the participants' involvement in the academic research study. This allowed participants time to reflect on their experiences of taking part in the informed consent process for the clinical research study. Such introspective reflections on actions and meaning making could only have been carried out retrospectively. A reasonable timeframe was also crucial to avoid memory lapse on the part of the participants. A lapse in memory can lead to recall bias, an inaccurate recollection of events from the past owing to a change in the patients' perceptions or lapse in memory (Janssens et al, 2018). Conversely, an increase in exposure to an event may result in a positive shift in perception, owing to an increased knowledge and understanding from the repeated exposures. Relating to the informed consent process, a research participant could develop a change in perception resulting from increased knowledge following involvement in a study. For these reasons, conducting the interviews as soon as was practically possible

after the participants' involvement in the process of informed consent for the clinical research studies, helped to minimise recall bias. These considerations underpinned the rationale for the approach of 'soon after recruitment has happened'.

Interviews were conducted in the participant's natural settings. Prior to the start of the interviews, participants were reminded of the purpose of the research, and the questioning format. At the same point, the participants were reminded that the interview interactions would be audio-recorded (with their permission). The participants expressed satisfaction with the information provided and gave a written and verbal consent for the audio recording of the interviews. Cohen, Manion and Morrison (2011) emphasised that it is crucial that the researcher strives to put the research participants at ease by explaining the format of proceedings regarding the organisation of the interview. The researcher, a former clinical research nurse, utilised her enhanced interpersonal skills to reassure participants and explain the encounter before the interviews commenced.

The researcher, being the key instrument for data collection, asked questions proactively and listened attentively while observing the behaviours of the participants for non-verbal attributes throughout the interview process. This was a strength of the NI paradigm in combination with the constructivist methodology and the individual face-to-face semi-structured interviews. Of particular help was the effective use of mood, tone of voice, speed of talk, pauses, and the skills of probing, summarising and occasional reflections on remarks made by the interviewee (Cohen, Manion and Morrison, 2011). This strategy supported the researcher to maintain a sustained focus on learning the meanings that the participants expressed (Cresswell, 2018).

During the interview, the researcher asked questions in a manner that encouraged open and holistic answers. Exploratory research questions consisted of non-directional exploratory verbs, as recommended by Cresswell and Poth (2018). Creswell and Poth (2018) suggested that such an open-ended technique to questioning enables the

participants to provide holistic and in-depth responses in the exploration of the phenomenon under investigation. An example question is: “Can you tell me what you remember about being asked to take part in the clinical research study?” Fundamentally, the researcher recognised that complex human experiences cannot be retold by a prescriptive approach, and that for depth of insight, the researcher must be able to steer the interview process in a subtle, sensitive, therapeutic, and progressive manner (Billham, 2000). Using follow-up questions and probes, the researcher remained attentive to the participants’ thoughts, feelings and beliefs about their experiences while discussing personal and sometimes sensitive issues. The process undertaken yielded a natural therapeutic conversation that was also a comprehensive and systematic research outcome that uncovered the meaning of participants’ experiences from their unique perspectives.

Risk assessment and researcher safety

Naturalistic inquirers collect data in the field at the various sites where participants experienced the phenomenon under investigation (Cresswell and Poth 2018). Instead of a laboratory environment, the setting included patients’ homes and private interview rooms at various hospital locations. These locations were pre-approved by the Research Ethics Committee with due consideration for both the researcher and research participants’ safety. To diffuse the threat of lone working, the researcher implemented a strategy whereby a member of the research team was notified by telephone upon arrival and departure from the interview locations. This was in addition to a personal break-away alarm device that was carried by the researcher.

Data Analysis framework: Constructive ‘Manual Analysis’

Data analysis was a continuous process in which the collection and analysis of data occurred hand in hand (Erlandson et al. 1993). Lincoln and Guba (1985) explained that the

procedure for naturalistic data analysis is an inductive, generative, constructive, and subjective process whereby conceptual categories are arrived at in terms brought into the inquiry by the respondents. The data source comprised of interviews, which were recorded with consent and then transcribed. Following guidance from Lincoln and Guba (1985, pg. 336 – 356), Tesch (1990, pg. 142 – 145), Erlandson et al (1993, pg.111 – 122), Harding (2013) and Bernard, Wutich and Ryan (2017), thematic analysis was conducted. Braun and Clarke (2006) describe thematic analysis as a method for identifying, analysing, reporting, and interpreting themes from within a dataset. The following discussion specifies the steps and rigorous decisions made by the researcher in the analysis of data yielding to the conceptual categories, themes, and constructs (Lincoln and Guba, 1985).

Many approaches can be used to analyse naturalistic data such as the Framework approach (Hackett and Strickland, 2018; Gale, Heath, and Cameron et al, 2013), Constant Comparison analysis (Varghese, 2009; Marrow, 1996; Appleton and King, 1997; Glaser and Strauss, 1967), computer assisted qualitative data analysis programmes (Chandra and Shang, 2017; Welsh, 2002; Tesch, 1991) and other foundational models of qualitative data analysis (Kalpokaite and Radivojeve, 2019). However, for personal preference, the researcher engaged a constructive “manual analysis’ approach to achieve thematic analysis (Braun and Clarke, 2006). After reviewing the abundance of frameworks, it was felt that a manual approach would support a flexible and more simplified exploration of the dataset. Although this approach was time consuming, it enabled a deeper understanding of the dataset and supported the interpretation, meaning making and theory building process. The ‘manual analysis’ process was guided by various theoretical frameworks such as those highlighted previously. Sharing the views of Braun and Clarke (2006), it was considered that a lot of qualitative analysis approaches are essentially thematic analysis, but are often described by different terminologies such as Framework approach (Hackett and Strickland, 2018), Constant comparison analysis (Appleton and King, 1997), content analysis or even constructivist grounded theory analysis (Charmaz, 2014; Mills, Bonner and Francis, 2006).

However, this research considers it important to acknowledge fully how the researcher went about analysing data to enable clarity and a genuine evaluation of the processes that informed the research outcome. Morse (2020) supports this traditional position as she cautioned that the several emerging strategies of analysis appear to truncate the naturalistic process of inquiry itself.

Getting a sense of the recordings

The first step, according to Tesch (1990), was to make sense of the raw data. The researcher listened to each audio recording on several occasions, on the day of the interview and the days that followed. This enabled the researcher to engage more deeply with both the content and the emotions of the respondents while at the same time taking further notes to consolidate the interactions during the interviews. The noting down of the emotions and context of each interview is recognised as a rigorous approach that supports the interpretation and meaning making process of naturalistic research (Denzin, 1971). The repeated listening to audio recordings could be understood as a form of persistent observation of the raw data, while the noting down of emotional and contextual influences during and shortly after the interviews is a form of memoing (Lincoln and Guba, 1985). Memoing is the sporadic oral or written briefings regarding one's emerging interpretations of data or sense of project progress, as well as introspections about the interviews conducted during the day (Belk, Sherry and Wallendorf, 1988). Text box 1 illustrates this with 'interview Naomi_6' to show how the awareness of such contexts enabled the identification and weaving of diverse interpretations. This is part of 'naturalistic data analysis', where collection and processing of data goes hand in hand in a 'continuous and simultaneous' manner (Lincoln and Guba, 1985 pg. 335; Denzin, 1971). In the interests of demonstrating trustworthiness, writing a memo is a useful way to get ideas down with the initial freshness of the interview situation serving both 'cognitive and cathartic' functions (Lincoln and Guba, 1985 pg. 342).

This was an interesting interview with an older female adult at own home. It was a relaxed and natural environment that supported the participant to express self without undue environmental adversities. The participant was welcoming and in good spirit. The participant demonstrated impressive cognitive abilities and great insight into issues pertinent to involvement in clinical research. The participant is recognised as having physical disability due to medical illness and had taken part in a longitudinal thyroid/diabetes research. She had been seen by a research nurse recently for a new phase of clinical research activities. Interview took place 3 weeks after the patient had participated in the process of informed consent for the clinical research study. Although the interviews were individual face-to-face interactions, the husband was present mid-way into the interview as he returned home from dog-walking. This did not present any challenge as the husband was not needed and swiftly shifted to the lounge to watch television with his dog after introducing himself. He occasionally joined the conversation as he pleased, but not in a destructive way (his voice was therefore captured in the recording occasionally). I did feel a little unease for possibly interrupting the family routines by my present but the participant was reassuring and the interview continued without further interruptions.

Of additional insight in this interview was the unique issue raised concerning the considerations for prospective participants with a range of disabilities. This insight illuminated a previous negative case as similar concern had been mentioned previously by another participant of this research, who although was not registered as disabled did have some physical limitations due to ageing. The participant felt strongly that all eligible potential research participants ought to be supported to take part in clinical research in an inclusive manner without discriminatory limitations by the way of research designs or infrastructure. As an insider researcher being a former clinical research nurse, there appeared some sense that her message would be taking seriously by myself or at least passed on to those with influence.

Text box 1 Naomi_6 Memoing & context of data.

Supporting a reflexive approach, Clarke (2006) recounted her experiences of fieldwork as a qualitative researcher and the challenges of developing personal relationships of trust and rapport during qualitative interviews. She argued that researchers ought to be mindful of the impact that trust and rapport could have on both the researched and the researcher. For the researched, depending on the nature of the researcher-participant relationship, Clarke noted that trust and rapport could enable research participants to talk about personal and distressing situations in a manner that may provoke strong emotions during research interviews. For the researcher, Clarke acknowledged that emotional connections to the research process can be challenging to manage. She recalled that researchers are often

required to function in multiple roles beyond that of asking questions and listening for answers. This insight was made manifest at several occasions during this research. As evidenced in the memo above, the researcher was often challenged to function in multiple roles especially due to her position as an insider researcher, being a former clinical research nurse. To maintain a non-hierarchical relationship with participants, effort was made at the start of each interview to establish and maintain rapport throughout. This was useful and encouraged open conversations with the interviewees in a manner that enabled honest and rich data. However, managing distressing dialogues with participants was often distracting as the researcher sought to prioritise the emotional well-being of the interviewees by responding as necessary. Such emotional encounters required additional skills such as empathy and compassion. Memoing in the manner described above therefore enabled deeper engagement with what was said and the context in which it was said, which enhanced familiarisation with each recording. The depth and dimensions of meaning captured through memoing may not have been achieved by reading of transcriptions alone, especially given that the task of transcribing was outsourced to a professional transcriber. Memoing therefore supported depth and richness of data by highlighting emotions and identifying assumptions soon after each interview. This approach was vital in situations where the researcher did not have the chance to write detailed notes during the interview process as some interviews required sensitivity and intense focusing.

Memoing also enabled moments of debrief for the researcher after often emotionally challenging encounters during fieldwork. Clarke (2006) acknowledged that listening in a sensitive and empathetic manner can be emotionally demanding and suggested that qualitative researchers should maintain a reflective diary as a measure for promoting goodness in the qualitative research process. Similarly, Marrow (1996) cautioned against becoming so immersed in the participants' world that there may be a danger of 'going native'. This research demonstrates the difficulty with attempting to maintain any sort of distant stance with NI, which investigates real life situations in real life contexts (Lincoln

and Guba, 1985). It would have been impossible to control or detect how each participant expresses matters of importance to them. From their positions, the researcher was understood as a healthcare professional and so was taken as a fitting vessel for resounding individual concerns related to the healthcare system. This was the consequence of being an insider researcher, yet it would have been unrealistic and unproductive to avoid such a level of rapport and familiarity or to attempt to assume a distant stance. Guba (1978 pg. 44) acknowledged the challenges with boundary but warned against imposing constraints that would force naturalistic interview situations into 'unnaturalistic forms'. Instead, it is suggested that naturalistic researchers should allow themselves to be exposed fully to the risks of the interview situation for the many benefits that it offers including the potential therapeutic and empowering benefits (Clarke, 2006). Although it is acknowledged that the goal of the research interview is not therapeutic (Gilham 2000 pg. 30), in this research it proved difficult not to become involved with clinical conversations of interest to the participants and doing so may have interrupted the naturally occurring conversations achieved. The naturalistic researcher strives instead for confirmability through their ability to sieve and work through the dataset for context-relevant details (Guba, 1978). The discussion of the relationship between a researcher and the participants and its influences on data quality provides for quality appraisal and acknowledges the place of values and the necessity of 'taking context into account' (Appleton, 2002; Walsh and Downe, 2002; Lincoln and Guba, 1985 pg. 338). Lincoln and Guba (1985) support that creative human involvement in data processing is not only important to the receiver but also crucial to the naturalistic data processor and must be made apparent.

Transcription of data

In line with the systematicity requirement of the thematic analysis process (Lincoln and Guba, 1985 pg. 337), the audio recordings were transcribed verbatim. As mentioned, the task of transcribing was outsourced to a professional transcriber, as it was decided this would be a better use of time due to time demands and the physical pressures on the researcher who was also pregnant at the time of data collection. Gale et al. (2013)

suggested that the process of transcription is a useful opportunity to get more immersed with the audio recordings but acknowledged that certain projects and circumstances may benefit from outsourcing. The purpose of verbatim transcription is to reproduce the content of interviews word for word, to allow for content analysis, reading and coding of textual data (Gale et al, 2013; Lincoln and Guba, 1985 pg. 336). Immersion, often referred to as familiarisation, was achieved by listening and re-listening to the audio recordings, and reading and re-reading the transcripts following verbatim transcriptions.

Unitizing of significant statements

Unitizing involves the extraction of significant statements or codes pertinent to the objectives of the research from the transcripts after reading and re-reading of each transcript (Harding, 2013 pg. 56). Lincoln and Guba (1985) described unitizing as a heuristic process involving the identification of the smallest piece of information that can stand by itself and that is aimed at some understanding. Such pieces of information can be in the form of sentences or paragraphs (Lincoln and Guba, 1985) and are also referred to as codes (Harding, 2013). As the first steps in the analysis of interview data following verbatim transcription, the guidance is to start by reading and summarising one section of a transcript at a time (Lincoln and Guba, 1985). This was done by way of an open coding of significant statements from participants. The researcher looked line-by-line for comments within the text that revealed meaning in relation to the purpose of the study, then highlighted the comments and questions (Park, Griffin and Gill, 2012; Thomas and Harden, 2008). The summaries or significant statements were extracted by way of brief notes along the margins of the transcripts through an inductive approach, avoiding repetitions where noted (Harding, 2013). It was at this point that member checking, an activity to check data, analytic categories, interpretations, and conclusions with participants would have been initiated for credibility and dependability (Lincoln and Guba, 1985). However, member checking could not be carried out in this research due to the participants being patients with complex needs and ongoing challenging medical conditions. In the interests of participants' well-being, it was agreed to keep discomfort to a minimum. Instead, peer debriefing was

undertaken with postgraduate research peers following each set of unitizations. On this occasion, issues of ethics took precedence over methodological conventions. It is acknowledged however that member checking following unitization may provide the participants of naturalistic research with the opportunity to check and agree to the adequacy of the codes and summaries made (Lincoln and Guba, 1985). Tables 4 and 5 provide some examples of the unitizing process undertaken in this research.

Table 4 Unitizing A: section of transcript Naomi_6

Significant statements within section of a transcript	Extracted codes
I After she had explained things to you, did you find the need to ask further questions?	
R1 I'm trying to think if I did ask anything. I think I did, probably. I think I just asked if I was going to get any results from them, you know. And I think she said that they would let me know. And that was another thing – I said would it be used for anything other than… Than research. You know, it wouldn't be passed on, my information. And she said no. No, it would not be. It would be… I would be a number, and my name would never be referred to, and I thought, "Great." You know, because I think people do want anonymity to a certain extent – not just for myself. I mean, I maybe wouldn't bother for myself, but for other people, that is a good way to go about research. Because some people are very wary of ever… I mean, people younger than me who maybe couldn't get a job if they knew they had, like, diabetes or something like that. It would make prejudice of them going into some kind of work. So I can understand that it should be kept… It should be kept like that.	• Outcome of research important • Confidentiality important • Anonymity important • People weary of prejudice for their medical diagnosis
…Well, nothing, really. Apart from… Is there any stairs? Is there a lift? That's the things I rang and asked about. Is there a…? You know, is there anywhere, you know…? What kind of… What kind of… You know, what's the clinic room like? Am I able to get onto the	• Is there any stairs? • Is there a lift • What's the clinic room like? • Am able to get onto the beds and things like that

beds and things like that? Just for the… That's with me, because of having disabilities.	• That's me because of having disabilities

Table 5 Unitizing B: section of transcript Don_9

Significant statements within section of transcript	Extracted codes
I So did you ask any question at the time? Do you recall that? **R** Initially, I think I probably just asked the obvious. **I** Which was? **R** What may happen? And anything that may happen, may happen. You know, would I have time off work, or would I have hair loss? Would I be ill? How would it affect my family life in the house? And it was all maybes. Which I probably didn't need to ask…	• Would I have time off work? • Would I have hair loss? • Would I be ill? • How would it affect my family life in the house? • And it was all maybes • Which I probably didn't need to ask

Category constructions

Following unitizing of significant statements, the next step was to reduce the codes or units of information to manageable domains by categorising various participant terms into identified domains. Lincoln and Guba (1985) described the process of making categories as the grouping of 'intuitive look-alikes and feel-alikes' and the judgement of whether a new incident exhibits the category properties that have been tentatively identified. It involved a dynamic process of working back and forth to achieve data that focuses and agrees with the properties of an identified domain. Harding (2013 pg. 59) referred to the process of category construction as 'making summaries and comparisons' whereby the researcher writes brief notes in the form of phrases to appear in the summary of the interview, having eliminated repetitions. The process was conducted by the researcher and repeated through

the dataset until stable and meaningful categories were converged (Lincoln and Guba, 1985). The sets of categories were further examined for possible overlaps or duplication (Lincoln and Guba, 1985). In cases where new codes failed to exhibit identified properties, a new category or sub-category was initiated or existing categories redefined, thereby clearing up anomalies or conflicts to domains. The process was ongoing throughout the research until relationships between categories were coherent and saturation achieved (Lincoln and Guba, 1985 pg.343). From a critical perspective, category construction is evidently a subjective and selective process that may present conflicts in thinking and in the judgements made by individual researchers. In the interest of trustworthiness, a sample of the resulting domains were scrutinised by an expert member of the PhD supervision team, a form of peer debriefing as recommended with the NI paradigm (Lincoln and Guba, 1985).

Table 6 Sample of category constructions

Extracted codes	Category construction
• Outcome of research important • Confidentiality important • Anonymity important • People weary of prejudice for their medical diagnosis	• Information need
• Would I have time off work? • Would I have hair loss? • Would I be ill? • How would it affect my family life in the house? • And it was all maybes • Which I probably didn't need to ask	• Information need
• Pile of information • About 20, 28, 30 pages • It was a small book • Risks given in percentages • Percentages didn't mean much • Percentages seen as: 'if it happens, it happens' • Blisters seen as acceptable level of risk	• Size of study documentation • Research terminology • Understanding of study information • Perceptions of risk
• That's me because of having disabilities	• Personal attribute
• Documentation said to be: …"For me, it was a bit blasé" • Documentation not read in detail: "…, I read through it quickly – I literally scan-read it. So… I haven't returned to it at all, so…" • Decision made before reading of PIS • Health situation more demanding (vital) than reading of study documentation • Study documents likened to thick car insurance documents, looks at one sheet to make sure dates were right. • "…but she said, "Read it, read it." And I said, "Read what?" I said, "Where are we going with this, you know?" • Bottom line: "want to be in the computer for the draw for the tablets." • Self-belief: help other people, look after people, what goes around, comes around.	• Perceptions of risk • Reading of study documentation • Size of study documentation • Motivation: Hope for cure • Motivation: Self-belief to help people (Altruism)

Category integration to form conceptual analytical themes

A theme represents repeated patterns of meaning prevalent within and across a dataset (Braun and Clarke, 2006). After categorisation, the next step was to examine the set of categories for possible relationships to form conceptual themes (Lincoln and Guba, 1985). The logic of conceptualisation is to achieve 'as internally as homogenous as possible and as externally as homogenous as possible' category sets with possible relationships among them (Lincoln and Guba, 1985, pg. 349). The sets of categories bearing relationships from the previous analytic exercises were integrated to form the conceptual themes that emerged. The process of conceptualisation required both descriptive (supported by quotations), analytical and explanatory capabilities to arrive at the conceptual themes. The themes that emerged after all the transcripts had been analysed were study invitations, researcher attributes, study information and personhood. The themes epitomised the formulated views of the research participants embodied within the categories and interpreted into themes. For example, the theme of personhood comprised all the categories relating to the individuality of each participant such as self-beliefs, values, personal, social, psychological, intellectual, cultural, emotional and environmental attributes. The thematic maps of the final four themes that emerged in this research are presented in the findings chapter following further reviews and refinements. For example, there was a theme on 'motivations' at the early stages of the analysis process, which was subsequently merged with an emerging theme of 'patient demographics' to form the theme of personhood'. The decision was made when it was realised that the patterns within the emerging theme of motivations, such as altruism, cohered meaningfully with participants' values, self-belief and personal attributes, hence personhood fitted well with the combined dataset.

Formulating meanings from the conceptual themes to make sense of data

When no new categories emerge after all the transcripts had been exhausted and the themes reviewed and refined, the researcher is guided to put into a propositional statement the properties that seem to characterise the themes that emerged from the dataset (Lincoln and Guba, 1985 pg. 438). Braun and Clarke (2006) likened the stage of formulating meanings from the conceptual themes to the beginning of a 'concise, coherent, logical, non-repetitive and interesting account of the story the data tell – within and across themes' (Braun and Clarke, 2006 pg. 93). Fundamentally, the analysis of data transcends beyond methodological procedures into the writing of findings and the interpretations of data within the discussion chapter. Evidently, effective conceptualisation requires the researcher to go beyond description of the dataset to make an argument in relation to the research objectives and existing published literature (Braun and Clarke, 2006). The themes that emerged from this research, while initially appearing diverse, can be seen to relate to the patterns of meaning that influenced the decision-making processes of the clinical research participants that took part. For example, in the theme of 'study invitations', the pattern suggests that trusting relationships between patients and clinicians impacted on most participants' willingness to engage with study information or readily sign up for research. At a broader level, the theme points to the concept of trust in healthcare and indicates that medical paternalism may yet remain in play and possibly interferes with the validity of consents obtained for purposes of clinical research. The emergence of themes therefore can be seen to extend beyond formulation towards meaning making and conceptualisation and by so doing contributes to existing or new knowledge.

Statement of researcher reflexivity in methodological decisions

At this point, the researcher is guided to consider how their position may have supported the practical delivery of the research through reflexivity (Lincoln and Guba, 1985). In

naturalistic research, reflexivity relates to the relationship of the researcher to the research process and how that sensitivity may have influenced the collection and processing of data (Birsks, Harrison, Bosanquet et al, 2014). Evidently, naturalistic analysis does not occur in isolation but is linked to the epistemological positions of the research. Park, Griffin and Gill (2012) acknowledged that the conduct and analysis of naturalistic inquiries such as this research can be influenced by the researcher's philosophical positioning regarding what they set out to investigate, and the researcher's stance on how to go about achieving that which is believed can be known. This research believes that human agency can be supported to interpret its own experiences and accepts a subjective and multiple stance on reality (Lincoln and Guba, 1985). In that position, this research was focused on generating the meaning that patients attached to the process of informed consent after they had taken part in that process. It also sought to represent the patients' voices as authentically as possible. The data was therefore concerned with the 'micro' aspects of the patients' views, which influenced the choice of semi-structured individual interviews and the manual inductive content analysis that ensued. The flexibility of the semi-structured interview method allowed for a wide range of thoughts and comments, yielding a rich and broad dataset (Gillham, 2000). In addition to the 'what' aspect of this research, the researcher sought to produce an analysis that explored the participants' words and statements in meaningful ways. To achieve this, the researcher engaged practically with each comment and transcript line-by-line. Such deep engagement with the data supported unambiguous interpretations and meaning making in a manner that allowed the researcher to connect the texts to the emotions and context of every recording and transcript. It also supported a fair approach in terms of reducing bias, as codes and categories were driven by every line of the transcripts as relevant. It was thought that such depth of analysis and meaning making may not have been achieved by the surface reading associated with the use of computerised qualitative analytic systems. The researcher's positioning of a 'bottom up' approach to healthcare systems, including clinical research, therefore influenced the choices made. This included ensuring that the analysis of this research was data driven

with no effort to limit or fit the participants' views into a pre-existing coding frame or preconceptions (Braun and Clarke, 2006). The commitment to rigorous inductive analysis enabled rich descriptions of the dataset and insight into the complex aspects of the informed consent process for clinical research.

It must be acknowledged that the rigorous processes undertaken throughout this research may not have been accomplished without the professional background, experiences and skills of the researcher as a former clinical research nurse. This background enabled the researcher to build and sustain interpersonal rapport with the participants throughout the interview process. Eager to avoid a 'top down' approach, the researcher drew upon her professional skills to show dignity and respect for all persons at all stages. In a deliberate but guarded process, each interviewee was allowed to lead the agenda of the research interviews. Such an approach was useful in ensuring a dignified and natural atmosphere, where each participant felt relaxed and safe to talk to the researcher. On the other hand, this also meant that some participants often 'drifted' to matters that were unrelated to the focus of the research. However, it was judged that such interpersonal rapport impacted positively on the scope and depth of data. By being less prescriptive, and respectful of the social dynamics between the researcher and each interviewee in the natural settings, the researcher supported natural conversations that yielded deep insights that might not have been possible otherwise. Awareness and respect for social dynamics has been advocated as enabling participants to feel a measure of control over the interview process (Birsks et al, 2014). It must be cautioned however that such a commitment to open dialogue did bring with it some additional expense of time when reading and re-reading the data and extra transcription costs. This is an aspect that might need to be considered if handled by novice researchers in the future. Nevertheless, the strategy was successful and worth the investment in achieving the focus of this research.

Prolonged engagement

To enable richness of understanding and depth of meaning, the researcher observed a prolonged engagement during data collection and interviews, and sought to establish a natural and comfortable working relationship with each of the participants. The interviews occurred in private locations that allowed the participants to freely engage in the research proceedings. The settings included private offices and in some cases patient's homes. Before starting out on the individual face-to-face visits, the researcher encouraged a balanced and approachable atmosphere by firstly engaging with the participants over the telephone in a friendly and caring manner. This enabled a more cordial reception at the first meeting as the participants were made to feel somewhat familiar with the researcher.

Upon the face-to-face meetings, the researcher allowed for warm-up conversations over a pre-interview drink of warm tea or water. A cordial and welcoming start to the research interviews helped to diminish any perceived anxiety or uneasiness that the individuals might have harboured. It was observed that the participants appeared more at ease and engaged to share more details about themselves and family networks prior to the recordings. By establishing a relaxing atmosphere at the outset, the researcher gained a holistic insight of the individuals and of the contexts of their natural worlds, an insight that contributed to enhancing the interpretations and meaning making process in the ongoing analysis of data. An appreciation of 'slice of life' episodes enhances a richer contextual understanding of the findings of a NI (Lincoln and Guba, 1985; Appleton and King, 1997).

The researcher allowed enough time for the interviews, was not in a rush and did not rigidly constrain the participants to any set time limit. The participants were encouraged to guide the interview proceedings. Without appearing in a rush to delve in, each of the participants progressed along the proceedings at own pace, becoming more open and relaxed as the interviews went on. In doing this, it was observed that some of the participants did delve into, and out of some other matters of significance they considered important to them. However, effort was made throughout to search out and establish the meanings that the

individuals harboured. Erlandson et al (1993) support that allowing enough time in the natural context enables the researcher to detect and understand occurrences and relationships influencing meaning making. During the interviews, the researcher was particularly attentive to both the verbal and non-verbal communication, or of the spoken and expressed languages. This is an essential component in naturalistic research as the researcher must be attentive and skilful to determine when to probe for further details and when to steer or move on the research interviews (Gilham, 2000). Despite encouraging a sense of being unhurried and a non-rigid structure, effort was made to steer and keep the focus of interactions to the research agenda, as participants could otherwise get bogged down on matters that may be irrelevant or unproductive to the research goal.

Ensuring trustworthiness

Persistent observation

Persistent observation was a particularly useful strategy as the researcher engaged vigilantly in the field to both verbal and non-verbal communications during data collection. Unlike postal surveys, direct and persistent observation during individual face-to-face semi-structured interviews enabled the researcher to linguistically engage with the participants throughout the interviews. The researcher was particularly vigilant to the tone of voice, body language and other occurrences considered important in the understanding and interpretations of the meanings. This was supported by field notes made during the interview proceedings.

Persistent observation extended beyond data collection and into data processing, as the researcher persistently engaged with the data through repeated listening of the audio-recordings and reading and re-reading of the transcripts. This was useful as it enabled a reflexive approach to both self and the participants soon after the events had occurred. Palagans et al (2017) supports that self-awareness can be enhanced through reflection in and on practice through persistent observation throughout the research process. Self-awareness is valuable as the researcher can develop and become more skilful in her

dealings with the population and individuals being studied. In this research, it enabled the researcher to reflect continually as to identify areas of strength and/or areas for development after each interview recording. Such involvement allowed the researcher to quickly adapt her behaviour, and to consider more effective measures while remaining in the field for subsequent interviews. A typical example is a field note that was written to prompt the researcher to avoid interruptions until the interviewee has completed his or her sentence or statement in the subsequent interviews. This was noted upon reflection on the very early recordings. Specifically, the field notes required that the researcher limit the use of “uhms” and “buts”, which appeared unproductive after listening to the early recordings. By this engagement, the research became more skilful and cautious to ensure minimal interruption during future interviews.

Bracketing

In constructivist-naturalistic research, researchers are encouraged to make open their backgrounds and preconceptions from own experiences, and most importantly to ensure that they suspend any influence of such judgement from the inquiry process (Guba, 1978). It is emphasised that the researcher should maintain neutrality in the dialogues with the researched to not influence or misrepresent their views. The act of suspending one’s own preconceptions in the research process has been referred to as bracketing (Smith, 1997). Bracketing implies putting aside, but not denying, one’s own knowledge of the subject under investigation. Parohoo (2014, p. 404) described the concept of bracketing as ‘the suspension of the researcher’s preconceptions, prejudices and beliefs so that they do not interfere with or influence her description and interpretation of the respondent’s experience’. Gary, Grove and Sutherland (2017) put it simply as the putting aside of one’s belief during qualitative research. This ameliorates issues concerning what is traditionally linked to matters of researchers’ biases in thoughts and deeds in the data representation and interpretations.

Using human instrumentation within naturalistic inquiries, subjectivity of thoughts and actions becomes an understandable concern where critics may argue threatens neutrality, a concept traditionally referred to within the hard sciences as 'threats to internal validity' (Fendler, 2016). Such a concern is taken seriously in the conduct of NI, and so measures were in place that supported the rigour and trustworthiness of the research findings. Indeed, one of the strengths of naturalistic research stems from its ability to utilise insider knowledge of the subject matter to guide the inquiry process. In this research, a research participant instigated an example of this benefit to the inquiry process. He expressed that a nurse conducted the informed consent process with him, saying that he was pleased with the nurse more than he would have been with a doctor. The researcher, having an insider knowledge of historical facts about the informed consent process, which used to be traditionally carried out by a medical doctor, prompted the research participant for further clarification. The researcher responded tactically by soliciting further explanations from the participant as to his reasons for saying so. The participant provided further in-depth explanations of the basis for his comment, explaining that the nurse was more approachable, which enabled him to ask more questions without feeling stupid. This response was carefully and conscientiously implemented in a manner that avoided imposing external thoughts or ideas on the respondent. This demonstrates how the researcher put to good use her intrinsic knowledge to prompt and cross-examine the data for richness and depth, while maintaining neutrality in the research process.

Of further concern to rigour is the threat of fabrication or misrepresentation of data (Gonon, Bezard and Boraud, 2011; Guba, 1978). It is common knowledge that critics of the constructivist- NI have been suspicious of the accuracy and dependability of research findings in naturalistic inquiries (Schwandt et al, 2007; Guba, 1978). Notwithstanding, there has not been a proven or documented instance of fabrication in naturalistic research findings (McInnes et al, 2017; Lincoln and Guba, 1985). Yet it is a threat that cannot be overlooked (Tobin and Begley, 2004).

I engaged in continuous reflection after each interview. As a participant-observer, I supported the participants in the co-production of knowledge in the manner that the researcher probed and responded to questions as well as in the maintenance of a working relationship with the participants. A participant-observer is an approach whereby the researcher is also part of the phenomenon being studied (Lanoe, 1992; Lincoln and Guba, 1985). In this context, a former clinical research nurse with natural insight into the phenomenon being studied cannot be considered an outsider. Such a position allowed for a more ingrained understanding within the natural environment, enabling the participants to offer deeper and more genuine insights from their real-life positions as patients.

Intense Focused Conversations during Interviews

Despite the researcher's background and previous experiences in data collection, they experienced some challenges in managing some of the concerns expressed by the participants during intense focused conversations (Mann, 2016). For example, issues emerged during data collection requiring the researcher to respond to matters outside of the traditional scope of the inquiry. In particular, some participants expressed unresolved concerns from their encounters in clinical studies of the nature that required expert judgement. With depth of experience and competence, the researcher was able to reassure the participants using common vocabulary (Mann, 2016; Gillham, 2000; Erlandson et al., 1993). Careful choice of words and an awareness of appropriate resources proved reassuring to the participants as they commented on their concerns. Such matters of significance would have been difficult to deal with, without an insider knowledge of the state of play in good clinical research practice. This is a valuable insight that could be beneficial to stakeholders, and that would serve the researcher in future considerations of ethical research design and conduct, and in the support of academic researchers involving NHS patients in the future. Reflexivity of this nature that looks back on methodological issues in a meaningful manner is recognised as a crucial element in ensuring quality in qualitative research (Mann, 2016). It would have been unproductive to assume a distant and detached

position. Instead, the researcher effectively enabled the participants to open their worlds, yielding honest and genuine data from their experiences. Mann (2016) acknowledges that analysis of methodological interviews in relation to methodological choices, interests, subjectivities, and the influence on the data collected is a crucial aspect of reflexivity.

Finally, a positive step in this research was conducting interviews in locations convenient to the participants. This enabled more diverse participation from individuals that may otherwise have been discouraged from signing up for research. As reflected in the findings, travelling and the associated inconveniences impacts on the successful recruitment of potential clinical research participants. With a sense of duty of care, it is advocated that every effort must be made to minimise the discomfort that study procedures may have on those volunteering to contribute to knowledge and science.

Summary of chapter

Conducting NI within a clinical environment involving real-life patients in the UK NHS was not without challenges. It required the researcher to negotiate with frontline staff issues of value and power at various layers in a complex clinical arena. However, with a focus on solutions, the researcher employed rapport, regular communication, and tolerance of group processes and leadership variables with both patients and staff to achieve the expected outcome. The researcher was able to penetrate barriers to achieve the deep-rooted knowledge of the views of real-life clinical research participants after they had taken part in the informed consent process for participation in clinical research studies. Chapter 5 presents the findings of this rewarding research as examined through the lens of real-life clinical research participants.

Chapter 5

Findings

Introduction to chapter

This chapter presents the key themes identified through this research as those which influence the decision-making process by participants to either accept the invitation to take part in clinical research or not. It considers both intrinsic and extrinsic factors that motivated the participants, as well as those that may have hindered or limited their willingness to take part in research. The research also examined participants' engagements in the standard protocol for informed consent, and their understanding or perceptions of the quality of care delivery during the consent process. Using NI research, the approach inductively pursued points of relevance to the participants, to reflect the matters of importance to real life patients, as viewed through participants' lenses in respect to the research focus (Lincoln and Guba, 1985). The philosophical underpinning guiding this research allowed the retrieval of deep and dense descriptions from the participants' voices, alongside the researcher's interpretation of those voices (Huston and Rowan, 1998; Denzin, 1989a). This approach was fundamental to allowing for the blending of participants' voices with the researcher's complex engagement in the meaning making of the feelings, actions, intentions, and unwritten expressions experienced in field work. Sections of the transcripts will be presented alongside the researcher's illustrations, to allow the reader to match some of the participants' accounts to the researcher's expressions. Figure 4 illustrates the emerged themes and the sub-categories within.

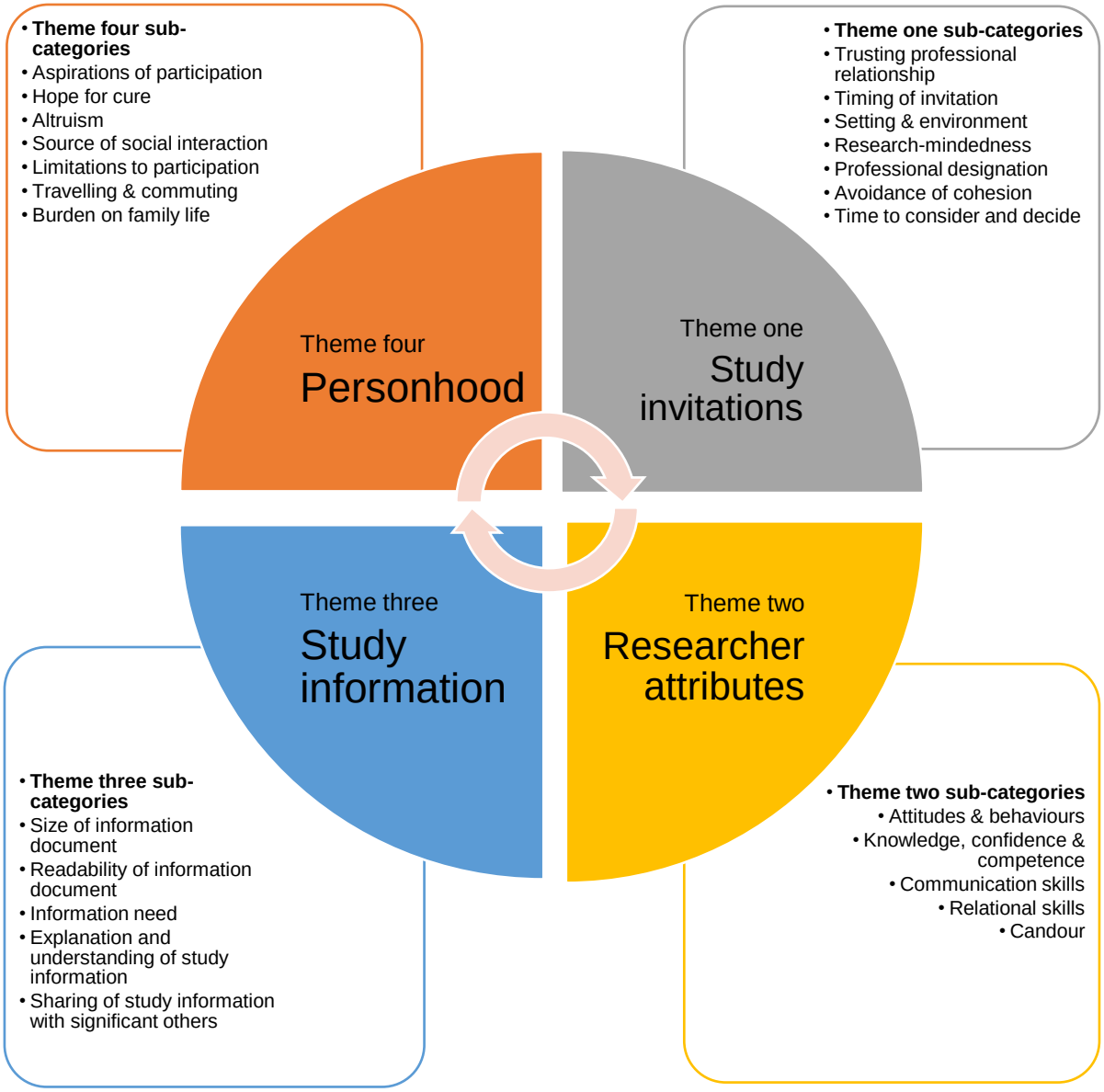


Figure 4 Emerged themes and subcategories

Theme One: Study Invitations

In clinical research, the expectation is that potential clinical research participants need to be identified by a clinician who is completely independent of the proposed study (GCP, WMA 1996), e.g. a member of the clinical team caring for the patient's clinical needs. The reasons for this include that a potential research participant ought to be supported to provide informed consent without any form of duress, including such that may arise from

dependent relationships or therapeutic relationship. An independent clinician may be better suited to invite potential research participants to prevent the patient from feeling intimidated into taking part in the study against their will. Research staff are therefore often discouraged from approaching patients or potential research participants without prior invitation by the clinician responsible for the patient's clinical healthcare needs. Further, clinical staff hold access to patient's clinical and personal data for purposes of providing clinical care and should not disclose such data for reasons other than clinical care, unless with specific approvals. In addition, clinical research staff do not normally have access to patients' data until granted specific permission before they should access patient's clinical data (The Caldecott guardian: GPDR 2018). For these reasons, it is common practice for clinical staff who have rights of access to a patients' information for clinical purposes to invite potential research participants on behalf of those researchers who do not have such rights. Accordingly, study invitation strategies used by clinicians are designed to introduce a line of communication between potential participants and members of the clinical research team. Such introductions do not extend to establishing a longer-term relationship, which continues into the consent process. This highlights that study invitation approaches can play a significant role in the process of informed consent for participation in clinical research. As well as raising issues about the ethics of clinical research recruitment more generally.

This research identified that approaches to study invitations influenced participants' decisions about whether or not to sign up for a clinical research study (the categories are shown in Table 7). This included the nature of professional relationship between the research staff and the participant, the timing of the invitations, the setting and environment in which invitations took place, the designation of the research staff, the participants' readiness to embrace scientific research, and the absence of coercion.

Table 7 Categories in the theme of study invitations

a.	Professional relationship
b.	Timing of invitation
c.	Setting and environment
d.	Research mindedness
e.	Professional designation
f.	Avoidance of coercion
g.	Time to consider and decide

Professional Relationships

A trusting relationship of the nature that exists between a family doctor and his / her patient was suggested to contribute to a positive response from patients when invited to take part in clinical research. The majority of participants believed that hospital clinicians are 'brilliant' in what they do and that they know best. For this reason, the patients tended to accept study invitations on the basis that clinicians have superior knowledge and know what is best for their patients. This meant that some patients willingly accepted study invitations when the study was introduced by a trusted member of the clinical team. This is was captured in the quotations below;

> *"I think the clinicians have been absolutely brilliant with the way they've handled my case. And I put my faith wholly in them. And we both do. We put… We put our faith wholly in them. And if they say, "This is what you have to have. This is what…" Fine, you know…I've been selected on that particular trial because [Name] [00:01:45] thought that would be the most appropriate one for my condition. I'm quite happy at that. I can't question that – although I can question it."*
>
> (Philip_18.6/18.1)

> *"… My life is in their hands, that's the day… That's the old saying of the hospital, you know. My life is in their hands. We would be lost without these people. And I've got good faith in them".*
>
> (John_7.10)

Few participants acknowledged the need for detailed study information, in addition to the study being introduced by a senior clinician.

"*It's obviously got to be recommended by some… Your consultant who thinks or fits your case. But, you know, you really do need need (sic.) all of the details."*

(Stephen_17.4)

Timing of the invitation

The timing of the clinical research study invitation appeared to influence participants' responses to both study invitations and to requests to engage in clinical research. This research suggests that patients experiencing ill health were more likely to consider and consent for research relating to their illness than they would have done had they not been in poor health. Study participants reported that their families were more likely to accept invitations where they were sick.

Talking about research and their motivations for consenting to take part in studies, most of the patients admitted that being ill had made a profound impact on their readiness to sign up to research upon receiving study invitations, whereas they would otherwise not have had the same level of interest. It was evident among most of this sample that an imminent threat to health and wellbeing served to spur some of the participants into considering study invitations and subsequently taking part in clinical research. Most expressed that they would not normally be amenable to ask, accept or act on clinical research study invitations had they not been faced with the reality and challenges of coping with ill health. It follows therefore that a period of ill health may render potential participants more vulnerable and more likely to accept clinical research study invitations. It was interesting to discover that patients were not only prepared to be involved in clinical research during a period of illness, but also rooted for members of the public within the community to also get involved in clinical research.

"To be honest, I would be more likely to do it now. But, in the same way, I think, unfortunately… People who get cancer or their brother gets cancer or their mother or father, and they'll do the charity… You know, you can do a charity run, you can raise money, you can… But only when you face, you know, that specific threat. And then you're spurred on to sort of say, "Right, let's do something." You know, but I'm… So if… 33 years old when I first found out, I don't even think it was on my radar, you know.."

(Stephen_17.12)

> *"Because I had no idea – I knew people did various things, but until you're actually there, right, until you're actually involved in something, then it doesn't hit you in the eye…….. And the things is, as far as things like this are concerned – that you're involved in – there must be… There must be, you know, some form of getting to people. You're not talking about people in hospitals, you're talking about people who are not in hospitals to get involved".*
>
> (Nicolas_14.27)

Setting & environment

The environment in which the study was introduced to potential participants also appeared to influence responses and engagement in the proposed clinical research study. Some of the participants' accounts indicated that a busy clinical environment served to hinder their ability to engage and assimilate the information that was being presented to them. A busy environment appeared distractive when 'there was so much going on', such that participants were unable to concentrate and were therefore unable to take in study information. This meant that some participants emerged from the consent consultations unable to remember the study information that was presented to them. This concern was thought significant given that some of the participants described signing the consent form shortly following its introduction. They could also vividly recall the scene where the study was introduced to them.

> *"But, I mean, what they did say was that it wouldn't be... You know, sort of... I think... I don't know whether they said it would be just a blood test …As I say, there was so much going on, because I was... You know, I'd moved from admissions into short stay and then I was only there a day, and I was moved to the cardiac department. So there was a lot happening, you know".*
>
> (Ivanka_10.10)

The location and setting were also thought to influence potential clinical research participants' experiences of their care, and willingness to engage in further services such as clinical research. Some participants appreciated a more convenient setting, where research activities were to be conducted in same venue as routine clinical activities and where the patients did not need to 'go to any other meeting' or venue. This was reassuring to some patients and encouraged involvement in clinical research activities. Patients were positive

when they knew that they would not be required to travel about for research-specific activities. Further and in relation to the influence of the environment, patients appeared appreciative of nice and 'lovely surroundings', suggesting that a less welcoming environment may put patients off from engaging in further health services such as clinical research.

> *"Well, very convenient because it was all… Mostly all done at… While I was at the surgery. At the podiatrist. Because they would… The nurse, who was running the test, was in the office upstairs. So she would come down and have a word. So I didn't need to go up there or go to any other… Any other meetings or… It was all done during the… During the treatment times or as an extension to the treatment times".*
>
> (Winnie_2.12)

Research-mindedness

An awareness of the place of research in healthcare and the appreciation of the need for research participation did not appear to enhance participants' willingness and readiness to proactively involve themselves in research. The majority of the participants were not aware that they could proactively ask about ongoing opportunities for participation in clinical research. Almost all participants suggested that they would not wittingly enquire about ongoing research studies during a meeting with clinicians but would be willing to engage with research if reminded or invited to do so. The onus for seeking out opportunities for participation in research was perceived to be on healthcare staff. This is despite a long-running campaign by the National Institute for Health Research focused on generating interest and raising research awareness among members of the public (NHIR, 2013). The campaign encouraged patients, carers and members of the public to get involved in clinical research by asking healthcare staff looking after them to tell them of any research that they might be able to take part in (NIHR, 2015). Yet it was apparent that despite such efforts, the majority of participants appeared to lack the courage or remained unaware that they could enquire about ongoing clinical research projects during. Instead, the participants hinted that the majority of people would consent to take part in clinical research if only they knew what was going on and how they could get involved.

"The information was there. I mean, put it this way, I wouldn't have phoned up to ask if there was anything going on. But once the information comes, that's it. Yeah, yes".

(Mathar_1.7)

"I think somebody would have to approach me, because I don't know what's going on in this field. So… Somebody was… If somebody approached me, I would consider it definitely…..I wouldn't know what's going on. That's the problem – I don't know what's going on. So, yes, if… If I thought there was a trial going on something I would definitely take part in it. If I was suitable."

(Winnie_2.13)

"Well, normally I... I wouldn't ask. Because I just don't know what's involved. I don't know to what degree... It takes part. Or why they pick any particular person. So I think it's a case of the patient has no option, really…….. But, like, for... I think the man point is that the patient, as it were, just doesn't know what's happening. I don't know if there's research going on or not going on. And I think a lot of people don't even realise there is research going".

(Eric_12.7)

"Yes, I just wouldn't think. Again, I think part of it is the fact that I don't know what research is going on, or what it's all about. So I wouldn't dream of asking anyway".

(Eric_12.16)

Interestingly, a number of measures were put forward by the participants of this research, in which they felt could help raise research awareness more effectively among members of the public. The strategies put forward included putting up information in chemists and GP surgeries for patients to read while waiting for their appointments, involvement of volunteer recruiters, research cards, and media broadcasts on the radio and TV channels. However, some participants did express a dislike to blanket recruitment approaches whereby members of the public might be invited to studies that do not relate to them. Recruitment strategies such as postal surveys or direct telephone marketing were seen as a nuisance put off many. This was reflected in the comments below.

"…why don't doctors put a notice up in the surgeries, you know, just to say ask if, you know, you're interested in clinical trials for whatever, you kno… I mean, I think television is a bit... There's too many things on there. But radio... I think even better would be to have something in the GP surgery. You know, a notice up. Because I think people tend, when they're waiting... They're looking at... And even... I mean, would doctors not get involved with it?"

(Ivanka_10.8).

> *"But, yeah, why not have research cards. Have a blue one or a nice green one or something that stands out or… And I've got to carry this flair card about with me all the time. There's no reason at all why… There's no reason at all why you can't have something like that… Whatever kind of research you're doing, get a card for it. If it's research into cancer or leukaemia or whatever… Everybody that walks through the door downstairs, into the haematology unit – which is, in the main, where it's diagnosed. Have a card. You know, take part in research… If you so desire, give me a ring…. I mean, the first contact with… With yourself, it was very informative. And it was like, "Phone me up if you want to." So there you go… I think I phoned… I think I rang you the same day. I've got a choice."*
>
> (Don_9.14)

Staff designation

Another significant theme was the influence of professional status of the research staff on patients' willingness to engage or sign up for participation in clinical research. This relates specifically to the historical issues of role boundaries and the public's expectations of who they expect to conduct an informed consent process for participation in clinical research. In this regard, one of the participants commented that study invitations have 'got to be recommended by …your consultant'. This was thought to be intriguing and prompted further probing by the researcher.

> *"It's obviously got to be recommended by some… Your consultant who thinks or fits your case. But, you know, you really do need all of the details."*
>
> (Stephen_17.4).

On further probing, it was discovered that the participants were divided on who they believed should seek consent for medical procedures in clinical research practice. As with clinical practice, it is traditionally the role of a responsible clinician to seek and obtain consent from patients before any medical examination or procedure takes place (GMC, 2010). The clinician should normally be the one who can perform any intended procedure, or a clinician who has been assessed as being 'competent' to obtain consent for the

intended procedure (GMC, 2010). The virtue of 'competence' can be said to be meaningful and dependent on the perception of those involved. This research is of the position that the service users are better situated to determine for themselves the notion of competence from the lens with which they view the care they received.

This study discovered that, for all intents and purposes, most participants would prefer that informed consent consultation for participation in clinical research is conducted by clinical research nurses than medically trained clinicians. The participants believe that nurses are more suited to interact and explain information to patients, whereas medical clinicians were deemed to be less approachable and less friendly.

Although doctors were understood (in the words of participants) to be *'a bit higher up than what the nurses are'*, patients explained that they dreaded talking to medically trained clinicians and *'feel more comfortable talking to nurses than doctors'*. Overwhelmingly, nurses were deemed by participants in this study to be the most suitable to facilitate effective communication and nurture a supportive interpersonal relationship with patients and potential clinical research participants. Patients described their dealings with nurses and some other allied healthcare professionals as being friendly, approachable, available and quicker in responding to their needs and concerns. It was said that doctors do not listen as much as nurses do and are more likely to show that 'they are better than' the patients, which leaves patients feeling less empowered and worst off. Hence, patients were less likely to engage in the informed consent consultation dialogue or ask questions for the fear of looking stupid. This discovery, though reassuring in many ways, is extremely momentous given the increasing involvement of nurses and some allied healthcare professionals in the conduct of informed consent consultations both in clinical and research practice. Nurses have long been taking on such roles, albeit as an extended role. There is implication for practice and workforce training/development, considering emerging legislative changes and societal and political landscapes.

"you know, it's… Dr Whatnot is a consultant, but the consultants really, really don't want to talk to you at all. And they don't listen for a start. But nurses – I find nurses and the podiatrist… They're very friendly and they'll listen to what you say, and they don't try and do any, like, bossy business or try and pretend that they're better than you. So they're very good at it. And I think nurses… And I've always found it's nurses and the podiatrists I go to are very good at listening. So they don't try and pretend they're anything other than just a normal person. Whereas you can't say the same for some doctors…... But I think I definitely feel more comfortable talking to nurses than I do to doctors. Because they seem to be, you know, more friendly".

(Winnie_2.5)

"I've asked… I've asked questions. But it's always been a case of, "Oh, God, does he think I'm thick?" I think it's just the way that you… Like, they sit and they look at you. You know, they look – and you're thinking, "Are they going to say something to you?" But then you sort of like go, "Oh no, it's fine…..Where with the nurse, I just tell them. And… Because I had… There was something… Something was the matter, and I said, "I'm not really happy with the medication" and things like that. I said, "But every time

"I think she was a clinical study nurse…. Oh, she was lovely. She was really… She explained everything that was going to happen. And just made you feel at ease. And you really felt… Felt very good about it all…. It gave me all of the… What was going to happen and what was going to be used, and did I mind the blood being taken and did I mind having the different procedures …And I just said yes. She was very nice. She was a lovely girl"

(Naomi_6.3)

Coercion

Issues relating to any form of intimidation or pressure in the recruitment of potential clinical research participants are frowned upon and taken very seriously in the conduct and monitoring of clinical research practice. The fundamentals of clinical research ethics and, by extension, the informed consent process for research, is predicated on volunteering through free will. The guide to Good Clinical Practice (GCP) (EMA, 2015) stipulates clearly that in the course of informed consent consultations, 'neither the investigator nor the trial staff should coerce or unduly influence a subject to participate or to continue to participate in a

trial'. Any such practice should be concerning and would bring the integrity of the informed consent consultation process into scrutiny.

Correspondingly, this research found that a significant number of participants felt 'compelled' to take part and a 'sense of duty' to help out with research studies when presented with study invitations. Some participants perceived a strong force by a person introducing the study to them in a manner that made them feel duty-bound to take part in the study. In some cases, it was said by some participants that patients were persuaded to accept study invitations with minimal consideration for what the patient really wished to do. Some participants described some research staff approaches as constant and persuasive, and a 'bit of a pest' in terms of the way they were compelled to help with clinical research.

While it must be said that the majority of the participants in this research felt delighted with their experiences of care, even just one incident of coercion should be considered one too many. Persuasive language such as 'you would be an ideal candidate' and 'we haven't got a lot of them' could make a patient feel duty-bound to help out in the research study. Also, constant and persuasive invitations may intimidate potential participants into research involvement against their will at a time when they are already lonely and vulnerable.

> *"I was in there the nurse came and she sat and she just sat for about quarter… Explained, and realised what I'd been in for. How did I feel? What was happening? You know, "You're alright now?" And this is in the (hospital name) before I went for the stents. And then she said, "Well, you're the perfect candidate. Because of your two…" The condition. Because of you angina condition and because you're borderline thyroid, you would be an ideal candidate. And we haven't got a lot of them. She said, "I would just approach you to see if you would be prepared to…" So I thought, well, fine. If it'll help".*
>
> (Andrew_16.7)

> *"Well, I was approached by the nurse first. And then by the doctor in the… When I was in the (HOSPITAL)…., It wasn't the doctor who did the operation or anything else. Or put the stents in or anything. It was just a doctor from another department. He… He did become a bit of a pest, mind. Because he was… He was… He must have been back and forwards to me at least four or five times….. Yeah, while I was in there. He would just get… Back again, "Oh, just another… Just another little point." And… For goodness sake."*

(Andrew_16.1)

Few participants expressed a preference for postal study invitations, highlighting the freedom of choice that comes with these. The participants preferred having the option to request more information. This is different to the situation where potential participants feel compelled to respond to research invitations when invited in person by a clinician.

> *"for me, personally, it was alright. Because the letter came and you just… You read it. If you had any queries you could ring up"*

(Mathar_1.12)

> *"…I could have just signed their form – when that came through the post, I could have read it, said, "Oh, I've done it in the past, I don't want to do it now." I could have signed it and just sent it back and said, "No, I'm not…" You know, I had plenty of chances either to phone or to write back or to… You know, to let them know that I didn't want to take it and… So I was well… It was well… I didn't feel pressurised at all"*

(Naomi_6.9)

However, these experiences are far removed from the experiences expressed below, where patients were supported more reassuringly and allowed the time and space to consider the study invitation and information before deciding on whether to get involved in the study or not.

> *"Well, there was no pressure put on either way, as far as I was concerned. I was just given the information, asked to do it, and from what I understand there must have been some people refused it because they only had two clients doing it, as far as I know. Two patients. So some must have felt… And I felt… I didn't feel that I had to take it or had to decline it. I wasn't put in that position at all, by anybody".*

(Winnie_2.6)

> *"…No. If I wasn't happy, I wouldn't do it. Simple as. I would just say. I don't think I'll… I don't think I'll carry on with this. You know what I mean? So… I mean, I could have turned round and said, "I don't want anything to do with it." But I think the more people know, the better it is for everybody. And then other people mightn't be like me. "*

(Silas_5.10/11)

Time to consider and decide

It is noteworthy that not all patients required an extensive period between study invitations and their decisions to take part in studies. A significant number of expressed readiness to help in research instantaneously, albeit for reasons other than their understanding and explanation of study information. Typically, there is the expectation that time must be allowed for potential research participants to consider study information before they should decide on whether they wish to take part in potential clinical research studies or not. This corresponds with the idea that patients must not be put under any form of duress explicitly or implicitly but should be supported to decide for themselves freely. But the notion of how much time should be allowed between study invitations and decisions to participate in various studies appears unclear in the field of ethical research practice. This is often a matter for REC committees and may be nonconforming to individual patients' needs.

However, this research found that most of the patients did not appear to require any length of time before deciding to get involved in clinical research following study invitations. Some reported knowing what they wanted to do even before detailed study information was presented to them. It was also discovered that patients made their decisions with minimal involvement of their loved ones, often signing the consent form straightaway, with no need to delay or wait for discussions with family members. Most patients understood and were satisfied to sign consent forms, knowing that they could still 'drop out' at any time or 'say no' at any point in time without consequences whatsoever for themselves.

> *"When the doctor spoke to me before he'd even discussed it and asked me if I wanted to do the study, there was no doubt. You know what I mean? It wasn't… There was no doubt that I was going to do it."*
>
> (Simon_15.4)

> *"I knew straight away. I knew straight away I would do it. Yeah…It's just I'm a strong believer in research of any kind, you know. Cancer research – any sort of research. Regarding, like, medical. It's all for, like, my benefit – my family's benefit. Future generations and things like that, you know. And if I can help in any way – however small it is, you know – I will… I would help…….I suppose even if they*

had asked… Say they wanted a little bit of bone off my leg, I would agree to it. No, no – I was quite happy to do it. Quite happy to…"

(Maggie_13.3)

"I don't think there should be a great length of time in between. I think it only should be short. And maybe come one day, get it, read it properly, read… Which I didn't do… Yeah, read it properly. Go through it. And then come back the next day and say, "What's your thoughts on this?" You know what I mean? And… And then… Yes, to sign and talk and…"

(Silas_5.8)

Some patients however, appeared to need time to consider study information before they should take part in clinical research studies.

"…To read it properly, what I got, about an hour… like I say the wife is an ex-nurse, so she read it as well. She goes through it a bit with me… I mean, if you've got… If you're married, you've got to talk to the wife or the husband or whatever, you know, just to get their side of it as well."

(Ron_8.7)

"I think… Within, about, the first day, I'd sort of pencilled it in, so to speak. I thought I will… I would go ahead with this, as long as it's within… I think about the next week or so, as long as I don't find anything that would, you know, really put me off. So I kind of thought, yeah, I'll probably do it – on the first day – but I gave myself about a week and if there was any deal breakers or anything where I thought I can't… I can't do that… I mean, the takeaways, you know…"

(Stephen_17.4)

Theme Two: Researcher Attributes

The next theme that emerged as influencing the process of informed consent for participation in clinical research relates to the professional attributes of the research staff conducting the consent consultation. This theme was quite strong and significant in the factors influencing the recruitment and retention of clinical research participants, in relation to informed consent. This theme consisted of several categories, outlined in Table 8.

Table 8 Categories for the Theme Researcher Attributes

a.	Attitudes & Behaviours
b.	Knowledge, Confidence & Competence
c.	Communication Skills
d.	Relational Skills
e.	Candour

Attitudes & Behaviours

Professional attributes relate to standards of conduct expected from registered professionals working within healthcare. It refers to the core values that the public expects to see from healthcare professionals in the manner that they conduct themselves in dealings with others. These attributes go beyond clinical practice or knowledge, and often extend to an individual's character and persona.

The character and charisma of an individual was found to be invaluable and influential to patients' responses and subsequent engagement in further healthcare services, such as clinical research. Within this research, a significant number of participants expressed that their decisions to take part in clinical research was based on their confidence in the clinical staff that looked after them, having looked after them so well (clinically). On the other hand, negative experiences of care were said to deter potential research participants from engaging in further healthcare services such as clinical research.

It was discovered that patients embrace and appreciate when a healthcare professional conducts themselves in a manner that is polite, helpful and reasonable. Patients described feeling happy to take part in clinical research studies because of the way they were treated by staff. Respect for patients' dignity in a manner that is sensitive and considerate encouraged potential participants to engage and sign up for research. Professional behaviours such as punctuality and reliability were commended upon and embraced.

"Anyway, I was quite happy to… To take part in it. And the basis that the clinicians here, and at (hospital named), that have looked after me very well – and I'm quite happy. I'm very happy with the treatment I received. So I was quite happy, therefore, going on to a trial."

(Philip_18.1)

"It was great. To be honest, the respect I've had off the doctors and the nurse has been fantastic. So if it was research with them again, I wouldn't hesitate. Do you know what I mean?…And if all doctors and nurses treat you the same way then, like I say, there's no… We're basically, we were on the same level. There was no, like, I'm up here and you're down there. It was… It was great…

There was no… Like, he didn't… Yes, he probably is better than me, but he didn't show it. You know what I mean? We were speaking on a level"

(Simon_15.6)

Conversely, some participants expressed that unprofessional behaviours, such as collegial interruptions during consent consultations were distasteful and off-putting to those receiving care or from whom consent was being sought. Engaging in irrelevant and unnecessary chats during consultation was thought to be off-putting and was frowned upon by participants. Participants suggested that derogatory behaviours such as appearing to talk down to someone could cause potential participants to think twice before they engage in further healthcare services such as clinical research. There was the expectation that research procedures such as informed consent should be performed with due regard for patients, ensuring minimal interruptions or distractions, and making patients' care the first concern always. In this regard, most participants recognised and expressed high expectations in the professional behaviours and ethical standards expected at the heart of ethical research practice. Fundamentally, it was found that patients engaged more positively when treated with dignity and respect, especially in the manner that they are spoken to, listened to or responded to. This finding has implications for workforce training and development, highlighting the importance of care and respect by all those involved in frontline healthcare delivery, including administrative and support staff team members.

"… to me, is sort of like… Respecting my views and everything like that, you know. My wishes and everything. And just, sort of, like… How the… How people, like, approach you. If somebody is a bit offhand with you, and that, and you know, and they haven't got, like, the right sort of attitude and things you might think twice about participating. Because you might think, oh, you know, they're not a very nice person"

(Maggie_13.4)

> *"No, that's one thing you don't get there – because there's about 3 or 4 people in at the time. They've got… They usual have two podiatrists in. And the other nurse came in and they were all chatting on. Not that I bother, but… But that's the only thing. The only thing I could fault them on is that I'm sitting there with my foot getting done and then the receptionist comes in and has a chat. And, "Oh, that looks bad."*
>
> (Winnie_2.7)

Knowledge, Confidence and Competence

Potential participants expect that all research staff should be competent and confident in relation to their role in the informed consent process. Lack thereof was said to be discouraging to signing up for a clinical research study. The participants conveyed that they were willing and comfortable to engage with various levels of staff provided that the research staff were able to respond to patients' queries and concerns confidently and competently. They acknowledged that staff might not know the answer to every question but insisted that healthcare and clinical research staff of all levels ought to realise their own limitations and must be able to do so in a professional manner, seeking appropriate help where necessary. The participants stated that any attempt to cover up inadequacies by using 'airy fairy explanations' was damaging and discouraging to further involvement.

> *"I think you realise when you… Once you're in that hospital bed and you're being attended to by the nurses, you get to know whether or not… By the way the carry on in their job and the way they talk to each other, whether or not they know what they're doing. And you can leave it to them, and that fine. And you feel confident"….. Yeah, yeah. And I found that at the (xxx -hospital name omitted). They were always busy, but never too busy to speak to you. And you could tell by their attitude and the way they went on they knew what they were doing.*"
>
> (Andrew_16.13)

> *"You can generally find out, once you speak to the nurse, whether they say… Whether they know what they're doing and they're competent at their job. By… Just by their demeanour and the way they speak to you back. And the way they… And I'm quite at ease listening to some… Listening to the nurses, when you know they're talking sense and you know that they're… You know, they're telling you the truth. So I'm quite au fiat with that. But, you know, I don't necessarily want to take the doctor's time up, for him to tell me something that they… Because I expect the nurses, who are working there, to be at that level and be competent enough to convey to me… "I'm quite comfortable… You know, comfortable, asking a nurse, provided you get a sensible answer from them and you… Because you know straightaway if someone*

is either hedging or they don't know. You would rather they would say, "I don't know" rather than try and give you some airy fairy explanation, which you look and you can see yourself, and I'm not medical – you know, I'm not stupid …Most of the times that I've found – particularly as I… When… They haven't known, you can tell straightaway"

(Andrew_16.12)

Communication skills

Pivotal to the process of informed consent for clinical research participation are effective communication skills. Aligned to informed consent, consultation is the ability of research staff to talk to patients in a language that patients can understand and assimilate easily. In this research, the effectiveness and validity of the informed consent process was associated with the researchers' use of language and preparedness to continually appraise a participants' understanding. Patients were pleased when spoken to in an understandable and respectful manner; whereas an 'offhand' or condescending attitude was deeply hurtful and offensive for patients. The participants embraced plain speaking and the avoidance of technical language.

"The doctor was a very nice doctor. And, like I say, he spoke to me on my level. He didn't use any big words, like ___ [00:07:29] or ___ and… You know. He kept it simple and straight. And straightaway, it was like, well, I trust this guy. You know, I've got faith in him. And I don't think he'd sell me down the river. Does that make sense? So he builds up that trust. And I do feel safe and secure. I don't mean that the way it sounds."

(Jude_19.3)

.."The doctor was absolutely… He was explicit. He was great. I've got a lot of respect and time for him"

(Nicolas_14.2)

"they didn't use any of the technical terms. They just said they would separate the blood out and use part of the blood to, yeah, form the patch. They didn't say what it was. It was just a part of that blood that helped healing. So it wasn't complicated, it wasn't technical"

(Winnie_2.5)

"She says people shouldn't be spoken to and words slip in and you can't understand. You know, I think that's… That's… Just speak to people normally. Uh-huh. Because most people are nervous when you go to the doctors or something, you know. Because I did say to the nurse my blood pressure had probably gone shy high because…. And she was fine. Because she said, "Oh no." She said, "It's not that bad, actually." So I thought, "Oh well, at least she's telling me it isn't bad." So I'm not sitting there, thinking, "Well, what is it? I can't quite see." You know?

(Hannah_11.7)

Relational Skills

Relational skills were identified as important independent of communication skills. In this context, relational skills refer to the manner that the research staff engaged and accommodated potential research participants to make them feel comfortable and at ease. Participants appeared more likely to engage with health services more generally and in research recruitment when dealing with friendly and approachable staff members. Effective interpersonal attributes appeared instrumental in building professional trust with patients. Being pleasant, considerate and friendly, with some element of fun and good humour, helped patients to feel more confident and less on edge. This yielded more trusting relationships with patients and improved patients' experiences of their care. In this context, as discussed earlier, a positive experience of care is associated with increased willingness to take up further healthcare services such as clinical research.

> *"Well, if you need privacy, you're got it. And the staff treat you with a bit of respect once you get here. That's all you want, isn't it?... They don't lose their temper at you and little things like that, you know. You do something wrong and they have a bit joke with you and things like that. I mean, first time I came, I came about switching that off automatically, you know. Just it was coming up. And they didn't moan on or anything like that. They just put it right and... Fair enough… Yeah, and they're always pleasant to you when you come in. That's all you want.*
>
> (Ron_8.12)

> *"Respect? It's been first class. Yes, they've… There's an element… Particularly with the nurses here, but also in where I was treated at (Hospital name). You know, there was an element of fun and good humour about it. Always within the idea of they respect the dignity of the patient. Yes."*
>
> (Philip_18.9)

> *"Well, the way they conducted themselves. The way [Name] [00:19:24] conducted himself with me. And the way the nurses at (hospital name) conducted themselves. And also here. When we were at (hospital name) they had, there, a dance, you see. And they had… They had one once a year for people who suffer from… With leukaemia, you see. For you and your partner. So we went along and we had a great time".*
>
> (Philip_18.9)

Candour

Most participants desired to be told the truth about what they are signing up for. Honesty was deemed essential for fostering trust and crucial in managing potential expectations with participants. It was identified that patients had often been let down due to what they perceived as dishonesty in the line of communications with clinical research staff. A patient shared an experience where they were led to believe that a given research procedure was being carried out for a dual purpose: of both clinical and research intentions, whereas the procedure, an MRI of the stomach, was completed merely for research purposes. This apparently occurred despite the patient's wish not to undertake an MRI if it was only meant for research purposes. The quotes below capture the participants' emotions concerning researcher honesty and its significance of this in the research process, especially the process of informed consent.

> *"Well, I was told by the doctor that this was… Because I do not want two MRIs." She said, "No, you've had an MRI on your stomach." I said, "On my stomach?" She said, "You've had an MRI on your stomach for the thyroid study. I said, "No, no, no, no – he said it was for the heart….. When I investigated, it appears this was an abdominal MRI related to the thyroid study." And that I haven't had one. Now, I thought, you rang me to back to say I had had one. Now, have I had one or have I not had one? So when the girl who… The nurse who was doing the thyroid study came on Monday, I showed her this letter. And I said, "Would you please clarify that? Find out what's happening here, because I'm a little bit annoyed with it in as much as I've either been told lies or I'm being mucked about here."*
>
> (Andrew_16.4)

> *"Because some people just don't want to be part of that. I think they've got misconceptions of what… Come here, Dash… Of what… Of what research… And I think, you know, a lot of people might think, oh, am I going to have to do this? Am I going to have to, like, take drugs and things like that? And I think if you, sort of, like… If you make people aware of that, right from the beginning, whether it involves… You know, they might have to take part in a drug trial or something like that. And I think if you're just honest with people in telling them what it involves and that, you know, you might get more people involved, and that. But you're always going to get an element of people that won't, under no circumstances, you know?" Just everything that it's going to entail. Is it going to entail, like you say, travelling anywhere? Is there going to be, like, drug involved in it, you know? Like drug medication and things like that. You know, what it's going to, like, involve me… Like, my body"*
>
> (Maggie_13.7)

Theme Three: Study Information

Table 9 Categories in the theme Study Information

a.	Size of information document
b.	Readability of information document
c.	Readability of information document
d.	Information Need
e.	Explanation and Understanding of study information
f.	Sharing of study information with significant others

This research explored the participants' views and perspectives on the written and oral study information provided to them. This theme consisted of several categories outlined in Table 9. The study sought to explore the impact that such views and perspectives may have had on the patient's decision to take part in clinical research study. The discussions were unstructured yet focused, to capture issues relating to aspects of the informed consent process. There were cases where the participants were probed further and asked to elaborate on issues raised. One particular set of themes centred around the size of the written information document; the participants' use of the information provided; their reading of the written document; the readability of the written document; completeness and relevance of the content of information; explanation and understanding of the information; and their involvement of significant others in decision making.

Size of Study Information Document

Study information, being fundamental to the process of informed consent, is meant to allow for full disclosure of specified elements during the consent process. The integrity of the informed consent process for research is conventionally dependent on the full disclosure of all aspects of a proposed study relevant to the participants' decision to participate (HRA, 2017; European Medicines Agency (EMA), 2016). Elements tend to include background to the study, risks and discomforts, benefits of taking part, alternative treatment options,

assurances of confidentiality, compensation procedures, points of contact and how to withdraw from study (HRA, 2017; EMA, 2016). This list is by no means exhaustive. Consequently, the amount of information that is covered during information sharing is thought to have steadily become boundless, with implications for ethical integrity and clinical research practice.

Some of the participants of this research asserted that the size and amount of the written information they received appeared to point towards legal and ethical justifications. Some described their study information document as ‘a small book’ (about 20 to 30 pages). Others described their study information document as a ‘pile of work’, which they had to take home to read, while others described theirs as about a size of ‘33 pages’ or ’50-page’ document. The minimum size was said to be three or four sheets long. Overall, the participants appeared indifferent and showed no grievances regarding the size or length of the study information document given to them. Rather, the study information documents were perceived by the participants to serve a legal purpose for the researchers and the participants appeared to expect and respect this position, referring to the changes in the societal culture of litigation.

> *“Really, when I read through this… This pile of information… Probably about 20… 28, 30, I would say. I think it was a small book. And the information that was given to us – 5% of all patients could have the side effect of, we’ll say, losing hair loss. 10% could have a side effect of severe ___ [00:05:14]. Another 5% could have… But it was all percentages. And, really, it didn’t mean much”*
>
> (Don_9.2)

> *“…it was thick. It must have been about 50 pages… About 50 pages. Telling you what all the drugs do, the side effects of the drugs and what have you…. I’m one of these – I like to read it twice. I read it quickly, put it away, and then go back a couple of days later and read it slowly. It still doesn’t go in, like.”*
>
> (Ron_8.4)

> *“The 33 pages all about the drug, type of thing. So I went through and read that…., it was clear and concise enough. Yeah… And I understand… Layman’s, you know, language and everything. So that was fine”*
>
> *(Stephen_17.3)*

> *“It had three or four sheets. And it went through everything as far as I could see. And there was enough there for me to be able to ask questions. So I could see what was right, what I wasn't certain about. So it was good enough to do all of that. So I*

could ask questions and accept things as being what was said on the sheet. So I think it was quite comprehensive, to be honest"

(Winnie_2.10)

Reading of written study information

Some participants explained that they only managed to 'scan-read' through the information and never returned to it again. Some explained that they had little interest in the written information as they had already made their decisions following a few discussions with their clinicians. Others chose to read the bits of information that they found interesting, and suggested that the study information was too much to take in. Most of the patients relied on a face-to-face interaction with the clinicians for the purpose of understanding or comprehension of the necessary information about the study. Other participants who felt obliged to read the study information document appeared to do so only out of respect for the clinical research staff, rather than for their own knowledge and understanding. In most cases, participants had already made up their minds to sign up for clinical research before the written study information was presented to them.

I had this… I had this information, I read through it quickly – I literally scan-read it. And that was it, and I put it into my files. So… I haven't returned to it at all, so… Well, the decision was already made. And that's, you know, one of the things….I had a number of discussions along the various documents. She didn't get annoyed with me, but she said, "Read it, read it." And I said, "Read what?" I said, "Where are we going with this, you know?" I said, "The bottom line is I want to be in the computer for the draw for the tablets." So that was the priority in my life, you know"

(Nicolas_14.7)

"He gave me this sheet and I just didn't get a chance to look at it. With being self-employed, and working for myself, I… I find it very hard to get… Sit down and do, like, other stuff other than work, you know".

(Silas_5.3)

For the handful of participants that did manage to read the information provided to them, they said they did so because there was little else to do during their hospital stay. Some participants pointed out that they may not have chosen to read the study information had they been at own home, amidst the other conflicting day-to-day demands of family life.

> *"I was given quite a bit of paperwork to read. Obviously I was in hospital at the time, so I read it in hospital….You know, if I'd been here, and I'd been at work and… Would I have got it read or…? Other things. My kitchen – I'm doing my kitchen and… Would I have got it read? But I managed to read it because I was in hospital"*
> *(Simon_15.2)*

Another participant described being given a rundown by his clinician as all he needed, commenting that it allowed him to read the specifics that were of interest to him on his own rather than being made to go through all the elements with the clinician. He preferred to ask questions in specific areas that he did not understand, hence emphasising the need for face to face interactions with clinicians during informed consent.

> *"He gave me the paper, and gave me a rough rundown. You know… We didn't go into the specifics – I read the specifics. When I went back and, you know, asked… He asked me a lot of question – you know, I would rather me have questions about things I didn't understand, rather than him explaining everything. Everything."*
> (Stephen_17.3)

Readability of study documents

As highlighted in Chapter 2, much has been written about the readability of study information documents, with most research on the subject comparing readability tools. With regard to clinical research participants' opinions on the readability of study information documents, this real-life research found that the participants were fairly satisfied with the display and choice of language used in the study information documents. For those that endeavoured to read through the written information, the clarity and readability of the written documents received mixed, but mostly positive, feelings. Some participants commented that study documents were 'swamped', making it difficult to read. Others found the small print too difficult to see. The majority were satisfied with the reading level of the study documents, commenting that the wording of study information documents shouldn't be 'too clever' but rather should be easily understandable by members of the public. It was said that complex words make people worry about the study and only serves to frighten them away from participation. The majority of participants felt that the study information documents were 'very well put down' and were quite happy with what they had seen.

"It's just swamped, basically. You get too much. And… Rightly or wrongly, I quite often put documentation to one side, you know. It's a bit like receiving your insurance documents for the car, you know. They're about that thick and I just… I look at one sheet"

(Nicolas_14.7)

"The only thing you, like… A lot of people don't like is if there's little, tiny print along the bottom of the thing that you don't understand. And you can't even read because even with glasses you can't even see it. You know what I mean?... The writing is that little on the side of the box, you need a magnifying glass to… To read it. You know what I mean? And even if you've got good eyes, you can't see it. It's that small."

(Silas_5.16)

"And… I mean, I think it… If you make it too clever, people end up not… If it becomes too much that you think we need to be… People might, one, get frightened. Or worried about it. And they might… You know, I think it doesn't want to be… It doesn't ever want to get too clever, because then people think, "Oh, what does that mean?"

(Peter_3.13)

Information Need

Some participants believed the contents of the clinical research study information was 'too much' and irrelevant:

"I think with most of this stuff there's a lot of information on it. I think it just has to be put there, but there was some of it wasn't relevant…. Not a…but it just seemed to… It does hide out… I think if they have too much – the words… Too many words on the sheet, it hides the bits you want to get to. So it's got to be… It's got to be more concise, I think." (Winnie_2.10)

Participants were supported to discuss what they would like to see in a study information document and the specific information they would like to know about before signing up for clinical research studies. This line of discussion was accommodated and considered an important contribution to existing knowledge, given that the participants had highlighted a minimal engagement with study information because they perceived parts of the study information to be excessive, irrelevant, and unnecessary. Most participants' dislike of study information content contributed to their disinterest and skipping of sections of the study information document. Without comprehensive reading of the study information, the integrity and validity of the choices and decisions that participants make, would become

doubtful. Participants were therefore encouraged to deliberate on the type of information they would wish to discuss during the process of informed consent for clinical research.

Most would wish to know what taking part in the study would mean for them, especially the purpose of study and study procedures. Some participants commented that they are not interested in all kinds of research, and therefore would need to know the purpose of the study to help them decide. Almost all participants said that they would want to know the outcome of the study, saying that this would enable research volunteers to know that their effort was worthwhile and not in vain. Others wished to know the specifics of investigations or whether they will be taking pharmacological therapies, as well as any side effects or adverse reactions from study procedures. Of additional importance to the participants was travelling requirements, accessible facilities and infrastructure such as lifts. They also expressed concerns about the sharing of data with third parties. Assurance of anonymity was understood as being crucial to maintaining confidentiality. Confidentiality was emphasised as essential, due to the impact of health records on employment and insurance privileges. Participants also wished to know the time commitment required. Some explained that they might be happy to take part in a study if it does not require frequent visits but would be hesitant to take part in studies that involve frequent visits.

> *"I would want to know what the possible outcomes could be – whether they were negative or positive. But I wouldn't shirk away from the fact that if it was… The needed to do something that would possibly help somebody else I would say yes. But that's me"*
>
> (Nicolas_14.18).

> *"…I mean, ethical… Ethically I would want to know what it was about. What the research was for. You know, because I'm not… I'm not keen on every kind of research. You know? For a start, I'm dead against embryo… Embryotic research, you know. I just don't think there's any need for it, at all. But I think for… For diseases. The things that… I think we definitely… All research is good, for any kind of solution to the diseases that people have… I just wish they would research more for blummin' arthritis. It's the forgotten… It's the forgotten disease"*
>
> *(Naomi_*6.11)

Explanation & understanding of Study Information

A key aim of this research was to capture real life clinical research participants' opinions on the process of informed consent for participation in clinical research studies after they had taken part in an informed consent process. Fundamental to this was their views on how the study information was explained to them, and the influence of that component on their decision to take part in the research study. This research therefore considered it necessary to discover the views of the participants on how well they felt the study information was explained to them and any other strategy that served to enhance their understanding of the information provided to them.

The understanding of study information appeared to be directly linked to an opportunity for a face-to-face interaction with the clinical research staff. Considering this, some participants explained that the reading of 'paperwork' alone was not helpful in their understanding of the study information. They voiced that sitting down with a research staff and having the research staff read and explain the information with participants helped the information to go in better than just being left to read an information document and to sign the consent form. Some participants underlined that some members of the public may find it challenging to read and assimilate such a depth of information on their own, and that the prospect may serve to put off potential participants from getting involved with clinical research in the first place. It was expressed that study information does go over patients' heads and they not be so keen to take part in a study if they do not understand the information provided to them.

> *"Well, I suppose somebody who didn't understand would just say they wouldn't do it, you know. If they didn't understand"*
>
> (Naomi_6.18)

> *"I think paperwork does help, but I think it needs to sit down with the paperwork. You've got a sheet, I've got a sheet, and you're going through the paperwork together, explaining what… What is actually on that paper. And I think that goes in there better than just giving something and turning round and saying, "Read it… Read it yourself. Go away, read it and…" But I think if it's… If you just sit there and you explain it paragraph by paragraph, if you have to. I think that goes in there*

better than just saying, "There's a sheet of paper. And there's a… Can you sign that?" You know?"

(Silas_5.15)

"Yeah, I think you need to have that much information. Because, you know, some people wouldn't do it very lightly, you know. So… You know, I think it's good to… And, to me, if people don't understand, well then they can question when they get there. They can actually ask it again.., Oh, yes, definitely. I wouldn't… I don't know if I would have been so keen if it had just come and said, "We want you to… Would you be keen to do this study, blah-blah-blah?" And just a letter, without the information, I think it would have been… "Oh, what's this? I don't… I want to know more about this." I would be ringing up and wanting to know what it was all about. So it would have been a bit of a long… You wouldn't be so keen to do it, if you didn't have that information."

(Naomi_6.17)

"Well, I think it's… It's good to talk. It's good to get everything out, and it's good to turn round and have somebody come and sit and talk to you about… about research. …I mean, there's a lot of people who… Who actually, maybe, are on the dole and they've got loads of papers and that to fill in, and they get a book like this. And they've got to go through this book and tick boxes and… And sign. And they've got that many boxes, a lot of them turn round – they don't even know what they're ticking at the end of… At the end of that book that they've got to fill in, they don't even know what they're ticking. And they just turn round and they're ticking for ticking's sake, I think. To me, as long as it's kept simple, you know. And I think it's much easier. And I don't think, then, you would have any problems with people joining research…. But you've got to, like, make sure that people aren't reluctant to do it, you know. Or you make sure that they haven't, or they don't have, that bad experience."

(Silas_5.21)

When talking through their individual experiences of clinician-patient interactions, most participants expressed deep satisfaction when research staff took the time to explain study information to them. It suggested that participants were more satisfied with their experiences of care. A clinician-patient interaction was said to enable an environment where patients would be prepared to ask questions more comfortably, as well as allowing the research staff the opportunity to address patients' concerns more promptly and more confidently. Talking through the study information with participants face-to-face was also said to enhance the clarity of the information provided. Consequently, participants made more informed decisions, having had the opportunity to discuss essential study information in a meaningful way before their involvement in research. Participants argued that poor explanations of study information may yield poor recruitment to a study, as patients may be

more likely to refuse involvement if they did not understand fully what the study is about, or where their concerns were not sufficiently addressed during the consent process.

> *"I was asked by a podiatrist if I was interested, and then a nurse or a sister – I don't know what the ones are with the purpose uniform – came in and explained everything thoroughly to me. When I said I would be interested. And she came down, she explained things, I was told exactly what would be going on. What the clinical study was. How it would going to work. And then I agreed to it. That's how I agreed to it….. It was just like this – it was consents and all that were written out. And there was a pile of work I had to do to take home to check over……. You know, I don't know if anybody is like me but they just read sheets and they don't really get the full idea from it. But it was from questions and asking the sister who was running the test – running the study – it was from her. And she was just great, as far as I was concerned. She told you everything you wanted to know and stuff you didn't need to know. But what she thought was important….. Yes. You can ask questions, can't you? If you don't understand. You can't with a sheet."*
>
> (Winnie_2.1)

> *"This time, definitely, it was a research nurse…..But, I mean, she was really taking you through it all the time. So you were pretty clear all the time she was doing it."*
>
> (Mather_1.8)

> *"…They were listening very well. So if I had something to say they would listen. They weren't interrupting or anything and trying to answer the question before I'd finished or that sort of thing that goes on quite often"*
>
> (Winnie_2.8)

Some participants recognised informed consent consultation as an ongoing process and articulated that it would not be possible to give such depth of information in one go.

> *"…It depends on what the research is about. The more knowledge, the better, you know. And I know you're not going to be able to give it all in one…"*
>
> (Silas_5.16)

Others voiced concerns regarding the explanation of study information, especially pertaining to the expression of risks in percentage measures. Some participants expressed that such a strategy did not support plain speaking and instead served to hinder a meaningful understanding of study information. It was said that the expression of risks in percentages 'didn't mean much' to participants.

> *"And the information that was given to us – 5% of all patients could have the side effect of, we'll say, losing hair loss. 10% could have a side effect of severe ___ [00:05:14]. Another 5% could have… But it was all percentages. And, really, it didn't*

mean much – the way I look at percentages is if it happens, it happens. If it doesn't, it doesn't"

(Don_9.3)

"I wasn't actually clear. Because I can't remember it as much. You know what I mean? Where normally I do… I was still very happy to take part."

(Silas_5.6)

Overall, an opportunity for ongoing dialogue between clinical research staff and the participants was fundamental to their understanding of the necessary study information. Patients were appreciative of the opportunity to ask questions or to clarify any concerns they had, even after the initial consent form had been completed or signed, highlighting the ongoing nature of an informed consent process. Face-to face consent consultations allowed patients to interact with staff in person and to ask questions and have their questions answered more promptly. Most participants described their experiences in a positive light when they had the opportunity to 'have a word' or to ask questions in a follow-on meeting after they had thought through the information. Patients often waited until a face-to-face meeting with research staff to express concerns or ask questions, even when they had been advised that they could telephone the research team should they have concerns. This served to underline the importance and significance of face-to-face clinician-patient interactions during the process of informed consent for clinical research studies.

It also highlights the potential inefficiency of requesting patients to telephone a researcher for clarifications of their concerns. It may be that the onus should be placed on a researcher to ensure a follow-on opportunity is provided to research participants for the reinforcement of study information or clarification of individual concerns. This research suggests that while a few patients may take up such an opportunity to contact a researcher with questions, the majority of the participants may not bother. It may therefore be beneficial to participants for all research studies to ensure an initial face-to-face informed consent dialogue, and potentially a follow-on opportunity other than merely saying that participants should call the researcher. This may serve to support and uphold the informed consent integrity.

"Because I went up there before I started and had a word with the woman and… So I had no problem in understanding what it was about, because they explained it. As I say, you ask… You ask questions when… And then you go home, and you think, "Oh, I should have asked that." And you can ask it the next week"

(Mather_1.4)

"[00:06:47] said if there was any… If I had any questions, just to ring her up and ask, obviously. And I made a couple of notes on it. More, kind of, what if. And the next time I saw [Name] [00:07:03], whose second name escapes me – the next time I saw her, I asked her what if and… And it was explained fine"

(Don_9.3)

Sharing of study information with significant others

After the study information had been explained to potential clinical research participants, the next step is for patients to be given the opportunity to consider the information provided to them, and be allowed the time and opportunity to discuss such information with other significant individuals in their lives (GMC, 2013; RCN, 2011;). In that regard, the participants of this research talked through their attitudes towards the sharing of study information with significant others. The participants articulated the influence of significant others (or lack thereof) on their decision making to take part in clinical research studies.

The majority of the participants indicated that participation in clinical research is a personal commitment of the individual taking part in it. They said that such decisions should not depend on the influence of other family members whatsoever. Most participants did share study information with significant others, such as close members of the family and their GPs but said that they did so merely for information purposes. They pointed out that they did so out of respect and not particularly for others to determine for them. In most cases, the participants shared study information with family members after they had already decided and signed to take part in a study. In this regard, family members and significant others were respectful of the decisions already made by the patient, by taking up a supportive stance in agreement with whatever decision the patient had made.

"My wife and my youngest daughter, who's coming up to 17, and number 3 daughter, who's 26, will support me on anything I do. Whatever I want, as long as it's legal. If it's my choice, then it's my choice. Nobody could say, "I think you should do this" or "I think you should do that." Because this stuff is going into my arm, nobody else's. So I've got a fairly supportive family. And yeah, I had made my mind up as soon as I was… As soon as… Long before I'd been selected for the treatment, I'd made my mind up that I was going to have it, it was offered. Dead easy. Simple as that."

(Don_9.4)

"I'm an only child and I don't have a family or anything like that. So… And when it comes to friends or work colleagues, it's… You know, I… Some people I do tell what's going on, but it's… You know, you don't want to go into all that unless it's, sort of, like a… You know….it's more for information because they worry more if there was something happening and they didn't know what it was…I mean, I would take their advice on board, but it's my decision. I mean, because it's me that has to do it. And so there may be more risks than benefits as well, so… Nobody else can make that choice for you, really"

(Stephen_17.5)

"I made my own mind up. Yes. I… I tend to make my own mind… Well, I did – I didn't discuss it with anybody. You know, when I got the letter and I thought, "Oh, right, yes." And that was it. Uh-huh"

(Mathar_1.7)

Family doctors and trusted health professionals appeared most likely to influence a participant's decisions regarding participation in clinical research studies. As discussed previously, any such influence is correlated to the nature of the trusting relationship between the patient and the clinician.

"There's two GPs that I use at [Medical Group] – [Name] and [Name] [00:24:47]. And, you know, I respect their opinions. And that's the right place to get the information sent to, if there's something that needs to be looked at that we can say, yeah, they'll get in touch with me and say, "Come in, we want to talk to you."

(Peter_3.12)

"They said, you know, this can… "Is it alright if I would send it back to your doctor?" No problem, you know. I didn't have any problems that way. I didn't… Because my doctor… I'm an open book as far as my doctor is concerned. He knows everything that's… That's wrong with me and what I… We work together on things, you know"

(Naomi_6.13)

Although some participants acknowledged that they required the support of family members in processing study information documents, almost all expressed that they reached the decisions to take part in research of their own accord.

"I discussed it a little bit with my husband and that, but he was sort of… He's a nurse anyway, you know. So he was sort of all for it anyway, you know"

(Maggie_13.4)

> *"I discussed it with my wife, because we've got a very good relationship. We know everything about each other. We tell no lies, nothing. I spoke to her and explained it like the doctor did. Excuse me. And she came to the same conclusion that I did – it's going to benefit me and somewhere else. It's going to benefit somebody else"*
>
> (Jude_19.4)

Ultimately, the discovery relating to potential research participants' attitudes towards the sharing of study information with others is significant. This is in consideration of the time required to allow for such deliberation to take place, and the weight of due process on the informed consent process for participation in clinical research. In view of the ethical review standards and requirements, this discovery indicates that any such blanket expectation or requirement to mandate a specific time period between study invitations and the granting of consent by potential participants could be considered unnecessary and unrealistic to real life situations. In the real sense of practice, participants' accounts seem to show that clinical researchers already allow for the signing of consent documents at same time as the study is being introduced to potential participants. There is therefore implications for the validity/rationality of current ethical research standards and practice.

Theme Four: Personhood

Table 10 The categories for the Theme of Personhood

g.	Aspiration of participation
h.	Hope for Cure
i.	Altruism
j.	Source of Social Interaction

In this research, the framework of personhood refers to the intrinsic and extrinsic personal components that influence the individual's capacity to reason and decide on whether to take part in a clinical research study or not. The theme of personhood includes four categories as outlined in Table 10. The notion focuses on a participant's self-concept and its influence

on the decision making for participation in research. It considers the differing moral principles inherent in a person and the associated influence on the person's decisions with regard to engagement in research. The elements regarding personhood emerged from participant conversations, illuminating their perceived thirst for self-determination, dignity and integrity. The discovery was thought to be insightful and beneficial in the considerations for a person-centred approach in the process of informed consent for clinical research. Four categories emerged: aspirations for consenting to research; influence of moral principles; perceived value of life; demographic structures; as well as barriers to participation. Clearly, overlaps were notable between the categories.

Aspirations of participation

The aspirations of participation refer to factors that stimulated or motivated the individual to take action towards an involvement in a clinical research study. In this regard, a range of factors emerged, including interest in medical check-ups, hopes for treatment or cure, social interactions from study visits, and doing good to help others.

Check-up

Some patients were motivated to take part in clinical research studies to receive a medical check-up that would otherwise not have been available to them in the standard pathway to treatment.

> *"…I thought it was going to benefit me. Because my thinking, my theory, behind it was when I come out of hospital having the heart attack I would have a follow-up appointment and then it would be "Come back in six months' time." But the way the doctor explained this thing, once a month I would have an ECG on my heart. And then I would have an in-depth 3d scan. MRI scan on my heart. So I thought, well, if I'm going to have that every month, that's going to benefit me. They're going to pick up on something that's…"*
>
> (Jude_19.2)

> *"And I just read all the papers and I thought, "Oh, I'll go again, because I've always been satisfied in the past." And it's a good check on your health. You know, it's a free MOT, let's face it"*
>
> (Naomi_6.2)

Clinical research therefore was perceived by some participants as an opportunity for additional medical investigation with a hope for diagnosis. This appeared an equivocal assumption on the part of the participants, given the uncertainty of benefit with clinical research procedures. The implication of this type of assumption being that there could be a risk of a potential mismatch in patients' expectations. There is also a danger that some participants might find themselves over-volunteering for clinical research procedures, for reasons that may be hidden from the researcher.

> *"…the motivation was to benefit them and benefit me, because having the heart scan and ECG every month. If there's anything wrong, they'll pick up on it, I think. Whereas if it's been, like, one visit to the hospital but six months later, have another one – anything can go wrong"*
>
> (Jude_19.2)

> *"I wanted to know whether or not this thyroid gland was causing the fact that… I'm not a big eater – I don't eat lots, and I don't eat lots of sweets and… And I just wanted to know whether or not it was a link. Yeah"*
>
> (Andrew_16.7)

Hope for cure

Some patients' willingness to consent for clinical research studies was born out of a hope that they would receive treatment that otherwise may not have been available to them within standard clinical treatment. This was particularly evident among patients living with chronic health conditions such as cancer and gastroenterological problems. The participants expressed that limited treatment options were an issue of concern for most clinical research participants. As such, participants were more willing to sign up for research due to a lack of alternative treatment. There was a clear indication that some individuals may not have chosen to take the risks involved in some types of clinical research studies, had it not been for a perceived hope for treatment and the lack of alternative options. Note

therefore the dissimilarity between this nature of motivation and that of those willing to participate in clinical research merely for the good of others.

> *"…What are you signing for? What are you signing for?" And I said, "Well, what options do I have?" I said, "It's advanced." I said, "You know…" I said, "It's a dilemma." I said, "If don't take the options…" I said, "I'll be dead sooner than, you know…" I said, "If it goes through my system." I said, "We've got to take a chance…..It was a fact of life, basically. It was… If I wanted to be around a few more years, the bottom line was, you know, I had to try to participate. And so that's what happened."*
>
> (Nicolas_14. 1, 14.4)

> *But again, it's going to benefit me. It's something I've got to go through to help me get better"*
>
> (Jude_19.3)

> *"For all it was experimental, my way of thinking was I was 60…65 at the time, when I agreed to go on the… You know, the list… Taking my name and that on the trial for it. If it gives me… If it gives my age, I've got a grown up family, there's nothing really to lose and everything to gain. ." (9.1) …you've got to try… You've got to try everything, even if you think you're up against a wall, you've got to try and get over it."*
>
> (Don_9.8)

Altruism

For others however, taking part in clinical research was considered to 'help out' with science and for the good of others. Some participants' accounts showed that a significant number of patients stood ready to sign up for research for the wholesome purpose of benefitting 'anybody', either in the near future or generations to come. For those, the feeling of doing good was the motivating factor that made participation in clinical research 'worthwhile' for them. In the case of altruism, it was discovered that patents were readily willing to take part in suitable studies provided it was not harming them or costing them anything. Unlike those participants that took part in clinical research with the hope of cure or treatment, those that took part to help others appeared less willing to put up with foreseeable risks or potential harm to self. In other words, those that took part in research for the good of others did so on the condition of minimal or no risks to self or with no real danger to wellbeing. This appeared to be a commanding factor in patients' willingness to

consent for research for the good others. The same could not be said for those that took part with hope of cure or treatment.

> *"Well, I think basically… I think, you know… As far as I'm concerned, with my being in the position that I am – you know, I'm on a one-way ticket, we all are – but if… If you can help somebody else, why not"*
>
> (Nicolas_14.18)

> *"Well, I feel that some good will come out of it. And even if one thing good came out of it, it would be worthwhile and that. A cure for something, and what have you"*
>
> *(Mathar_1.5)*

> *"If it's going to make things better and easier for people to be treated, then… That's basically it. Like I say, if it makes it easier for people to be treated, then I would do it every day"*
>
> (Simon_15.2)

Nonetheless, few of those that took part in the research studies for the good of others also said that they may be willing to take part in research studies involving minimal risks to self (such as rash) and those with no real danger to wellbeing. Still, the level of risks to potential research participants remained a significant factor. Participation in research for the good of others occurred when the participants considered that they would have 'nothing to lose by participating'. It is fundamental therefore that information regarding all levels of risks or harm ought to be fully disclosed by research teams during the process of informed consent for clinical research studies. This is given that information regarding risks or potential harm seems vital to potential research participants' deliberations and decisions. Risks and potential harm should therefore not be downplayed, concealed or neglected during disclosure of information. Any manipulations of such information would be concerning as it could be deemed as invalidating the integrity of any consent obtained.

> *"I come back to what sort of risks? If it was just a simple thing, that I may come out in a rash or something, but there's no real danger, yeah. But if it's going to… I don't know. Like I say, mentally disturb you or something… If I can still be the same person, yes. But, like, little risks, like I say, like having a rash – but after couple of days that rash is going to go away, then there's no danger."*
>
> (Jude_19.6)

> *"They didn't ask me to involve myself. It was totally down to me. I came to my own decision, because I make decisions fairly quickly. That… You know, I had nothing to lose by participating. And so, accordingly, I signed."*
>
> (Nicolas_14.4)

Source of social interaction

Social interactions were also reflected in participants' aspirations for taking part in clinical research studies. Some participants expressed that social support and company was integral element to their decisions to sign up for research. Their accounts indicate that some older adults may be isolated and long for company and social interactions from study visits. Some participants said that taking part in healthcare research benefited them as it gave them 'something to focus on'. Participation in healthcare research was likened to a hobby by one participant, who explained that life after retirement was idling for her and that taking part in clinical research was something she looked forward to.

> *"Again, I know it's research but I do feel it's benefitting me, because it's giving me something to focus on. I'm not working now. I've got nothing – I've got my fish. I've no real hobbies or things. You know, I'm not getting out. So it's giving me something to focus on. And you can… It sounds silly, but I'm looking forward to it. Like, somebody is coming out and they're going to do this and do that. Does that make sense? "*
>
> (Jude_19.3)

> *"Like I say, there's no great risk. And especially now that I'm retiring and the only thing I've got is that. I've no garden or anything. So it's... That could be my hobby"*
>
> (Jude_19.12)

Social relationships (or lack thereof) among the aging population therefore impact on some participants' decisions to consent for clinical research. This is significant as it illuminates a concerning trend that ought to awaken the consciousness of ethics reviewers and clinical research staff during the process of informed consent for clinical research. There is a risk that some older adults might over-volunteer for clinical research studies for reasons that are contraindicated in the process of informed consent.

Moral Principles

Moral principles may serve to sway a person into certain actions or inactions. Little research has been done that articulates the relevance of moral principles in guiding the dispositions of potential clinical research participants' decisions regarding clinical research. This

research however noted participants' references to their moral senses of right or wrong, and other moral necessities. In the course of determining how individuals respond to the consent process for research, and the meanings patients make of it, the moral senses of right and wrong were seen to interfere with some participants' engagement in clinical research. This included beliefs about what is morally permissible, such as mutual respect for self and others, dignity and integrity, honesty and trustworthiness, caring for the good of others, and having an optimistic outlook on life.

Self-respect

Self-respect refers to a belief that one is worthy and deserving of being respected and treated well. Individuals that flaunt self-respect tend not to put up with others when they feel that they are being disrespected or treated dishonourably. It was not surprising that the participants of this research expressed their concerns for issues of respect and the impact on a participants' overall willingness to sign up for a clinical research study. Ultimately, there appears a connection between past experiences of care and the uptake of future healthcare services. Focusing on self-respect, this research discovered that there is an expectation by patients that all NHS staff ought to show regard for the dignity of individuals and not treat patients with discourtesy. It was projected that all frontline NHS staff were expected to always treat patients and service users courteously and with utmost respect. Failure to uphold such expectations presented barriers to some patients' engagements with further services, including involvement in research. Some participants commented that staff attitudes, such as talking to patients in a condescending manner, may cause a patient to change their mind from taking part or continuing in research studies.

> *"..By the way people speak to you. I'm 67, coming up, but they don't… There's much older people than me coming here, but they're not treated like children. And they're not… There's no… There's nobody condescending, which I think could happen to older people. You know, "Come on, pet. Sit yourself down, sweetheart." You're just, "Get off, I can sit down myself." But, yeah, it's very respectful… Very pleasant. And you can have a bit laugh and bit joke with them as well, which kind of makes it pass a bit quicker"*

(Don_9.9)

> *"You know, regardless of if you'd said yes or no, the only thing outside of that, that could change your mind, would be possibly somebody's attitude or their treatment of you, or you know… Sort of, trying to… Force something on you or, you know… But, again, I haven't experienced any of that"*
>
> (Stephen_17.10)

From the views of some participants, healthcare staff, regardless of status or whether in clinical, research or administrative roles, were taken to represent the NHS as a single entity. Consequently, any form of disregard by any NHS staff appeared to resound strongly negatively with patients. Some participants referred to some unwelcoming attitudes that they had encountered from clerical/reception staff, and how such experiences impacted on their willingness to engage further with healthcare services. Some participants told of situations where service users felt 'hard done by' or not listened to by the clerical, clinical and research staff. They explained that negative experiences of disrespect put patients in a bad mood, making them less willing to volunteer for research. Of emphasis was the attitudes of some clerical/reception staff, who are normally placed to receive and welcome patients on their arrival to a healthcare facility. Some participants expressed that some reception staff were ignorant in the manner that they dealt with service users or were inconsiderate of patients' concerns when approached. Another expressed a dislike to when staff talk to one another about a patient but do not involve the patient during consultations. This was said to be irritating and displeasing to service users. These comments indicated that patients' experiences of their clerical, clinical or research care are important and influential in patients' willingness to sign up or continue with further health care services such as clinical research.

> *"I don't know what it is with these girls or women that get these jobs. They immediately… As soon as they say, "I'm a doctor's receptionist – you lot, that side of the counter are all idiots. I'm the boss. You'll do what I say and you will see who I tell you to." That's the opinion… That's the… You know, they're very officious"*
>
> (Andrew_16.7)

> *"You know, if you're ignored and people talk over your head, then... Then you lose your dignity. You're... You're just a number. You're somebody there. You know, it's*

like when the consultants come around on their inspections, and they don't speak to you. They're speaking to their team. And I find that irritating!"

(Mary_4.7)

Further, this research found that patients generally appear to harbour honourable regard for the professional values attributed to healthcare professionals. The saying goes that 'to whom much is given, much is also expected'. The participants of this research articulated in consensus some standards of behaviour that the public expects from healthcare professionals in positions of influence. Some participants voiced discontent with healthcare staff appearing to show disregard for professionalism, such as engaging in casual conversations of the sort that may not be expected of a healthcare professional. This included talking about TV programmes while on duty. Some others frowned upon unprofessional behaviours such as eating or drinking in the presence of patients. Such behaviour was taken to portray a lack of respect for professionalism and a disregard for patients.

"You don't want them coming out and then talking to each other. "Did you see Coronation Street last night? Have you been watching…? I'm an Idiot, Get Me Out of Here?" This sort of thing, you know. Excuse me…I'm sitting looking at this girl, you know, and I'm thinking, God… And then she came… "Oh, [Name] [00:05:39] is going to…" [Name] [00:05:42] – this is another thing – walked down from her office, with her coffee cup and stopped at the end and looked to see who was in the surgery, and then walked out the back. Ten minutes later, came back with her cup of coffee and sauntered back down to her office. Now not once… And [Name] [00:06:03] may think different"

(Andrew_16.17/19)

However, the majority of the participants reported positive experiences of their care with regard to the professionalism of staff in the manner that they were spoken to or treated. They expressed their satisfaction with majority of the healthcare and clinical research staff that treated patients with mutual respect. Some participants conveyed an appreciation for healthcare staff, acknowledging that 'good nurses, know what they're doing'. Another praised all staff that attended to her, expressing that 'even the cleaners' were so kind and lovely. Punctuality of staff was also commended.

"But up here, they're absolutely brilliant up here. On this unit. On the day unit, they're tremendous. Really, really nice people. Good nurses, know what they're

doing. And they just… I mean, it's not a nice place to be. Nobody wants to be sitting in here once a month. But they could be in worse places"

(Don_9.9)

"I had no problem. I never thought I was being looked down on or… I was being told what to do or being forced to do anything. So I think I was respected by them and my dignity wasn't affected one little bit, I don't think…. I think dignity is that I'm involved in what's going on, rather than being told what's going on. And I think that's what they do"

(Winnie_2.6)

Clearly, the behaviour of healthcare staff, including clinical research staff is a significant factor that can affect and influence the behaviour of other people, including that of patients and potential clinical research participants. In the words of one of the participants of this research, 'respect goes both ways' and ought to be acknowledged. This is given the findings of this research that patients' past experiences of care in either clinical or research practice situations have served to influence patients' willingness to consider or take up further healthcare services, including clinical research participation.

Honesty and Trustworthiness

Having expressed a desire for respect, participants also spoke of a desire for honesty and trustworthiness in their dealings with clinical research staff. They spoke frankly of their preference for 'straight answers' rather than to 'mess about' with the truth. Any undue hesitations by staff were negatively received by patients as a 'glossing over' of essential information. Some participants were more appreciative of staff who appeared prepared to clarify patients' concerns in an honest manner, including full details of what taking part in the research may mean for participants, as discussed previously.

"…."As long as they're honest. As long they don't, kind of, beat about the bush. If somebody comes straight out… I said it a couple of times – if I'm going to be told something, I want to be told it. I don't want to be going round the perimeters. I just want to be told straight away…You can ask him anything, and he just tells you a straight answer. He doesn't mess about. He's… Which is what I like in people. I don't like people who go round the houses to tell you…. If it's the way it is, just tell me what it is, you know... What may happen? And anything that may happen, may happen. You know, would I have time off work, or would I have hair loss? Would I be ill? How would it affect my family life in the house? And it was all maybes"

(Don_9.6)

> *"The doctor… The doctor who was the pest at the (hospital name), he was more like a double glazing salesman. He was making… Glossing over things when he said… Because the nurse said, "Oh, a doctor will come and explain other things when you're… When you're at the (hospital name)." But he said, "Oh, all we need is a blood test and what have you." And then he kept, like, adding in… He added the MRI in. And all of a sudden this… "It'll just be for a couple of hours on the Tuesday" – it finished up the whole day"*
>
> (Andrew_16.8)

> *"…And I think if you, sort of, like… If you make people aware of that, right from the beginning, whether it involves… You know, they might have to take part in a drug trial or something like that. And I think if you're just honest with people in telling them what it involves and that… Just everything that it's going to entail. Is it going to entail, like you say, travelling anywhere? Is there going to be, like, drug involved in it, you know? Like drug medication and things like that. You know, what it's going to, like, involve me… Like, my body*
>
> (Maggie_13.7)

A feeling of trust was essential for potential clinical research participants to feel safe with those providing care to them during the disclosure of study information. Concerns about trust were recounted by a participant when he disclosed an experience whereby a member of the clinical research team appeared to have manipulated and coerced him into signing up for a research study against his will. The account said that study procedures were not fully disclosed, and that research-specific procedures were completed under the guise of a clinical intervention. This was despite an emphasis by the participant that he did not wish to have 'two MRIs' due to it being 'very claustrophobic' for him. In the end, the participant recounted that he had been made to have an MRI for a clinical research study instead of the proposed investigation for his clinical care. This account is captured below.

> *"Right, now, I said… I told the doctor – I said, "Right, he wants to do one, and you want to do one. I don't want to have two." I don't like MRI… I'm not a fan of them, but… I don't know… I don't know what it is – as I'm getting older, I'm getting a little bit claustrophobic as well….. It is very claustrophobic. So, no, no, no, no – it's definitely an MRI for the heart. So, fine – I went up, had the MRI. Actually I was there from 9 o'clock in the morning, I was still there at 5 o'clock in the afternoon because there was just lots of delays and what have you. And he had to finish up… When we got into the taxi to come home, he got an urgent call to go to the (hospital A name), so we had to drop him off at the (hospital B name) first. So do a long way round. Anyway, it all comes… I then have to go to the (hospital A name) to have my check-up with the coronary nurse. The coronary nurse checks me, gives me a list, and then said, "Right… The doctor from the (hospital B name) is going to organise…*

We're organising an MRI." I said, "No, no, no – I've had the MRI." She went, "No." I said, "Yes. I had the MRI last week at the (hospital name)." She said, "No, the (hospital A name) don't do MRIs – heart MRIs." I said, "Well, I was told by the doctor that this was… Because I do not want two MRIs." She said, "No, you've had an MRI on your stomach." I said, "On my stomach?" She said, "You've had an MRI on your stomach for the (study name) study. I said, "No, no, no, no – he said it was for the heart." "No, definitely not. They don't do them there….. When I investigated, it appears this was an abdominal MRI related to the (study name) study." And that I haven't had one. I'm a little bit annoyed with it in as much as I've either been told lies or I'm being mucked about here."

(Andrew_16.3)

Privacy

Participants expressed that a private setting was important to them when dealing with staff. A private setting was said to minimise embarrassment when dealing with staff during information sharing and dialogue, and lack of privacy appeared to hinder participants' ability to engage with staff more freely and confidently. Feelings of insecurity were associated with patients' encounters in public places during conversations with staff. A busy clinical environment was considered unsuitable since patients were not always able to hear or engage in dialogues, especially those with altered abilities in communication and perception. Public places and lack of privacy therefore limited potential participants' abilities to concentrate on or engage in consent dialogues. Telephone interactions were also met with extreme caution given that patients did not always hear what was being said over the phone. Instead, talking face to face in a private and quite setting was favoured by all participants as the most effective environment for sharing study information. There is an obvious implication for research ethics reviewers and investigators alike in the development and review of clinical research proposals, and throughout the research process.

"I do like privacy. You know, I don't like showing about. Again, because I've got two hearing aids and distractions everywhere and… Horrible. I feel... It sounds horrible, but I feel disabled, even though I'm not. And in public places people see two hearing aids and they think, oh, look at him, he's deaf. He's this... I'm very conscious of that. I shouldn't be."

(Jude_19.8)

"I think it's… I think… Talking, one-to-one, like this. Is good… Yes, yes. Well, apart from anything else, you see, at present… Well, now, I'm… I've got hearing impairment. And I wear a hearing aid. So, in a crowd, it's difficult to hear. I don't lip-

read… And the telephone – I'm absolutely hopeless. I must get something done about that… I keep saying, "I'm sorry, I didn't get that… Yes. One has to concentrate, as we get older."

(Mary_4.13)

Many other participants expressed satisfaction when informed consent was conducted in a private environment. Sitting down on a one-to-one basis in a private setting appeared to improve patients' experiences of their care during the informed consent process for participation in clinical research. Participants felt reassured when research staff made efforts to protect their privacy and dignity by drawing bedside curtains during informed consent consultations. It was noted however that drawing curtains on its own may not be adequate in protecting a patient's privacy and dignity given that the person in the next bed could also hear the details of the informed consent dialogue. This suggests that a private room would be preferred by patients for a person-centred approach to the consent process.

"I thought they were done very well, because if they wanted to speak to me on my own, they used to pull the curtains round. And if they're needed, they… To look at anything, they pull the curtains. So you were very… It was made private for you. I'm not saying the next… The person in the bed next door couldn't hear what was going on"

(Silas_5.12)

"They made it clear that I would expect the same privacy as you would get from any medical person"

(Winnie_2.7)

"… it was in the short-stay part of the hospital. And it was... There was only myself and another lady. And, you know, it was private"

(Ivanka_10.3)

Optimism & hope

Other factors influencing a participant's willingness to sign up for a clinical research study related to an individual's outlook to life in often difficult circumstances. This research found that potential participants with a positive outlook were more likely to consider involvement in a clinical research study than those with a less optimistic outlook. In particular, the individuals who considered that some good may come out of their involvement in clinical

research appeared more likely to accept study invitations and sign up for research. A feeling of optimism was associated with strong desires to prolong life without appearing to give up willingly on loved ones. Individuals with strong family networks and those with a perceived quality of life were more likely to consider clinical research in the hope of prolonging their life, provided it did not harm their existing quality of life. A participant described wanting to see his young family grow up as his motivation for taking part in a clinical trial, while another described a wish to continue his interesting life as his reason for taking up all opportunities and chances. This finding implies that clinical research staff and ethical reviewers must ensure that potential participants are duly supported to make an informed decision that is not based on false information or false hope.

> *"I have enjoyed life. I've had a wonderful life, I've had an interesting life. And I'm not ready for giving up yet. So, yeah, I feel healthy. I go to the gym regularly. And I keep myself healthy. I eat healthily. I go out and about. I go… I hike and I do all sorts of things. So… I try to keep myself, you know… I'm nearly 70… I'm 69 years old, I'm nearly 70 years old, so…"*
>
> (Nicolas_14.4)

> *"For my good. I mean, I've got… I've got a 17… Almost 17-year old daughter who I want to see… I want to see her flourish. I don't want to be dead in a year's time. I don't want to leave her. But I enjoy my life. I like what I do. I love my job. My wife said a couple of times, "Why don't you retire?" Not a chance. Not a chance. It's what I do. But… I've got family. I've got, you know, good friends. And that's, kind of, my motivation. I've got the motivation anyway, because I'm always pretty positive about… Even the darkest cloud, there's always something above it, for me. You know, my glass is always half full, it's never half empty. But I've always been like that. And I just want to live. If I live until I'm 90, I'll be happy"*
>
> (Don_9.12)

Compassionate care

Just as with the patients receiving clinical care, a compassionate approach to the informed consent process was influential in the participants' willingness to sign up for clinical research studies. Some participants explained that they did not mind taking part in research when staff treated them with dignity and in the manner that staff themselves would like to be treated. Another patient explained that staff should treat patients like 'a normal person' and not label the person by their medical condition. Treating patients as persons and with

compassion was said to be of much value to patients, instead of treating patients in a distant or isolated manner. For the participants, compassion meant an attitude that is considerate, welcoming and kind-hearted, making patients to feel comfortable, being pleasant and listening to patients. Some participants noted that being overly nice to patients was not particularly appreciated as compassionate. Such an attitude was perceived as being patronising, rather than complementary to dignity and the ethos of personhood. There is an implication for workforce development and practice.

> *"I think the main thing is they probably don't treat you like a cancer patient. They treat you like a person and everybody else. Because for a lot of years I didn't tell anybody, really, bar my mam and dad and two other people. Because I found when other people slipped to them – I said, "Oh, by the way, I told such-and-such." And then they either take a wide berth of you, almost like they can catch it. Or they're just so overly nice to you, you kind of think, "Oh…" So I think the important thing is people just treat you like a normal person, rather than, you know, anything else, you know.… It's strange how much you value just being treated, you know, as a normal human being rather than, you know, anything else, really.*
>
> (Stephen_17.7)

> *"She listened. She was a very good… She was a good listener. She was doing well, very well, at her job. She was very good. Very efficient. She was very pleasant, everything. You know, I found her… I found the whole procedure pleasant, you know….She explained everything that was going to happen. And just made you feel at ease. And you really felt… Felt very good about it all. And also the fact that it would be helping, you know, in their study, you know. For this… For further investigations on these things, you know. It gave me all of the… What was going to happen and what was going to be used, and did I mind the blood being taken and did I mind having the different procedures. Which was the ECG, etc. Done, you know. And I just said yes. She was very nice. She was a lovely girl"*
>
> (Naomi_6.3/5)

Appearing to ignore patients or speaking over a patient's head was frowned upon as distasteful and damaging. Such behaviour was taken as a dig at a patient's dignity and served to deter potential research participants from engaging in clinical research and further healthcare services.

> *"It is important. You know, if you're ignored and people talk over your head, then... Then you lose your dignity. You're... You're just a number. You're somebody there. You know, it's like when the consultants come around on their inspections, and they don't speak to you. They're speaking to their team. And I find that irritating. But, having said that, you know, I've recently been in hospital and I just found everybody so... So kind and lovely. Even the cleaners"*
>
> (Mary_4.7)

Summary of chapter

This chapter has reported on naturalistic inquiry of the views of the participants that took part in this research. Guided by Lincoln and Guba (1985, pg. 336 – 356), Tesch (1990, pg. 142 – 145), Erlandson et al. (1993, pg.111 – 122), Harding (2013) and Bernard, Wutich and Ryan (2017), four themes emerged that provide insight into the perspectives of real-life clinical research participants on the process of informed consent for participation in clinical research. The four themes that emerged include: trusting relationships, researcher attributes, study information and personhood. There were some incidental but nevertheless significant findings. The next chapter will seek to make sense of the data by addressing the objective of this research to determine the process factors influencing informed consent for participation in clinical research, with a discussion about the implications of these findings for future practice.

Chapter 6

Discussion

Introduction

This chapter, underpinned by the principles of NI, will engage further in the co-construction of new knowledge by means of interaction between the enquirer and the enquired. It will examine the findings of this research in greater detail and consider the implications for ethical research practice. In doing so, this chapter will pull together the overall findings in relation to the specific research objectives and in comparison, with current knowledge and practice. By comparing the views of research participants and all those involved in research with existing knowledge, a triangulation is achieved, further corroborating the study's findings and interpretations (Lincoln and Guba, 1985 pg. 307). The technique of triangulation, whereby findings and interpretations are compared (but not necessarily verified) using multiple and different sources is a valuable method of quality assurance for naturalistic research (Lincoln and Guba, 1985 pg. 305). Through corroboration with existing knowledge, the influence of 'trusting relationships' on users' decisions to take part in research is examined, as well as participants' views on research staff in the process of informed consent for clinical research. The meaning of professionalism in the eyes of service users and its influence on recruitment and retention of clinical research participants is explored. More specifically, the participants' perceptions of dignity, care and compassion and its influence on the process of informed consent is considered. Information needs of the research participants is debated, noting the link between 'information need' and 'information use'. Participants' motivation and aspirations for taking part in clinical research is also considered, highlighting a new construct of altruism among patients taking part in clinical trials. The chapter will go on to explore barriers to participation and the implications for ethics review and research practice.

For coherence, these concepts will be discussed under the umbrella of the relevant themes identified in the findings chapter. Effort will be made to minimise repetition where there are overlaps in focus. The chapter starts with a discussion about the co-construction approach and the meaning-making process that guided this research.

Engaging in the co-construction of knowledge

Guba (1990) acknowledged how the generation of knowledge is a consequence of human construction and is therefore open to subjective judgement on the part of the inquirer. Within constructivist enquiry, knowledge centres on the relationship between the knower and the known and is supported by the interaction between the researcher and the phenomenon being studied. Meaning making is achieved through the researcher's efforts to understand the context of human experiences, their meaning, and the impact of such experiences on participants' perceptions of the phenomenon being studied (Guba, 1978). In this research, construction of new knowledge involved a subjective process whereby the researcher made decisions at the design, data collection, data analysis and interpretation stages. Unlike the positivist paradigm of inquiry, the constructivist accepts that there will be a degree of subjectivity in the interpretations made. Consequently, this research makes no claim to objectivity. This is because the researcher is a former clinical research nurse with an insider knowledge of the phenomenon being studied, and therefore cannot claim to lack knowledge of the context of care. Instead, the researcher used shared understanding and common language to identify and assess the meaning and impact of the expressions shared by the participants, reflecting the ethos of co-construction. Further, the process of construction and interpretation was enabled by the way the researcher used her knowledge of the phenomenon to probe and to ask follow-up questions, pursuing extended explanations when necessary. As a human instrument, the researcher rigorously engaged with data in a flexible and adaptable manner to identify, synthesise, understand, and evaluate the impact and meanings of the multiple realities as expressed by the participants (Guba, 1978). In doing so, the researcher made a genuine effort to bracket their own ideas, ensuring that the ideas presented was reflective of the views of the participants only. This

was enabled through expert judgement and careful choice of words at all stages of the enquiry. Nonetheless, the researcher's prior knowledge of the natural context of the phenomenon guided and shaped the conclusions and interpretations reached, consequently co-constructing knowledge.

The concept of co-constructing knowledge within the NI paradigm requires the researcher to negotiate permission from participants to synthesise and present their realities. The researcher drew from contextual clues in the field and verbatim expressions by the participants to make judgements on the multiple realities that influenced decision making. This required mutual simultaneous shaping during data collection, which enabled an authentic and consensual representation of human experiences and the influences of such experiences on meaning making. In taking this approach, it is recommended that the researcher engages with the participants after the constructions, to cross-check their interpretations (Lincoln and Guba, 1985; Guba, 1978). However, in this research, member checking was not possible due to the additional burden this would place on patients, some of whom were battling life-changing diagnoses. Instead, the researcher achieved cross-checking by engaging with the supervisory team to review and verify the constructions derived in comparison to verbatim transcriptions and the themes that emerged. The interpretations were compared with existing knowledge to further corroborate the study's findings and interpretations (Lincoln and Guba, 1985).

Specific research questions

1. What are the views and opinions of research participants on the process of informed consent for clinical research participation?

2. How do research participants describe their involvement in the process of informed consent for clinical research participation?

3. How have research participants constructed reality and meaning from their involvement in the informed consent process for clinical research participation?

4. What are the 'information' and 'care' needs of prospective research participants during the process of informed consent for clinical research participation?

5. How does the experience of the approach and process of informed consent influence prospective research participants' willingness to take part in clinical research?

Themes from synthesis of data revisited

The following themes emerged as influencing participants' consent decisions:

A. Trusting relationships

B. Researcher attributes

C. Study information

D. Personhood

Key findings for discussion

Following corroboration with existing literature, the following key findings are discussed with implications for future clinical research practice.

1. Trusting relationships and their influence on decision making for research: the dichotomy between autonomy, paternalism, voluntariness and choice
2. Participants' views on research staff: perspectives on professionalism and their influence on the process of informed consent
3. Information need and information use: correlations and the dilemma for research ethics

4. Personhood and decision making: motivations, limitations and barriers for research participation

Theme One: Trusting relationships and their influences on decision making for research

Most of this study's participants did not appear to engage well with the written study information provided to them. Instead, most appeared to make their decisions based on several other factors. One such factor is an assumption that a proposed clinical research study must be the 'right thing to do' or the right path for them, where the study has been introduced to them by a trusted clinician. Being introduced to a study by a trusted physician was considered by the patient to be a 'recommendation, suggestion or counsel'. With such a view, participants appeared to readily accept a clinician's recommendation on the grounds of trust in the clinician-patient relationship, and the belief that a physician knows what is best for their patient (Kelley, James and Kraft, 2015). In almost all cases, it was found that studies had initially been introduced to the participants by either their family doctor or a clinical specialist involved in a therapeutic relationship with the patient. This meant that the participants had accepted to 'go with the flow' of what they perceived as a recommendation or counsel from a trusted clinician. This was especially true for participants who saw research as the only option or the only part to treatment. Consequently, participants readily accepted study invitations, with a forgone decision to sign up for the study.

The findings suggest that inviting patients to take part in clinical research at a time of illness served to influence their decisions to sign up for clinical research, especially when the invitation came from a trusted clinician. The overall indication was that the timing of study invitations, i.e. at a time of vulnerability, and being invited by a trusted clinician, contributes significantly to speeding up participants' decisions to sign up for research, even before they had been given detailed study information. It appears therefore that participants' decisions

were predetermined in most cases, owing to the study being ‘introduced’ by a trusted clinician.

These findings are consistent with Symonds et al (2012), who reported that patients have a considerable amount of trust in their General Practitioners (GPs), and that a greater partnership role between hospitals and GPs tends to increase recruitment to clinical research. They highlighted the significance of a personal invitation from a trusted figure and suggested that this influence needed to be explored further. The findings of this study therefore strengthen existing knowledge, but also add new knowledge by identifying the dichotomy between trust in clinicians, in their role as patient advocates, and the primacy of meaningful informed consent for participation in clinical research. The giving of personal invitations by trusted clinicians is an effective method of recruitment but should be viewed with with caution, as it appears to interfere with prospective participants’ decision making and the manner in which they consent to clinical research. The influence of ‘study invitation by a trusted clinician’ on participants’ engagement in the informed consent process has not previously received much attention in the existing literature.

This study contributes to the assertions by Agre, Frances and Campbell et al (2003), who suggested that the Research Ethics Committees needed to invest more effort in learning and understanding the factors that influence prospective clinical research participants’ decisions, rather than using only a narrow perspective on written study information. They identified that many individuals decide to take part in clinical research before the consent process occurred and suggested that future research should explore when and how individuals make decisions about enrolling in research. The present study further supports this knowledge but also provides fresh insights into how the individuals made decisions to sign up for research. These findings hold implications about the notion of human dignity, choice and individual rights to self-determination. There are also implications for the concepts of paternalism and the clinician-patient relationships in healthcare versus research participation.

The notion of human dignity, choice and rights to self determination

As discussed earlier, the concept of informed consent is underpinned by the recognition and respect for the concept of the person and the promotion of patients' rights to self-determination (Leino-Kilpi, Valimaki and Arndt et al, 2000). The concept of informed consent sets the minimum standard to give value to the rights, views and preferences of a patient as an autonomous individual. As a rule, medical treatment of any nature should not proceed without informed consent from the person (The United Nations, 2015; Council of Europe, 1997; WHO, 1978). The notion of human dignity acknowledges that a competent individual is in the best position to judge what is in her own interest or what is done to their own bodies (Goldberg and Meier, 2011).

In healthcare, the extent to which patients can exercise their rights to self-determination varies from person to person and from clinician to clinician. This context influences the extent to which the patient can, or is supported to, exercise their right to self-determination (Lindberg, Johansson and Brostrom, 2018).

In both clinical care and clinical research, to give consent, a prospective research participant is required to exercise their autonomous right to self-determination, to decide on whether or not to participate in research after having been provided with both 'relevant' and 'standard' information (Montgomery v Lanarkshire Health Board, 2015; Bolam v Friern Hospital Management Committee, 1957). The patient or research participant relies on the trustworthiness of the clinician or researcher to provide both standard and relevant information to enable the patient to make an informed decision. Importantly, the clinician or researcher is obligated to ensure that the patient has the capacity for autonomous choice and to foster understanding and voluntariness (Coulter, 2002, Mental Capacity Act, 2005).

For the patient, the realisation of informed consent in the sense described above can be marred by other influences, which may serve to undermine independent reasoning and autonomous choice (Pilgrim, Tomasimi and Vassilev, 2011). A notable factor that

influenced participants' decisions in this research was: limited treatment options and the desperate hope for a cure, which caused most patients to put their trust in the hands of the experts – the clinicians. To the experts, it is known that clinical research defers from standard care in the sense that study procedures may only offer a chance of potentially improving health, if at all, as research procedures are by definition unproven, unlike standard treatment (Ellis, 2014). But evidence suggests that most patients fail to understand that research treatment is not standard treatment and could also involve additional risks (Barrett, 2005). Yet, limited treatment options appeared to persuade patients to take part in clinical research studies in the hope for treatment or cure (Hammer, 2016; Durand-Zaleski et al, 2008). This research agreed with previous evidence that in times of illness, the hope for treatment appeared to overwhelm patients, causing them to accept whatever chance they saw and hoping that the expert clinicians will fix their health problem (Probyn et al, 2017). In line with the opinions of Bayer and Fish (2003), other factors that encourage participants to sign up for research include situations when attitudes of clinical staff towards research are positive, altruistic motives and benefits to family members (discussed later). For these reasons, patients are vulnerable, having the tendency to sign up for studies and taking a passive role in decision making, without adequately assessing the risks of taking part, owing to trust in the clinician-patient relationship. A clear contradiction to the notion of self-determination and autonomous decision making is apparent.

The clinician-patient relationship

In clinical care, the clinician-patient relationship is generally underpinned by a paternalistic model that has its origin in 'the Hippocratic Oath' (Askitopoulou and Vgontzas, 2018; Sanchez-Salvatierra and Taype-Rondan, 2018; Mallardi, 2005; Gillian, 1985; Komrad, 1983). The Hippocratic Oath requires physicians to act always only in the best interest of their patients and to keep away from all ill-doing. More contemporary ethical codes reaffirm

the pivotal place of the clinician-patient relationship and a commitment to patient-oriented healthcare practice (GMC, 2013). There is the continuing duty to 'preserve' the health and wellbeing of patients through ethical use of medical knowledge and powers (American Medical Association, 2019; Starmer et al, 2015). Hence, most patients trust healthcare professionals to decide and act in their best interest owing to the belief that 'doctor knows best' (Komrad, 1983). When this happens, the outcome is medical paternalism, a latent manifest of trust in the clinician-patient relationship (Coulter, 2002; Komrad, 1983).

Paternalism in healthcare

Paternalism is regarded as an act to protect another's good but without the person's will or consent (Drolet and White, 2012; Dworkin, 1972). Taking a more therapeutic stance, Komrad (1983) emphasise that a paternalistic relationship is not necessarily a coercive relationship but a morally justified encounter whereby many patients 'still expect, hope for, and even urge (in both subtle and outright ways)' their clinicians to support them in healthcare decisions. Hence, some have described paternalism as when clinicians interfere with the autonomy of patients for the clinical benefit of the patient (McCullough, Coverdale and Chervenak, 2020, McCullough, 2010). There is perhaps some moral justification in clinical care therefore that paternalism is inherent in the concern, care and self-sacrifice of some clinicians in response to situations where autonomy may be diminished or wanting in the clinician-patient relationship (Jansen and Wall, 2018). Such situations may include a time of impaired capacity or diminished autonomy due to illness. McKinstry (1992) argues that patients often need to be guided firmly through the decision-making process, as they may not always know what is best for them. However, some critics have argued whether clinicians can be justified in making decisions about a patient's treatment if the patient does not have all relevant information concerning the treatment offered (Coulter, 2002). Under the notion of human dignity, every autonomous individual is to be considered of equal value, with the clinician having a professional obligation to promote and preserve the decision-making power of autonomous individuals. Ultimately, the intent to promote the

good of the patient in the context of clinical care appears to provide a strong argument in defence of medical paternalism (Komrad, 1983).

The researcher-participant relationship

Differing from clinical care, the obligation in clinical research to preserve and promote the decision-making power of a prospective clinical research participant is paramount. In the clinician-patient relationship, trust, defined as 'the optimistic acceptance of a vulnerable situation, following careful assessment, in which the truster believes that the trustee has his best interests as paramount', is prevalent (Bell and Duffy, 2009 pg. 50). However, in clinical research, there is an unwavering obligation on the investigator to preserve the autonomous rights and dignity of the human research participant (WMA, 2013). The emphasis on autonomous decision, regardless of the perceived benefit to individual or public health, is due to the potential threat to human health that could occur in the course of a clinical research study (Gobat et al, 2018). So unlike in clinical care, in clinical research the pendulum swings in the direction of an informative model of researcher-participant relationship, rather than a paternalistic model of clinician-patient relationship (Braude and Kimmelman, 2012).

Yet, clinical research participants appear to depend on the superior knowledge of healthcare professionals inherent in a paternalistic type of relationship instead of the informative model that is advocated for research participation (Jansen, 2018). For those that took part in this research, there appears a reasonable expectation that clinicians know best, even though the research context is different (Lawton, Hallowell and Snowden et al, 2017). A power-imbalance was observed. Clinical research participants appeared to sign up for research due to their trust in the clinician-patient relationship instead of a fully deliberated and thought-out decision-making process. In particular, the vulnerability of the participants was compounded by the involvement of a trusted clinician in varying parameters along the spectrum of trust and dependence, rather than a deliberated and

informed decision. This was especially the case when invitations for clinical research studies were introduced to prospective participants by a trusted clinician. The involvement of a trusted clinician in the early stages of the informed consent process for research is concerning and has not been properly examined in the available literature.

Paternalism and ethical research conflicts

The findings of this research suggest that the involvement of a trusted clinician at the early stages of the informed consent process appeared to hinder freedom of decision, instead of aiding it. It is argued that the involvement of a trusted clinician adds an undue influence whereby the offer to treat and hope for cure may cause a distortion of judgement, potentially resulting in an unreasonable choice (Largent, 2017). Understandably, it is not unreasonable for a clinician to feel overwhelmed by the pressure to treat and give care (Brazier and Lobjoit, 1991). However, the desire to treat and be cured might not always be in the best interest of the patient (Ubel, Scherr and Faggerlin, 2018; Brazier and Lobjoit, 1991). Also, participants who decide early without fully understanding the implications of taking part have been found to feel regret about their decision to participate in research (Stryker et al, 2006). So while paternalism cares for an individual's interest in place of autonomy in clinical care (Komrad, 1983), the ethics of managing affective and emotional relationships for therapeutic expectations can be corrosive in the context of clinical research.

Undue influence and the dilemma of limited treatment options

Much is written about undue influence resulting from financial interests (Paton, 2018; Lacbucci, 2018; Largent, 2017; Rendell and Geddes, 2007), but less is written about cases of undue influence resulting from the incentivisation of research participation with the hope for a cure. Largent (2017) describes undue influence as when an offer to provide an excessive reward causes a distortion of judgement that may result in an unreasonable choice. Hammer (2016) recognised that when clinical research involves treatment options,

the prospective participant's decision may be overshadowed by fear, especially when standard treatment cannot guarantee a cure. In such circumstances, the prospect or promise of alternative treatment can be titillating and appears to interfere with the decision-making process. Concerns of this nature with regards to the process of informed consent for research is yet to receive appropriate attention in clinical research practice, despite the recognition that it warrants further examination (Hammer, 2016). The findings of this research add to that discussion, indicating that more needs to be done with regard to the guidelines and mechanisms for the recruitment of patients at a time of extreme vulnerability.

Prospective clinical research participants could benefit from independent support at times of vulnerability, enabling them the opportunity to evaluate study information and to determine for themselves what taking part may mean for him or her before making a decision. Such an approach may encourage an informed choice, made without needing to rely on the recommendations of their clinician owing to a trusting relationship and the hope for a cure. It may also be that a clinician lacks appropriate insight about circumstances of a personal nature to patients, meaning that a clinician's recommendations, even with the best intentions may preclude a patient's hidden self/choice. It may also be that a trusting relationship between a patient and a clinician could yield to unnecessary discomfort for clinicians (Brown et al, 2004), who ideally should not need to be so involved in patients' decisions at such a fragile point in in the informed consent process. This is especially the case, given that a clinician's involvement was shown to disrupt the flow of information sharing and disclosure.

Moreover, the process of informed consent ethically necessitates the full disclosure of information, including alternative options, before a patient should make their decision (Benjamin and Curtis, 2010; Maclean, 2009; Mayberry and Mayberry, 2003). Alternative options could favour standard treatment, or in some cases no treatment at all, supported by a full explanation of what each option may mean for prospective research participants (Pick et al, 2013; GMC, 2010). Given that clinically-based staff may not know the depth of

information involved in a study, it follows that a trusted clinician may be unable to address fully a prospective participant's concerns, which is one major tenet of the informed consent process (Dougherty and Geller, 1996). Yet, this research has shown that some patients make up their mind based on the information shared by their clinician, which might indeed be limited in scope, impeding an informed decision (Ubel, Scherr and Fagerlin, 2018). Failing to communicate decision-relevant information overlooks a patients' autonomy and may undermine a patients' choice and goals. Further, some clinicians may harbour vested interests, such as the desire to support recruitment into scientific research or other forms of third-party interests (GMC, 2018; Pick et al, 2013; Flory and Emmanuel, 2004). For these potential impediments, the process of informed consent for research needs to be re-examined, to decrease the impacts that trusting relationships could be having on vulnerable patients' decisions.

In some codes of research ethics, it is thought that prospective clinical research participants are better suited to receiving support from a trusted professional such as a family physician or a clinical specialist who may have overall responsibility for the patient (Pick et al, 2013). However, in this research it appears that patients' motivations and readiness are compounded by the trust they have in their clinicians. First, patients' expectations and motivations may not be fully explored during clinician-patient interactions, owing to time limitations and in some cases, distortion between the voice of experts and the real world of the patients (Doody and Nooman, 2013; Barry, Stevenson, Britten et al, 2004). Barry, Stevenson and Britten et al (2004) advised that the distorted patterns of the voice of experts are often incompatible with the more natural, undistorted communication patterns of the voice in the lifeworld. In other words, a clinician's perspective may differ from a patient's desire, which ought to be examined to establish what patients are hoping for by taking part in research and to ensure they understand the boundaries of what participation can offer them. Without such depth of deliberation, and enough time to deliberate, prospective research participants may remain vulnerable, lacking the ability to reach an autonomous

decision. Failing that, expert communications may shape the direction of patients' decisions in a manner that may be uncensored, and which is influenced by patients' vulnerabilities and trust in the clinician-patient relationship (Doody and Nooman, 2013).

Second, this research found that participants were willing to 'sign on the dotted line' so that they could 'get on with it', having already made up their minds before the sharing of detailed study information. This was noteworthy, as it highlights the complexity and blurred boundaries between the recruitment phase and an apparent enrolment phase in the clinical research process. This has implications for delegation of duties in the consent process. Dougherty and Geller (1996) described the recruitment phase of the research process as the phase whereby potential clinical research participants, i.e. those considered to be eligible to participate in a given study following screening exercise, are invited and offered the opportunity to participate in a particular research study. They explained that the recruitment process should normally involve a discussion of the risks and benefits of participation, including detailed description of study procedures and any potential impact on the individuals' well-being and quality of life. Such discussions should not only consider the medical consequences of participation but the mental, emotional and social burden of participation as applicable to everyone (Leino – Kilpi et al, 2000), and should be guided by the research protocol (Dougherty and Geller, 1996). Only after an honest and thorough recruitment discussion with prospective research participants, including the option of no involvement, should patients be encouraged to decide on participation, and their decision implemented, marking start of enrolment (Dougherty and Geller, 1996). Hence the recruitment and enrolment phases of the clinical research process are parts of the decision-making process for clinical research; that being the informed consent process (WMA, 2013). A clinician who is not part of the research process but engages with prospective research participants in the informed consent procedure without appropriate delegation could be restricting the patient's ability to meaningfully engage in study information when it is subsequently presented.

It is for such reasons that the Declaration of Helsinki ethical standards specifies that: “In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information” (Helsinki Declarations, Principle 26, WMA, 2013).

Hence, professionals involved at any stage of the informed consent process must be knowledgeable enough about the study protocol to be able to inform and discuss study requirements adequately with prospective research participants. Otherwise, they risk tainting the values of the informed consent process for clinical research, as they may not discuss the study protocol in depth. Such dialogue by trusted clinicians outside of the research team may only present part of the whole truth yet appears to impact heavily on the decision-making process by prospective clinical research participants. While clinician support may be valuable to a prospective research participant, the untimely or premature involvement of trusted relationships appeared to impede informed decision making. Therefore, this research suggests that the involvement of trusted relationships should only occur after extensive information sharing by appropriate members of the research team within the delegation log of a study protocol. This stance has implications for NHS RECs and clinical researchers in the design and review of study protocols, and in the central debate about how best to improve understanding and recall of study information for clinical research participation. This insight may enhance freedom of action in decision-making by prospective clinical research participants.

Further, there is limited evidence in existing literature on how research ethics principles are applied or policed in real-life (Waligora, 2012; Tschudin, 2001). The findings of this research suggest that some prospective research participants may lack the confidence to challenge a clinicians' opinion or recommendation, owing to the belief that the clinician knows best, and that the clinician has their best interests at heart. Most patients, being respectful and trusting of the clinicians' superior knowledge (Calman et al, 2004), appeared to respond in kindness, and readily accepted study invitations more than they may have done had these been introduced by more neutral personnel. This insight is reflected in Symonds and colleagues' study, which reported that the research participants were biased by the hierarchical status of clinicians (Symonds, Lord, Mitchell and Raghavan, 2012). The study found that the participants were more likely to sign up for research when invited by a senior male doctor who was part of the treatment team, owing to a symbiotic relationship based on patient/physician trust (Symonds, Lord, Mitchell and Raghavan, 2012). In comparison, attempts to recruit patients by persons of perceived lesser hierarchical status, such as senior nurses and radiographers, were less successful (Symonds, Lord, Mitchell and Raghavan, 2012). That is a dilemma, which may bring the integrity and validity of the consent decision for research into question, especially as the current study suggests that such decisions are made without due consideration of detailed study information that should normally follow on from study invitations. This highlights the challenges from dependent relationships, whereby prospective research participants are particularly influenced by the imbalance of power in knowledge in their dealings with clinicians. A perceived lack of knowledge on the part of patients is known to play a role in the absolute reliance on expert knowledge of clinicians (Calman, et al, 2004). Such professional dynamics between vulnerable groups of individuals presents a barrier to informed autonomous decision by participants. This is common knowledge in healthcare literature; that people who are perceived, or who perceive themselves, as dependent upon the services of others may have trouble asserting their rights (Ipsos-Mori, 2016; BMC, 1995).

Ultimately, the findings of this research suggest that participants were less inclined to engage with study information once they had already made up their minds following an encounter with a trusted clinician. This may explain why prospective research participants are known to readily sign the consent form without reading 'between the lines' (Knapp et al, 2011), and are hence unable to remember study-related information (Ponder et al, 2008).

Importantly, it appeared that the process of informed consent for research started at the point of study introduction by a trusted member of the healthcare team, even when they were not part of the research team. This insight is novel and differs from the views of Gupta (2013), who stipulates that the formal process of informed consent starts from the point of an interactive session with the investigator, who reviews the entire study information with the potential participant before obtaining signatures. In contrast, this research has shown that some participants made up their minds even before such formal knowledge was made available. This is significant, as current standards stipulate that the process of informed consent ought to be delegated to staff who are trained and knowledgeable enough about the study to discuss it (EMA, 2017; WMA, 2013). There may be a case therefore, to suggest that the invitations or introduction of studies need to be undertaken by a member of the research team who is knowledgeable enough to discuss the study protocol at the first asking and answer any potential questions that participants may have. Such encounters need to be considered at the early stages of the informed consent process, i.e. at the point of study introductions/invitations. This research suggests that it should not be left as a follow-on exercise after prospective research participants may have already made up their minds. Interventions after the study has already been discussed by a trusted clinician may prove too little too late.

Third, it is acknowledged that clinicians are often faced with ethical dilemmas when recommending or deliberating on decisions about taking part in research with their patients (Tinkler et al, 2017; Brown et al, 2004). Relating to paternalism in medicine (Hanna, 2018; Komrad, 1983), and increasingly in nursing (Tinkler et al, 2017; RCN Research Society,

2011), clinicians are persuaded by the duty to do good. Those in support of paternalism have argued that protecting patients from harm is parallel to making every effort to secure the patient's wellbeing (Hana, 2018; Corn, 2012; Klitzman and Chung, 2010). Yet in clinical research, respect for a person's autonomy to determine the risk-benefit of a study, having been provided with necessary information, is inherent in the concept of informed consent (Dickert et al, 2020; Beecher, 1966). The critical debate is on how to respect a person's moral agency while at same time uphold their best interests, especially in the context of clinical research practice (Beskow, Lindsell and Rice, 2020; Wilford and Porter, 2020; Dickert et al, 2020). This is an enduring debate.

From the paternalistic perspective, the findings of this research suggest that patients who see clinicians as experts are likely to depend on clinicians' opinions when deciding on research participation. However, Daugherty and Geller (1996) warned of the critical dilemma between paternalism (representing beneficence) and respect for an individual's right to choose and decide for themselves, highlighting the limits of ethical rules and the challenges of implementation in the real world (Daugherty and Geller, 1996). Klitzman and Chung (2010) acknowledged the challenges of living with medical illness, which may be compounded by physical, cultural, social-economic, and emotional difficulties. These may influence how individuals relate with clinicians. At such times, the tendency is to rely on a trusted figure, such as a family physician or medical specialist (Rendell, Merit and Geddes, 2007).

The concern is that clinical research studies are led by clinicians who are often under added pressure to recruit to target by drug companies sponsoring the studies (Rendell, Merit and Geddes, 2007). There may be reservations therefore about the justification of clinicians' involvement in the process of informed consent, with the public being suspicious of the potential for bias (Ipsos-Mori, 2016). Dumez and Pomely (2019) emphasise a shift from medical paternalism toward care partnerships, a form of shared decision making, whereby autonomous individuals ought to be provided with relevant information and be

supported to deliberate and understand the information before they make their decision. In clinical research, this may be facilitated through meaningful deliberation by encouraging measures that will enhance a participant's engagement with the study information. A focus on enabling autonomous choice and rational decision making may achieve the greatest benefit by enhancing understanding and the recall of key study information, and a sense of satisfaction for all involved. Wright (2017) notes that paternalistic control is less desirable in clinical research and can be avoided by ensuring that an individual's time preferences, risk preferences and life preferences are duly considered during the informed consent process.

Considering the subjective nature of human intentions, motives and actions, it may seem impossible to imagine the rationality of regulatory controls, when such measures are not adequately policed at the frontline (Butler et al, 2020; Carson, Hinton and Kurinczuk, 2019; Hearnshaw, 2004). Having had the unique privilege to interact with real-life research participants at length, it does seem that rationality in consent decisions may not be a matter of abstract tendencies but are instead bounded to the environment and context within which the decisions are enabled. Ultimately, it is the view of this research that a truly free consent is one where patients are not told what to do but are instead encouraged and enabled to deliberate and decide what may be rational at a given time. Failing that, paternalism in clinical research allow some clinicians to undermine an open process (Jansen and Wall, 2018). The consequence being the legal implications that may ensue, as well as the demise of the fundamentals of ethical research integrity.

In 2018, the Medical Defence Union shared a cautionary tale, whereby a patient was consented for frequently occurring risks about a medical procedure, but for which the patient later brought a claim alleging that the procedure had been performed without properly informed consent (MDU, 2018). For the legal claim, the case of Montgomery vs. Lanarkshire Health was subsequently evoked with reference to 'what a reasonable person would be likely to attach significance to, or that the clinician was or should have reasonably been aware that the particular patient would be likely to attach significance to' (Montgomery

vs Lanarkshire Health, 2015). Such is the importance of autonomous decision making in clinical research participation. Clearly intentioned procedures, without the valid consent of the person to accept it or refuse it, would be steps in the wrong direction (BMC, 1995)

Crucially, the generally accepted ethical position of the Helsinki Declaration (WMA, 2013) emphasises that: “When seeking informed consent for participation in a research study, the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations, the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship”. Fundamentally, an insightful contribution to knowledge from the findings of this research is that the introduction element of the informed consent process is central to research participants’ decision process. It is argued therefore that the study invitation or introduction deserves rethinking in terms of who should be involved at such an early but crucial stage in the informed consent process. Berrios, James and Raraigh et al (2018) support this position and acknowledged that trust in clinicians results in unintentional consequences when signing up for clinical research.

Subtle coercion

Although most of the participants in this research felt that they reached their decisions freely, there were a few cases where some participants appeared to have been subtly coerced into signing up for research procedures, in some cases against their will. Obviously, even just one case of any form of coercion in research that involves sick and vulnerable patients is one too many. In one worrying case, a patient appeared to have been manipulated into undergoing an MRI procedure for research purposes without giving valid consent. The patient expressed his concerns and proceeded to put his trust in the clinical research team, who, by the patient’s own account, conducted a research-specific procedure without their knowledge or permission. Undoubtedly, some people take part in clinical research in order to benefit science and for the greater good, while others do so to benefit

themselves (Bardash, Parson and Gibson et al, 2020). Participation in research therefore holds different meanings for different people, making it crucial that participants are not misguided but are given opportunities to consider all aspects of the research, and to have their wishes respected.

Healthcare professionals are obliged to put the best interests of each patient first (Corn, 2012; GMC, 2010). But in clinical research practice, coercive tactics by some healthcare professionals are not unheard of (Klitzman, 2005; Breeze, 1998). For this reason, some patients are becoming more alert in their dealings with scientific researchers, especially when signing up for research (Ipsos-Mori, 2016; Coulter, 2002). Encouraging research integrity, Macfarlane (2009) warned that researchers should not deceive human research participants or coerce them into signing up for research, noting that this will result in negative injunctions against the values and validity of informed consent. Risks of coercion and manipulative behaviours may manifest through miscommunication or exaggerations about the benefits of taking part, therapeutic misconceptions, failure to fulfil a promise, or conflicts of interest between participants' wellbeing and the demands of sponsors (Ipsos-Mori, 2016; MacFarlane, 2009). The negative impact of these factors on the process of informed consent for clinical research ought to be acknowledged and managed at all levels of monitoring. The onus is on all researchers, health professionals, and local research ethics committees to ensure that any agreement to participate in clinical research reflects the free choice of everyone (GMC, 2008).

Theme Two: Attributes of Staff - Participants' views on research staff and influence on decision making

Having underlined the impact of trusting relationships on the process of informed consent, a further key insight was made around the ways in which research staff gained the trust of prospective clinical research participants. These included staff attitudes and behaviours;

knowledge and competence; and communication/relational skills. Findings indicated that trust in research staff during the process of informed consent was fostered by positive attitudes, such as being friendly and approachable. This finding reflects the accounts of Kelley, James and Kraft et al (2015), who found research participants indicated that support for research was often dependent on 'the way it's said' (Kelley, James and Kraft et al, 2015, p. 7). In the present research, staff were considered approachable when they acknowledged and responded to a patient's concerns. Participants were more willing to engage in the process of informed consent and to listen when attended to by friendly staff, whereas talking to potential clinical research participants in a condescending manner was said to put individuals off from listening further. The participants said that it was important that patients be treated as people, which implied being listened to and respected. Hence, the interpersonal relationship between research participants and researchers is vital in the informed consent process, as echoed by Kelly, Spector and Charkas et al (2015). Other attributes related to knowledge and skills and were reflected in the way research staff took time to explain study procedures, the language they used, and their overall display of competence. Attitudes and behaviours relate to the way research staff conducted themselves to make service users feel comfortable and at ease. Hence, there are overlaps between the themes of 'researcher attributes' and of 'study information'. The following section explores the behavioural attributes of research staff, and the meaning that research participants attach to such attributes.

Participants' perspectives on research staff were an important contribution to knowledge, given that positive staff attitudes and behaviours appeared to foster trust and to instil confidence among service users in signing up and continuing in research. Conversely, negative attitudes led to distrust and appeared to hamper research participation. Pearson and Raeke (2000) highlighted the limited availability of evidence in relation to the trust element of the patient-clinician relationship and how such elements may serve to influence interpersonal trusting relationships. Citing Mechanic and Schlesinger (1996), they defined

interpersonal trusting relationships as the trust built through interactions through which expectations about a person's trustworthy behaviour can be tested over time (Pearson and Raeke, 2000). They noted a gap in knowledge and emphasised the need to evaluate and understand the perspectives of research participants in relation to the trust element of the informed consent process for participation in clinical research. Similarly, Phelps, Tutton and Griffin et al (2020), in a recent review of the experiences of adults who took part in a surgical research study, reported that trust in the research staff was among the main reasons why prospective research participants sign up for research. Such insight into the trust element of the informed consent process is therefore deemed to be significant in future workforce development and in the recruitment and retention of prospective clinical research participants. It may also hold implications for REC reviewers and in the recruitment of qualitative research staff.

It was apparent that without enduring interpersonal relationships with research staff, research participants would be more likely to discontinue involvement in research. These findings are consistent with a recent study by Phelps, Tutton and Griffin et al (2020), who reported that clinical research participants consider trust in research as an important factor that influences decisions to sign up for clinical research. Carson, Hinton and Kurinczuk et al (2019) reported, from an organisational point of view, that lack of trust in healthcare organisations and trust in those asking affects individual decisions to consent, due to doubts around how healthcare organisations may keep or use participants' personal data. Gobat et al (2018), in a qualitative study about the factors that influence decisions for research participation, identified that participation was influenced by perceptions of trust, particularly during a period of illness. Significantly, they reported instinctive and intuitive patterns of decisions, representing a new dimension in the paternalistic model of trust discussed in theme one. However, a detailed understanding of such a trust element, as perceived by research participants, is lacking. Therefore, examining research participants' perspectives on how they decide to trust research staff is a useful contribution to

knowledge. Such insight about how prospective research participants decide to trust research staff and sign up for research intuitively may underpin existing knowledge and future practice about the process factors influencing informed consent for participation in clinical research. It may also advance research recruitment, especially in the current climate, where public trust in various pandemic research is of the highest importance. In the context of this research, the key elements were related to the behavioural attributes of research staff with regards to how staff accorded respect to everyone as persons.

Behavioural attributes of research staff

Evidently, the behavioural attributes of research staff were of professional significance to the research participants. Yet, there have been few dedicated studies on the behavioural attributes of research staff and their influence on decision making. Behavioural and relational elements of the informed consent process appear to have received less attention in healthcare research literature than the emphasis on the preparation of documentation and submissions of applications for ethical approval (NIHR, 2011: revised 2013). Available literature relates to the views of staff rather than the views of research participants (Tinkler et al, 2017). Those that explored the views of research participants focused on issues about the sharing of data (Cheah et al, 2015; RCN, 2011). A competency framework for clinical research nurses published by the Royal College of Nursing focused on quality data and safety issues, with little focus on relational attributes (RCN, 2011: revised 2013). Of interest were competences 3 and 4 of the framework, regarding the 'practice of obtaining informed consent' and 'professional knowledge and skills to facilitate efficient, safe and participant-focused clinical research' (RCN, 2011: revised 2013). The findings of this research therefore hold professional significance, and the lack of literature on behavioural elements suggests a need for further research.

Respect for persons

Participants appeared more likely to engage with health services both generally and in research recruitment when dealing with friendly and approachable staff members. Effective interpersonal attributes appeared instrumental in building professional trust with patients. Being pleasant, considerate and friendly, with some element of fun and good humour, helped patients to feel more confident and less anxious. This yielded more trusting relationships with patients and improved patients' experiences of their care.

The influence of nurturing and thoughtful professional relationships with patients is documented in the context of clinical care but has received little attention in the context of clinical research. In that regard, although in different context, this research reflects existing knowledge by Hovarth, Day and Greene at al (2017), who explored what patients deemed important in their experiences of a walk-in clinic. They found that patients felt comfortable and engaged positively even in busy clinical environments when staff did not rush them and spent time listening to them. Yet, Research Ethics Committees and the research community overall do not give sufficient attention to the interpersonal attributes of research staff at the frontline. RECs emphasise the use of user-friendly written study documents, but there is little emphasis on the behavioural conduct of research staff (Starmer et al, 2015; Hallowell et al, 2008). RECs do not always evaluate the interpersonal relationship skills of research staff nor identify areas for improvement in the same manner that they evaluate written study documents (Gillies et at, 2014). This study provides new insight in the context of clinical research into the value of interpersonal relationship skills and their influence on participants' willingness to sign up for research. The findings shed light on the core values that the public expects to see from registered healthcare professionals, and the influence of such attributes on clinical research. An understanding of the views and opinions of research participants after they have had direct experience of an aspect of care is fundamental to treating people as they wish to be treated (Macdonald, Kidney and Patka, 2013).

Advancing the valuable work of Gobat et al (2018), this research yields insights about the importance of the social attributes of research staff and suggest that how research staff

behave may be linked to intuitive decisions by prospective research participants. The participants' understandings of professionalism include being polite, kind, confident and considerate, with some elements of character and charisma. This provides areas for discussion in the education of trainee research staff. Patients engaged more positively when healthcare staff displayed courteous behaviours. Behavioural conduct and conversational attributes were highlighted. Conversational attributes referred to the way participants were spoken to, listened to or responded to. Derogatory approaches, such as appearing to talk down to someone, made participants think twice before taking up further healthcare services, including clinical research. Some participants commented that an 'offhand' or condescending conversation was deeply hurting, offensive, and discouraging. There is a clear need for research staff to be mindful of how research participants may perceive behaviour that does not reflect the expected standards, and the impact this has on recruitment. This has implications for future research and workforce development relating to professionalism and the standards of conduct that the public expects from registered healthcare professionals.

Additionally, this has implications for REC review protocols, which emphasise the importance of the written participant information sheet in decision making for research participation, but which now appears vague (GMC, 2013). The indication is that the review and monitoring of ethicalness cannot be based solely on written study documents (Pilegaard and Ravn, 2013). With such significance attached to behavioural attributes by research participants, RECs must include the behavioural qualities of research teams as reasonable elements in the review of proposed studies. One way is to examine the professional characteristics of frontline researchers beyond the PI's credentials, and to monitor these at grassroots level. A record of character testimonies by research participants could be applied as part of study closure reports. This would provide future evidence on staff to demonstrate appropriate relational skills and competence to seek consent (GMC,

2013). Such evidence of relational and behavioural skills can be reviewed and validated by a REC before staff are involved in studies.

Confidence in clinical staff

Some participants indicated that their decision to take part in clinical research was based on their confidence in the clinical staff who had looked after them so well. Therefore, it appeared that patients' overall experiences of clinical care swayed them into accepting further healthcare services such as clinical research. The implication being that a positive experience of clinical care was likely to inspire trust and influence prospective participants into accepting opportunities for research, whereas unpleasant behaviours from clinical staff would discourage patients from further involvement in healthcare services including research. The impact of patients' experiences of clinical care on research recruitment adds to knowledge, bringing some positives as well as some new concerns. This finding suggests that recruitment may be affected in settings where care is perceived to be of a poor standard, even if this has nothing to do with the research team. For example, some participants discussed that they were put off from signing for research due to the manner that the clerical and administrative staff attended to them on arrival to the setting. There appeared an obvious relationship between a patients' satisfaction with their experiences of clinical care delivery and their willingness to engage in clinical research. It could not be ascertained whether participants understood the unique principles of clinical research and how it is distinctive from clinical care. A welcoming and respectful atmosphere within the clinical setting encouraged potential participants to sign up for clinical research, whereas a distasteful and hostile environment deterred them. Some participants expressed disappointment when research staff were perceived to engage in irrelevant or unnecessary tête-à-têtes with colleagues while consulting with patients. Another talked about a situation whereby a receptionist was said to be having hot drink while patients and relatives needed help. Another spoke about being less than impressed when a member of healthcare staff engaged in low-brow conversations with colleagues about daytime TV programmes while in

the company of service users. Such behaviours were off-putting to some participants, discouraging further involvement in healthcare services such as clinical research.

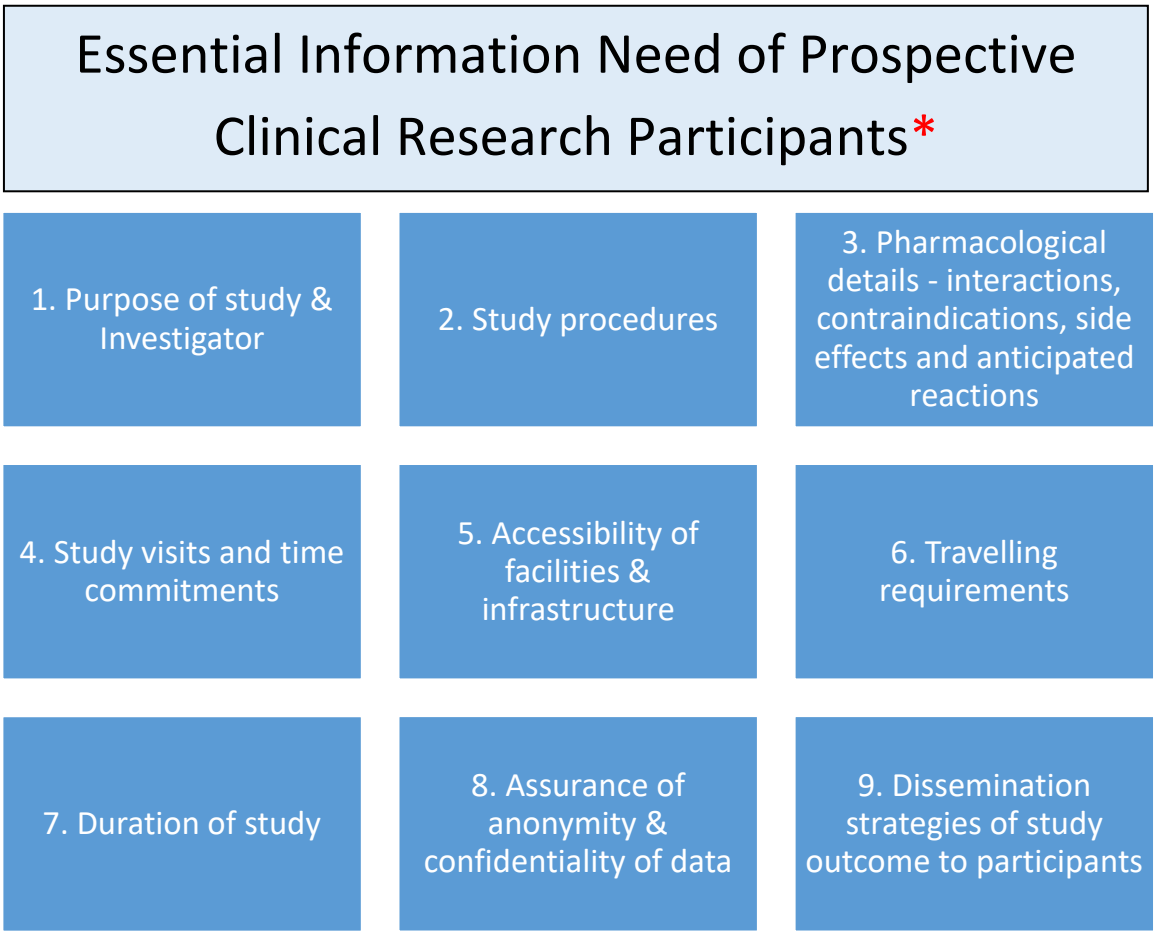
The insight on the relationship between patients' experiences of their clinical care and their willingness to sign up for clinical research was insightful and has implications for practice. First, there is implication for recruitment, given the evidence that clinical staff are often perceived by research staff as appearing territorial in the manner that they enable or limit access to potential clinical research participants (Gibbs and Lowton, 2012). Gordon (2008) reported that clinical nursing staff often do not appreciate the value of clinical research nursing and that nursing peers perceive research nurses as having a role defined by paperwork. Conversely, clinical research staff are alleged to interfere with access to patients and are often perceived to be intrusive and interruptive to the flow of clinical care (Gibbs and Lowton, 2012). Such conflicts lead to a lack of motivation and role conflict among research staff (Gordon, 2008; Roberts et al, 2006). In contrast, this research suggests that prospective clinical research participants value the cohesion and interdependency between clinical and research staff. Better understanding and improved interdisciplinary working relationships are therefore advocated as a positive strategy for attracting and recruiting prospective clinical research participants, as well as improving overall experiences of care. The Kings Fund (2020) in a recent report on workforce, skills and system leadership, adds that an improved interdisciplinary working relationship between staff is crucial to ensure effectiveness, wellbeing and motivation at work, and to minimise workplace stress for all involved.

Theme Three - Study Information

Given the overlap that was thought to exist between the themes, this discussion focuses on the correlation between information need and information use, and the challenges in achieving meaningful informed consent. The dilemma relates to participants' views about the size and content of the written information document; their use of the information

provided; attitudes towards reading of the written document; views on the readability of the written document; completeness and relevance of the content of information; explanation and understanding of the information; and their involvement of significant others in decision making (sharing of information with significant others).

Reasonable expectations of research participants in relation to information disclosure



**as identified during this research*

Figure 5 Diagrammatical representation of the essential information need of prospective clinical research participants

In exploring participants' needs for concise, relevant, and tailored information, this research aimed to determine the aspects of information that participants viewed as important and relevant to real-life needs, and that they expect to be included in the written information

document. Valid informed consent process requires the professional to first assess patients' information needs (Wood et al, 2014; Medical Protection Society, 2012, DH, 2009, GMC, 2008). Participants were particularly concerned about information regarding the accessibility of facilities and infrastructure; information on the purpose of the study and how the research outcome would be fed back to those that took part in the research; and information on the demands of taking part in the research. They were also concerned about the sharing of participants' data with third parties and expressed a preference for anonymity. Some aspects of the findings reflect existing knowledge, while other aspects, such as the information regarding accessibility of facilities and infrastructure, provide additional insight.

The views of real-life service users on matters significant to them underpins the philosophical assumption of this research, that no other agency is better suited to determine for oneself than the agencies themselves in order that their unique circumstances are reflected and respected (Lincoln and Guba, 1985). Staley et al. (2016) acknowledge that patients' perspectives are crucial in the development of meaningful evidence, given that service users' views are informed by their knowledge and experience, and may highlight concerns that healthcare professionals might otherwise miss.

In 2012, Kirkby and colleagues conducted a systematic review to establish some empirical evidence about what potential research participants want to know about research (Kirkby et al, 2012). Reviewing 14 studies, they reported that participants wanted to know about: purpose of study, result dissemination, investigator conflicts of interest, voluntariness, how long the research would last, potential benefits and confidentiality. As with this research, their study identified limited evidence to support the extensive list of information that is included in a participant information sheet (HRA, 2017; NRESS, 2011; Gammelgaard et al, 2004). They specified that more evidence was required about the views of service users. More recently, Gilles Duthie and Cotton et al (2018) conducted a review into patient-reported measures on informed consent in healthcare research. Their study emphasised

that a gap in knowledge persists, noting that meaningful consideration of potential research participants' views on issues of relevance about information disclosure is lacking. Grady et al (2017) also highlighted this as an area for future research. The present research's identification of the elements that clinical research participants wish to know about therefore both supports and adds to existing knowledge.

Pharmacological therapies

Regarding information need, participants wished to be provided with detailed information about study procedures and whether they will be taking pharmacological therapies. Some participants expressed the desire to be notified of possible contraindications of study drugs. There were concerns that pharmacological therapies could interact with regular medications or have side effects. Several participants talked about instances where pharmacological therapies had interfered with aspects of their lives. Others commented on the challenges with keeping to the regime of certain pharmacological interventions, including frequent study visits. One participant discussed having difficulty swallowing a large tablet, while another discussed her reaction due to interactions with regular medication and explained that she had not been made aware of the risks. It could not be ascertained whether these instances were foreseeable or were due to improper disclosure. Nonetheless, Happo, Keranen and Halkoaho et al (2020), in their assessment of medical study procedures in documents submitted to a European research ethics committee, reported that risks had been assessed in only 20% of 1,510 study procedures identified. The findings of this research appear to reflect existing literature, suggesting that medical risks, such as drug reactions are not always considered in detail during information disclosure (Happo, Keranen and Halkoaho et al, 2020). This reinforces concerns around the way potential clinical research participants readily make up their mind to sign up for research, without adequate consideration of detailed study information and what taking part may mean for them. Omission of such key aspects of information disclosure could potentially implicate research participants in harmful consequences.

Concerns about anonymity

Assurance of anonymity was expressed as being crucial for those volunteering for clinical research. Confidentiality was emphasised as being essential, with some participants highlighting the effect of health records on employment and other lifestyle issues. The concern about confidentiality for research participants concurs with findings by Dheesa, Fenwick and Lucassen (2017), who reported that sharing participant information is problematic because it could disrupt family dynamics and other structures, and thereby erode patient trust. However, as with many studies on ethical issues in medicine, their study investigated healthcare professionals' views on confidentiality at a familial level in genomic medicine. The findings of this research therefore advance knowledge in highlighting the views of patient-participants with regard to the emphasis on anonymity during the process of informed consent for research and the potential impact on recruitment and retention of clinical research participants (Jurate, Zivile and Eugenijus, 2014).

Considerations about purpose of study

Most of the participants wished to know what taking part in the study would mean for them, especially the purpose of study and study procedures. Some participants commented that they would not normally be interested in research, except for those that benefit either themselves or loved ones. Aligned to the emphasis on purpose of study was therefore to understand if a study is relevant or beneficial to their personal or family circumstances and needs, a view echoed by Kelley et al (2015). A distinctive component of such altruistic motivation being that the willingness to take part in clinical research was nevertheless borne out of self-interest to benefit loved ones or family members, rather than for the good of wider humanity. Such altruistic behaviour therefore differs from those that takes part in research to benefit science with no personal interest whatsoever (Bardach, Parson and Gibson et al, 2020). This insight was significant as it has implications for the information

need of potential clinical research participants, but also in the recruitment and retention of family members and relatives in future research projects.

The normal tendency is for research invitations to be targeted at individuals affected by a disease (Richesson, Lee and Cuthbertson et al, 2009). However, the accounts in this research suggest that people might also be willing to consider certain research proposals if they might benefit other members of their families and in some cases, future generations. This too is taken as altruism and highlights a more complex relationship than the self-interest highlighted by Bardach, Parson and Gibson *et al* (2020), indicating more complex reasons why individuals may volunteer for clinical research. There are implications regarding information on eligibility criteria in the study invitation or other recruitment outlets, to include eligible relatives and family members if indicated. Such a prompt may serve to signpost more potential participants to ongoing studies, thereby improving recruitment processes and retention.

Considerations about time commitment for research

Participants also wished to know about the time commitment required of them before they signed up for research. Some explained that they might be happy to take part in a study if it does not require frequent visits but would be hesitant to take part in studies that involved frequent study visits.

The informed consent procedure is an ongoing process (Probyn et al, 2017; Santillan-Doherty et al, 2003). However, there does not appear to be clear guidance on the extent to which information should be disclosed to potential participants before they can be considered fully informed for consent to be obtained (Gupta, 2013).

Concerns with length and the reading of written study information

This research found a correlation between what participants want to know about and their engagement with the information provided. Each of the issues identified had implications for

ethical research practice. More importantly, the research raised ethical concerns about the doctrine of informed consent as is currently practised, whereby potential clinical research participants are provided with lengthy pre-determined details of information that may not reflect what they wish to know about (Antoniou, Draper and Reed et al, 2011). Some participants expressed that the consent document often consists of irrelevant details. In some cases, this served to disengage participants from the process. It is not surprising therefore that clinical research participants remain uniformed about the studies in which they participate (Jenkins, Calvert and Draper, 2020). Previous studies agree that providing additional written information does not appear to enhance understanding of the risks and complications of medical procedures (O'Hare, 2018), nor alter anxiety levels of patients (Stanley et al, 1998). Instead, the lengthier the document, the more unlikely it is that it will be read (O'Hare, 2018; Tolich and Hapuku, 2009). It is advocated that more care and time for face-to-face discussion is needed to enhance engagement (Dickert et al, 2017).

Kirkby, Calvert and McManus et al (2013) reported that written study information may not be read by potential participants. Consequently, they emphasised the need for a review of the informed consent process and suggested a consideration of new ways of engaging participants. Specifically, their study reported that only about 9% of potential research participants accessed the detailed information presented on the Research Ethics Committee approved participant information sheet. And yet, in 2020, another study into potential research participants' use of information during the consent process of a clinical study found that participants only minimally used written information sheets after they had already signed up for research (Jenkins, Calvert and Draper, 2020). Reflecting this study's findings, their research reported that a high level of trust in medical professionals was given as a reason for not seeking to read written information (Jenkins, Calvert and Draper, 2020). This research adds to that knowledge by highlighting other reasons for non-engagement with written study information. Some participants expressed that they were put off from reading detailed information, as it appeared that 'it just had to be put there'. Some

participants commented that ‘too many words on the sheet, it hides the bits you want to get to’ and ‘some of it wasn’t relevant’. Others said that they did not read the written information, with the length and content of information being compared with the size of a book. Few participants found study information to be relevant to their needs and most that took part in this research believed that most parts of the written study information were irrelevant and appeared to serve medico-legal purposes. Participants found extensive written information to be important as a point of reference, but emphasised that some content was irrelevant and off-putting. It was highlighted that some patients often had to decline clinical research due to a lack of necessary information.

Written information therefore did not necessarily always meet participants’ information needs or influence their decisions. This is consistent with the research by Gammelgaard, Mortensen and Rossel et al (2004), which found that only 28% of those that signed up for research and 7% of non-participants read the information sheet before they made their decisions. Their study emphasised that physicians and research ethics committees should give more attention to researcher-patient interactions during the informed consent process for a more meaningful outcome, instead of a relentless focus on written documents.

Explanation and understanding of study information

The findings of this research point to the view that almost all participants preferred a face-to-face conversation with the research team, instead of being asked or required to read study information on their own accord. Participants preferred to be able to ask questions, and have these addressed in a personalised manner, to inform decision making. Patients are individuals, with unique health and social needs, and a generic form should serve as a starting point but not an end in itself. In terms of participants’ information needs, no single document could possibly cover everything, as patients’ circumstances are unique. There is an argument that the more information it contains, the larger a study document will become, which may further hinder engagement (Tolich and Hapuku, 2009; Jefford and Moore, 2008).

This underscores the need to engage in meaningful discussion with prospective research participants when seeking informed consent, instead of a pre-determined signing exercise (Heinrichs, 2019; Jefford and Moore, 2008). Given that individuals are better suited to determine for themselves the information important to them, meaningful one-to-one interactions with potential clinical research participants is advocated (Dickert et al, 2020). It is understood that this approach requires adequate time and resources, but it encourages and empowers each individual patient to express their concerns and have them addressed. Resources of time and space, as well as of charisma, skills and knowledge are essential for a person-centred approach in the process of informed consent (Oye, Sorensen and Glasdam, 2016). This evidence adds to existing literature as identified by Clement, Selman, Kehoe and Patrick et al (2019), who state that providing patients with clear and concise study information may be a step in the right direction towards a more meaningful informed consent process. It is recognised however that achieving a meaningful informed consent in acute care settings is challenging due to time constraints and the emotional stress associated with being ill (Dickert et al, 2020). Clearly, a meaningful informed consent in the real world of clinical research requires special measures from all stakeholders (Dickert et al, 2020; Blitzer and Sade, 2020; Heinrichs, 2019).

Concerns with the language of research

There was displeasure when research staff spoke to patients in languages that patients could not understand or easily assimilate. For example, one participant frowned upon a researchers' use of percentages in explaining the risks of harm; a choice of language which was said to mean nothing to service users. Participants' accounts brought to light the complexity of representing data in percentages during information disclosure. It was noted that such language made participants resort to a nonchalant attitude of *'if it happens it happens, and if it doesn't it doesn't'*. Some participants explained that complex language or 'talking over patient's head' only served to further prevent service users from engaging with study information. The findings of this research concur with the reports of a focus group

study conducted in Sweden by Dellson, Nilbert and Carson (2016), who reported that participants felt frightened and reluctant to sign consent forms when research staff used words such as ‘risks’, as such terms were associated with being careless. It seems that the choice and use of language serves to limit understanding of study information. Plain speaking, using everyday language such as ‘side effects’ instead of ‘risk’, and talking about ‘chances’ instead of ‘percentages’ is advocated to minimise the use of technical language during the process of informed consent.

Therapeutic misconception and being honest with participants

Also of importance to the participants was a researcher’s ability to discuss study information with candour. Most participants desired to be told the truth about what taking part in the study may mean for them. Honesty was deemed essential for fostering trust and crucial in managing expectations. During discussions, it was identified that patients had often been let down due to what they perceived as dishonesty in previous communications with clinical research staff. A patient shared an experience in which they were led to believe that a given research procedure was being carried out for both clinical and research purposes, whereas in fact, the procedure, an MRI of the stomach, was completed solely for research purposes. This apparently occurred despite the patient’s wish not to undertake an MRI if it was only meant for research purposes. Being honest with potential participants about what to expect was considered vital in preparing patients and helping them to make an informed decision and manage expectations. These findings reinforce the boundaries of professionalism and the magnitude of research staff’s responsibility to uphold candour in dealings with research participants regardless (Charkin and Breitbart, 1996). While it has been argued that the concept of a fully informed consent may never be possible (Boyd, 2015; O’Neil, 2003), it remains a fundamental ethical duty for research staff to provide prospective participants with a genuine and meaningful opportunity to refuse or accept research participation

(Dickert et al, 2012). This includes delivering study information with candour and commitment to human dignity (Turnham et al, 2020), even where such honesty may lead to a refusal by the participant. Dickert et al (2012) commented that an informed refusal should be celebrated as a rewarding outcome in the informed consent process for research, and so misconceptions need to be clarified on the spot and not left unexplained where evident. One of the fundamentals of informed consent is that patients are not to be deceived or coerced, ether implicitly or explicitly (Turnham et al, 2020; O'Neil, 2003). This emphasis reinforces the importance of competence and knowledge beyond a ritualistic approach, avoiding a 'tick-box' exercise in the process of informed consent for research participation (Boyd, 2015). There are implications for education and training of current and emerging research staff, who may not have had the extensive professional training and years of experience that are associated with the specialist roles in clinical research (Faulkner-Gurstein, 2019: Gordon, 2008). A recent survey by Nusbaum, Douglas and Estrella-Nula et al (2017) found that about one-third of research nurses did not feel prepared to communicate study information, while half did not feel competent to assess participants' comprehension and understanding of study information. This is obviously a worrying trend in the process factors that may influence informed consent for research participation.

Perceptions of competence and knowledge of staff

Competence was referred to as the ability of research staff to respond to participants' concerns and support potential research participants with the explanations they seek. Being knowledgeable of the study information and of what taking part in the study may mean for participants reflects confidence in the staff conducting the consent process and encourages participants to sign up for research. Participants indicated that it was discouraging when staff appeared to 'bounce patients about' without addressing their concerns competently, whereas they were encouraged when the research staff displayed a level of competence in responding to participants' concerns. Some participants stated that any attempt to cover up inadequacies by using *'airy fairy explanations'* was damaging and discouraging to further

involvement. These findings reinforce significance of participants' perceptions of staff competence regarding research staffs' communication strategies (Nusbaun et al, 2017).

Attitudes towards hierarchy and designation of research staff

In exploring what works well and how best to ensure that potential clinical research participants are supported to engage meaningfully in the process of informed consent for participation in clinical research, this research found that most participants were impacted by the hierarchy of staff conducting the informed consent procedure. Participants' accounts indicated that although a highly placed clinician appeared to command the respect that comes with knowledge and power, as discussed previously (Symonds et al, 2012), most felt more at ease talking to allied health professionals, such as nurses, than with clinicians. In general, participants reinforced that they were willing and comfortable to engage with various levels of staff, provided that they were able to confidently and competently perform their duties.

There was an apparent need for self-confidence and respect when participants sought reassurance from nurses, compared with when they sought it from doctors. Almost all participants cited that they would be more likely to ask questions of nurses than doctors. Some doctors were perceived to make patients look or feel subordinate, which clearly impacted on patients' willingness to ask questions or seek clarifications during the process of informed consent. Nurses on the other hand were perceived to be more approachable, and that encouraged potential clinical research participants to talk freely and engage more during the consent procedure. Almost all participants believed that nurses were more skilfully suited to interact and explain study information at a level that they found approachable. Doctors were considered 'a bit higher up than what the nurses are'. Participants also appeared hesitant to take up doctors' time, owing to an assumption that doctors' time was too valuable to be wasted in addressing further concerns from individual

patients. Hence, participants largely felt more comfortable conversing with nurses and some other allied healthcare professionals. Most of the participants described their engagements with nurses and other allied healthcare professionals as friendly and respectful of patients. Some also claimed that nurses were more responsive to their holistic needs and concerns than doctors were. Nurses were said to have enough time for patients when discussing information with potential participants. Nurses were also said to act on added concerns that patients had, even when the concern did not relate particularly to the research. Such accommodating and tolerant attitudes appeared to contribute to the positive ambiance that patients described of most of the nurses that they dealt with.

Participants reported that some doctors, though efficient and knowledgeable, were not as accommodating. Some participants alleged that doctors did not always listen as much as nurses did, and that some doctors appear to show that *'they are better than'* the patients. This meant that some participants were reluctant to ask questions, for fear that they might come across as being stupid. Consequently, some potential clinical research participants could have been inadvertently discouraged by some medical staff from engaging in the informed consent process.

Unlike some existing literature (Symonds et al, 2012), the involvement of a highly placed clinician did not always enhance engagement in the informed consent process. Instead, a more neutral category of staff, such as research nurses, enabled deeper engagement. This finding is insightful and gives insight into the extended roles of nurses and some other allied healthcare professionals. There are implications for professional identity, service delivery, workforce training and professional pride or identity.

This finding makes a unique contribution to existing professional knowledge in terms of service users' perspectives of the role of the clinical research nurse, not only with regard to the process of informed consent, but also in other stages of the research process. Existing knowledge has it that clinical research nurses are invisible and undervalued, and that their

contributions to health service research go unrecognised (Tinkler et al, 2017; Kunhunny and Salmon, 2017). As a result, many clinical research nurses feel invisible within the larger clinical research team, which often consists of various other disciplines depending on the nature of the study (Faulkner-Gurstein, Jones and McKevitt, 2019; Tinkler, 2018; Kunhunny, 2017). Most existing research also appears to stem from studies that explored the views of nurses themselves (Hakansson and Stenmarker, 2019; Tinkler et al, 2017), and report extreme job dissatisfaction by clinical research nurses, who felt undervalued (Tinkler et al, 2017). However, the clinical research participants that took part in this study spoke very highly of the contributions that nurses make in healthcare research.

This research found that nurses are highly valued by service users for the manner in which they communicate and promote compassionate and holistic care within healthcare research. The participants' accounts also indicate that clinical research nurses were better suited to facilitate dialogue with potential participants during the process of informed consent, given that service users found nurses to be more approachable, friendly and better listeners than medical staff. This suggests that clinical research nurses possess the skills to promote more active engagement by service users during the process of informed consent. These sentiments, by those who the informed consent process is meant to protect, are an encouraging and valuable finding that makes an important contribution to knowledge in terms of the perceptions and relevance of the role of the clinical research nurse in today's heath service. The challenges that research nurses face in balancing values and obligations are well documented (Hakansson and Stenmarker, 2019). This unique finding may contribute to job satisfaction and a sense of self-worth among clinical research nurses.

Given the renewed shift from traditional role boundaries, towards a culture of role integration (Beech, Bottery and Charlesworth et al, 2019; NHS Improvement, 2018; NMC, 2018b), nurses and allied healthcare professionals are to be empowered, by ensuring a team-based approach that makes the best of everyone's skills and knowledge (DH, 2019). However, concerns exist that nurses are not always provided with appropriate training and

education opportunities that match their expected roles (Kunhunny and Salmon, 2017). In this regard, time and continuous workforce development by way of a structured career development framework is advocated (Bailie and Taylor, 2015). Participants expect expert levels of skills, knowledge and competence. This requires professionals who are not only knowledgeable about the content of a written study document, but are also able to respond autonomously to patients' concerns and queries. Participants' individual concerns may fall outside of the remit of a written document, but the professional should be able to inspire confidence in the manner in which they address unanticipated concerns. A failure in this was said to undermine participants' confidence or willingness to engage further in the study.

The role of informed consent used to be designated to expert practitioners and, in the not too distant past, was predominantly undertaken by chief or principal investigators (Nijhawan et al, 2013; NRES, 2011). The typical research team used to consist of a sponsor, the sponsor's legal representative, a chief investigator, principal investigator and a data controller (NRES, 2011). However, the ever-changing landscape of roles and responsibilities has seen other staff take up these roles (NIHR, 2019; Faulkner-Gurstein, 2019; RCN; 2017). There may be conversations to be had on how best to ensure that all those taking on the role of gathering informed consent are suitably trained and qualified to deliver such a complex role in a manner that meets users' expectations. Training programmes may need to be reviewed to ensure that services reflect the needs of those for whom they are meant to serve, especially given the recent emergence of 'Clinical Research Practitioners' (Faulkner-Gurstein, 2019). These measures require a shift in focus, where the informed consent process is to be considered an individualised component in the conduct of ethical research.

Often, clinical research procedures can be highly technical encounters, requiring in-depth knowledge before they can be explained to patients (Gordon, 2008). Taking on extended roles, such as the consent consultation, could therefore have implications for tomorrow's workforce training and the profession at large. The findings of this research point to the

significance of participants' views and expectations and the need to consider discussions on how to ensure that all those taking on the role of informed consent for clinical research are appraised of the needs of service users. Given the changing landscapes in professional boundaries and roles (NHS Improvement, 2018; NMC, 2018b), a person-centred approach to the process of informed consent ought to be grounded at the earliest opportunities within pre-registration curricula, as well as early carrier frameworks. Like various practice development needs, such a mandate requires further research, time and resources. Further, clinicians also need to be conscious of the impact that hierarchical differences place on the clinician-patient relationship, given that such imbalances affect patients' engagement in the process of informed consent. These recommendations will be elaborated upon in Chapter 7, Recommendations and Conclusions.

Environmental considerations

Without enough time and appropriate space, some participants were discouraged from expressing their own needs or concerns. For example, some participants in this research said that they could not engage in conversations during the informed consent process, nor even hear what the staff were saying, due to the consent procedure being conducted in a noisy environment. One participant had a hearing impairment, and did not lip read, so a noisy environment incapacitated them from fully expressing their information, yet he proceeded to sign the consent form. Without a conducive environment or adequate opportunity for conversations with individuals, some participants may be discouraged from participation (Clement, Selman and Kehoe et al, 2019). This finding is consistent with a recent report highlighting the need for the informed consent process to be sensitive to the needs of research participants *and* to the context in which clinical research takes place in the real world (Dickert, Benard and Brabson et al, 2020). The lived reality at the front line needs to be considered at all stages of policy development.

Some studies are known to require potential participants to telephone research teams for further details if needed, however, this approach does not serve the interest of most service users. This research found that some patients were reluctant to telephone for information, preferring a face-to-face meeting instead. This indicates that information is best captured and deliberated at the earliest opportunities, during the initial stages of the informed consent process. Otherwise, potential participants may be disempowered from taking part in the informed consent process, owing to a lack of access to the relevant information.

Theme Four: Personhood

The notion of personhood considers a participant's self-concept, and how this might interfere with the individual's choice and decision to sign up for a research study. From the participants' accounts, this notion was significant factor that appeared to influence the way people made decisions. This study's findings suggested that the traditional rules of thumb did not fully reflect the guiding behaviours that informed how real patients made decisions to sign up for clinical research. It revealed that the process of informed consent is not immune to the standard models of human behaviour, which include rational and presumed irrational biases. The theme reinforced the need for a personalised approach in the conduct of informed consent for clinical research. Issues that emerged included the participants' aspirations for consenting to research; the influence of moral principles; perceived value of life; demographic structures; and some specific barriers. Of the outlined categories, the element of interpersonal principles was thought to be insightful and more encompassing, with some obvious implications for ethical reviews and in the considerations of person-centred approaches in the conduct of informed consent process. Additionally, age and aging appeared to interfere significantly in some presumed biases that played out in the responses and decisions made by the participants in signing up for research.

Motivations for research participation

Altruism

In this research, it was evident that the participants were challenged to take part in clinical research studies due to the burden of illness and a desperate need to find treatment and the hope for cure. Others took part in clinical research for the good of humanity and to benefit the course of science in general (Avent et al, 2013). Most participants appeared to nurture a changed outlook on life as they got older, which influenced their engagement in clinical research. The change in outlook considerably influenced what the participants were willing to take on and the level of risk they were willing to consider. Older participants were more likely to embrace participation in clinical research. For example, one participant pointed out that he would not have considered involvement in a clinical research study before he turned 40, but he had become more amenable to consider helping out in clinical research after the age of 50-55. Another participant explained that he would be more willing to help others to live longer, if opportunity presents, than he would have done without the heightened awareness of his own mortality. Some participants were nudged by a belief that death was inevitable for the older person, and that the older person had less to fear, having lived their lives, than younger individuals. As a result, older individuals appeared more ready to sign up for clinical research, without the need for due consideration of the study information presented to them.

Opportunity for social interaction

Likewise, findings suggest that some potential clinical research participants' decisions to sign up for clinical research was impacted by loneliness and a desire for social interaction with others. Some older adults experiencing isolation longed for company and social interactions from study visits, while others embraced clinical research as 'something to focus on'. Others likened it to a hobby. Some explained that life after retirement was idling, so clinical research involvement was perceived as something they could look forward to. Social relationships (or lack thereof) among the aging population therefore impacted on some participants' decisions to consent for clinical research. There are obvious implications

for this insight in the considerations for ethics reviews and the recruitment of such vulnerable groups. The finding illuminates a concerning trend whereby older adults may be more likely to over-volunteer for clinical research studies.

Limitations to participation

Travelling and commuting

This study further highlighted that age and aging was implicated in some of the perceived difficulties that inhibited participants' willingness to sign up for clinical research. Participants indicated that travelling and commuting presented a significant hindrance, especially for some older adults. Some older participants expressed that they would be more willing to take part in research studies that offer home visitations, than those requiring them to travel to hospital locations. Some participants explained that public transport was often inconvenient and expensive, especially given that the older adults were normally more inclined to travel during off-peak times, when concessionary travel passes permit. In some cases, participants relied on family members for commuting to and from hospital settings.

A few participants resided far away from the town centres, necessitating more complex travel arrangements. Yet, most clinical trials take place in regional centres, often during work hours, so the associated travel and parking costs to those that are already dealing with the burden of illness and healthcare can be prohibitive. It was no surprise therefore that such circumstances were considered off-putting by those that would otherwise be willing to volunteer their time for the furtherance of science. It is acknowledged however that for some others, the privilege of a voluntary choice may not exist, due to the need for treatment or lack of alternative treatment options.

Impact on family life

Personal circumstances played significantly on the minds of those considering participation in clinical research, more so than some of the issues traditionally addressed within participant information documents (HRA, 2017; GMC, 2013). For example, participants were less concerned about compensation schemes, the number of people involved in a

study, or the format or wording of the study information document. Instead, they expressed genuine concern about the impact of participation on significant others. Interference beyond family support structures was considered a determinant to signing up for research.

Individuals without a reliable support network clearly faced tougher challenges, highlighting the need for greater inspection into recruitment approaches. It would be problematic if a vulnerable population supported the interest of science at the expense of their own well-being. This is an implication for ethics reviews in the consideration of what should be an acceptable burden for those volunteering to take part in clinical research. These findings further underscore the importance of an individualised approach to the informed consent process for participation in clinical research (Tutton, Seers and Langstaff, 2008; Agre et al, 2003; Dewing; 2002).

Reflections on the role of the clinical research nurse in the process of informed consent for research

This section reflects on the reasoning patterns and processes used by patients as they assess, interpret, and engage with study information, as well as the views of the participants in relation to the role of the nurse. The findings mainly support existing knowledge that the public recognises the nursing profession as one of the most trustworthy (IPSOS-mori, 2019). In comparison to the accounts of Symonds et al. (2012), participants in this research were more likely to engage in the process of informed consent when dealing with clinical research nurses than with medics. This focused discussion reflects also on the professional standards of practice and behaviour for nurses, midwives, and nursing associates (The Code: NMC, 2018). The Code emphasises that all registrants must prioritise people, practise effectively, preserve safety and promote professionalism – the '4Ps' (The Code: NMC, 2018). These fundamental themes signify what good nursing and midwifery practice must entail (NMC, 2020). Additionally, an outright analysis of the congruence between the Code and the informed consent process for research is lacking in existing literature. This analysis, which reflects the perspectives of the participants of this

research, will therefore add to existing knowledge and help to clarify any ambiguities. It sheds light on the perspectives of research participants in relation to the informed consent process and the 4Ps of the Code (NMC, 2018).

Prioritising people (NMC, 2018)

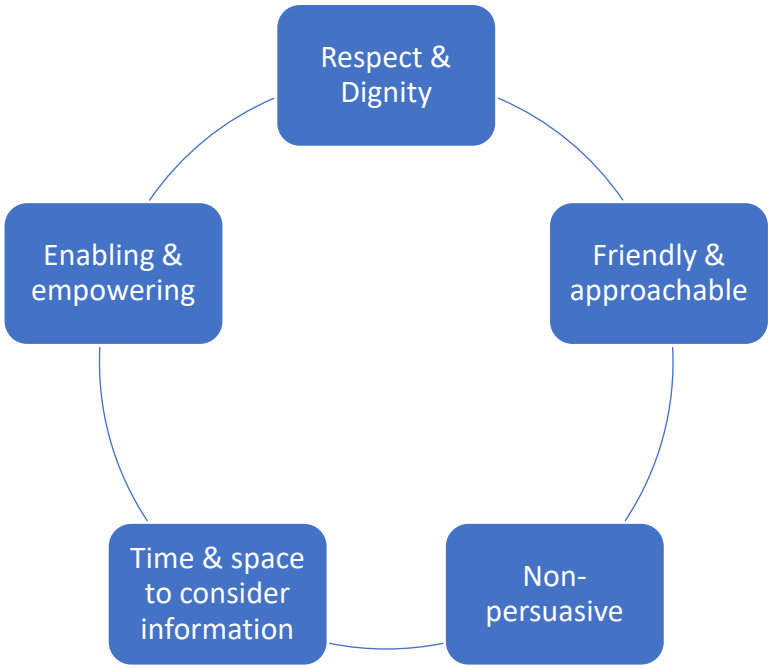


Figure 6 Fundamentals of care when seeking consent for research as suggested by research participants

The first theme of the Code is 'Prioritising people', which stresses that nurses and midwives must 'make the care and safety of people using or needing nursing or midwifery services their main concern and make sure that their dignity is preserved' (The Code: NMC, 2018). In this regard, and based on the findings of this research, respect for the dignity of prospective clinical research participants was fundamental during the informed consent process. An 'offhand' or condescending attitude from research staff was deeply hurtful, offensive and frowned upon by the participants. Interestingly, nurses were deemed by participants in this study to be the most suitable to facilitate effective communication during the informed consent process for research. The participants broadly perceived nurses to be nurturing and supportive. They described feeling happy to take part in clinical research

studies because of the way they were treated by staff. Respect for patients' dignity in a manner that is sensitive and considerate encouraged potential participants to engage and sign up for research. Professional behaviours such as punctuality and reliability were also commended and embraced.

In comparison to other professions, the participants considered nurses to be friendly, approachable, available and quicker in responding to their needs and concerns than medically trained clinicians. Most participants believed that nurses are skilled at and suited to interacting, approachable, and explain information to patients clearly, whereas medical clinicians were deemed to be less approachable and less friendly. Based on the findings of this research, effective interpersonal attributes such as being pleasant, considerate and friendly, with elements of fun and good humour, helped patients to feel more confident and less anxious. This yielded more trusting relationships and improved patients' experiences of their care. Crucially, a positive experience of clinical care was associated with increased willingness to take up further healthcare services such as clinical research. For most participants, the decision to sign up for research was influenced by previous experiences of care, especially clinical care. Confidence in clinical staff was associated with increased confidence to sign up for research. Similarly, previous negative experiences of care deterred potential research participants from engaging in further healthcare services such as clinical research. This emphasises the interconnection and significance of a collaborative relationship between clinical nurses and research nurses. It is important therefore that clinical staff are seen to be positive and supportive of ongoing research studies, as their attitude may influence recruitment of participants.

Relating to strategies for study invitations, some participants described some research staff approaches as overbearing and persuasive, and even 'a bit of a pest' in terms of the way they were compelled to help with clinical research. An overly persuasive attitude to recruitment was concerning and frowned upon. Given the power imbalance between the

potential participant and the researcher, coercion is an unwelcome attribute. This research suggests that research participants would engage in the informed consent procedure when strategies for study invitation are less persuasive.

Participants were more likely to be reassured when allowed the time and space to consider the study invitation and information before deciding on whether to get involved in the study or not. In typical circumstances, potential research participants are given time to consider study information before they decide on whether they wish to take part in clinical research studies or not. The notion corresponds with the idea that patients must not be put under any form of duress, explicitly or implicitly, but should be supported to decide freely for themselves (WMA, 2013). However, the notion of how much time is sufficient appears unclear in the current literature. This is a matter for REC, research staff and individual participants, and needs to conform to individual patients' needs. It is noteworthy that not all patients may require extensive time, as a significant number expressed readiness and willingness to reach decisions quickly. In any case, it is important that the participants are reminded that they could still 'drop out' or 'say no' at any point without consequences whatsoever for themselves.

Nurses were considered more enabling and empowering to research participants during the process of informed consent. Although doctors were understood (in the words of one participant) to be *'a bit higher up than what the nurses are'*, patients explained that they dreaded talking to medically trained clinicians and *'feel more comfortable talking to nurses than doctors'*. It was said that doctors do not listen as much as nurses do and are more likely to show that 'they are better than' the patients, leaving patients feeling less empowered and worse off. Hence, patients were less likely to engage in the informed consent consultation dialogue or ask questions for fear of looking stupid.

Practising effectively (NMC, 2018)

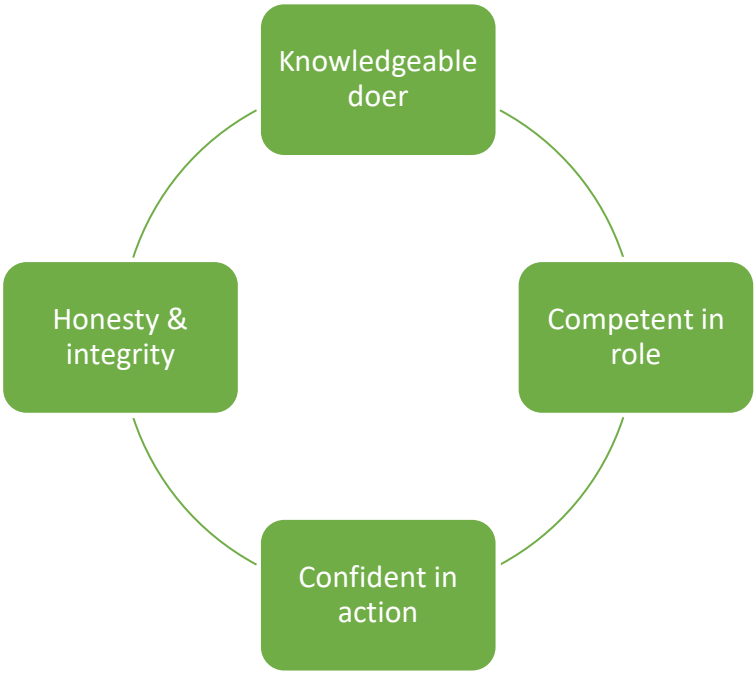


Figure 7 Expected attributes from research nurses when conducting informed consent for research as suggested by research participants

The next theme of the Code is 'practising effectively'. It emphasises the need to 'communicate effectively, keeping clear and accurate records and sharing skills, knowledge and experience where appropriate' (NMC, 2018 pg. 06). In that regard, the participants of this research remarked that research nurses must be knowledgeable, competent and confident in their role during the informed consent process. Lack of knowledge was said to be discouraging to participants when deciding to sign up for research. The participants conveyed that they were willing and comfortable to engage with various levels of staff, provided that the research staff were able to share knowledge and respond to patients' queries and concerns confidently and competently. The participants acknowledged that staff might not know the answer to every question but expected staff to be knowledgeable and able to acknowledge their own limitations, seeking appropriate help where necessary. The participants stated that any attempt to cover up one's inadequacies by some '*airy fairy explanations*' was damaging and discouraged further involvement.

Being competent related to the researchers' use of language and vigilance to continually explain and appraise a participants' understanding of study information. The participants embraced plain speaking and the avoidance of technical language. They also emphasised that the nurse, as with doctors, must be 'competent' to obtain consent for the intended procedure (GMC, 2010). This research indicates that participants were pleased to be spoken to by clinical research nurses, providing the nurse was perceived to be knowledgeable, competent, and confident in their role. Given the increasing involvement of nurses and other healthcare professionals in the conduct of informed consent processes for both clinical practice and research, this was an important finding. It is suggested therefore that the task of seeking informed consent must only be delegated to experienced research nurses and must not be allocated to new nurses who might not yet have the knowledge, experience, and confidence to function optimally in that role.

Preserve safety (NMC, 2018)

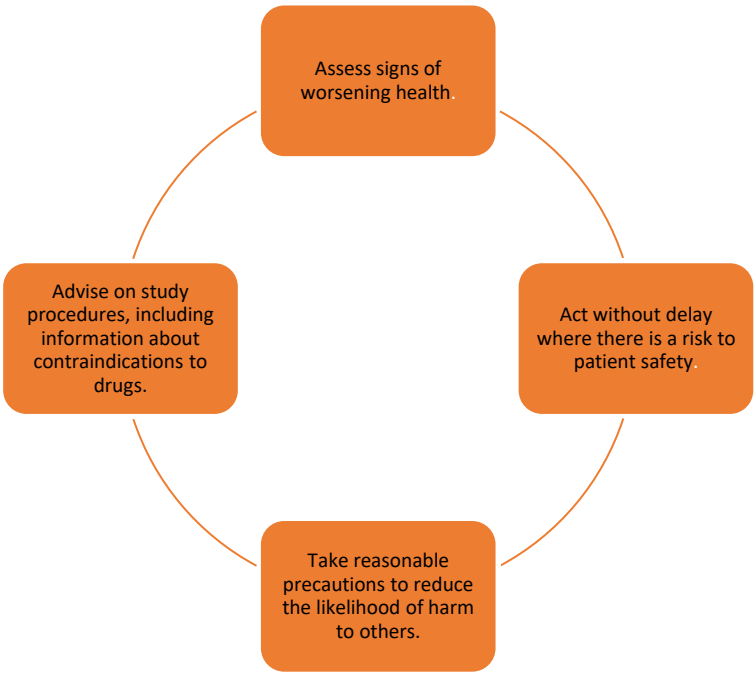


Figure 8 Measures to promote patient safety when seeking informed consent for research as indicated by this research

The third theme of the Code, ‘preserving safety’, requires nurses and midwives to ‘make sure that patient and public safety is not affected… and to take necessary action to deal with any concerns where appropriate’ (NMC, 2018 pg. 13). In that regard, some participants wished to be provided with detailed information about study procedures and whether they will be taking pharmacological therapies. There were concerns that pharmacological therapies could interact with regular medications or have side effects, so some participants wanted to be notified of possible contraindications of study drugs. Several participants talked about instances where pharmacological therapies had interfered with aspects of their lives. One discussed having difficulty swallowing a large tablet, while another discussed her reaction due to interactions with regular medication and explained that she had not been made aware of the risks. Omission of such key aspects of information disclosure could potentially implicate research participants in harmful consequences. The findings of this research appear to reflect existing literature, suggesting that medical risks, such as drug reactions are not always considered in detail during information disclosure (Happo, Keranen and Halkoaho et al, 2020). This research recommends nurses to be sensitive to the concerns of individuals especially when discussing information about study procedures and drugs, and to act without delay where there is a risk to patient safety (NMC, 2018). The nurse must reduce as far as possible any potential for harm (NMC, 2018).

Professionalism and trust (NMC, 2018)

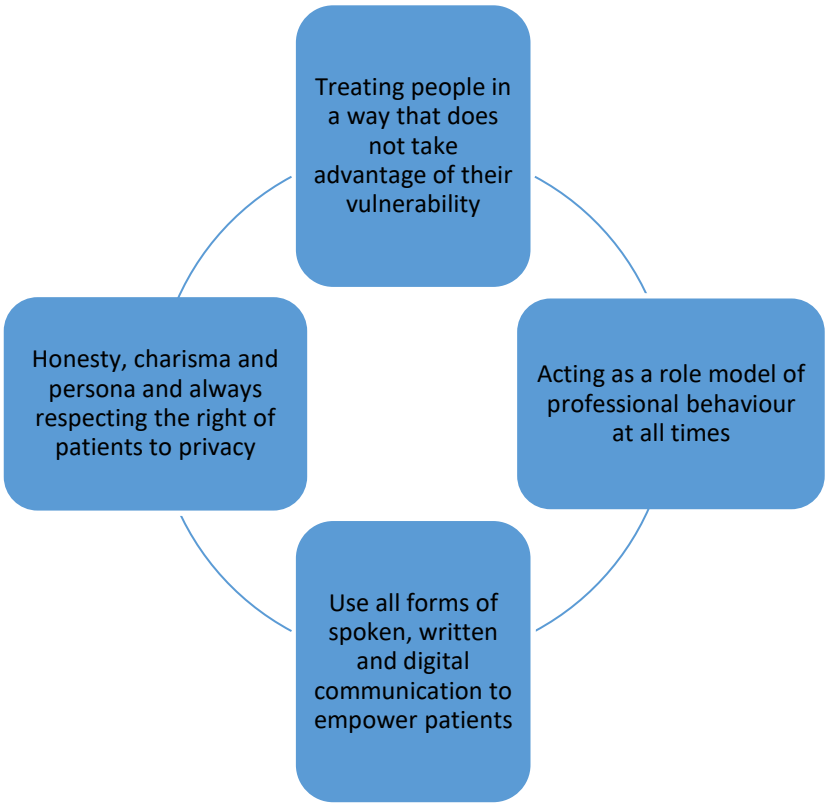


Figure 9 Key factors that enhanced trust and confidence in research nurses when seeking informed consent as indicated by this research

The 4th P, 'Professionalism', requires all registered nurses to uphold the reputation of the profession. In this, the nurse is guided to act with honesty and integrity, and to not seek to take advantage of vulnerable individuals (The Code: NMC, 2018). These attributes go beyond clinical knowledge and extend to an individual's character in dealing with patients, especially during informed consent. Character and charisma appeared to be an invaluable element in the processes that influenced participants' decisions when signing up for research. For an example, unprofessional behaviours such as talking over an individual were discouraging to participants. Nurses were considered approachable when they acknowledged and responded to a patient's concerns. Participants were more willing to engage in the process of informed consent and to listen when attended to by friendly nursing staff, whereas talking to potential clinical research participants in a condescending manner was said to put individuals off from listening further. The participants said that it

was important that patients are treated as people, which implied being listened to and respected. Other attributes related to knowledge and skills and were reflected in the way research staff took time to explain study procedures, the language they used, and their overall display of competence. Ultimately, attitudes and behaviours of nurses contributed significantly to trusting professional relationships, helping service users to feel comfortable and at ease, which supported patients to engage in the process of informed consent for research in a more meaningful way. As echoed by Kelly, Spector and Charkas et al (2015), this research suggests that the interpersonal relationship between research participants and research nurses is vital in the conduct of a person-centred informed consent process and must be guided by the ethos of professionalism (NMC, 2018). This includes treating people in a way that does not take advantage of their vulnerability; always acting as a role model of professional behaviour; using all forms of spoken, written and digital communication to empower patients; being honest, charismatic and personable; and always respecting the patient's right to privacy (NMC, 2018).

Clearly, the findings of this research hold implication for practice in relation to the role of the clinical research nurse. Although this research provides evidence of the significant contributions that research nurses continue to make at all phases and stages of the clinical research process (Burn, 2020), and healthcare in general (NHS England, 2020). It also highlights the dichotomy between the role of a clinical research nurse as a research staff and the standards expected by the public from a registered nurse. Broadly speaking, nurses are increasingly expected to work in autonomous and commanding positions to improve the quality of care to patients (Burn, 2020; NHS England, 2020). McLeary et al (2011) argued that nurses receive very different training to doctors and suggest that nurses may not be as competent as doctors when practicing in autonomous positions. They acknowledge however, that evidence about patients' preferences regarding who they wish to provide care to them was limited. This research adds to that debate and gives insight into the views and preferences of research participants about research nurses' competencies

and the effectiveness of nurses' involvement in the process of informed consent. Further research will be beneficial for a better understanding of patients' endorsement and level of confidence in research nurses in their role as autonomous practitioners. Notwithstanding, for clinical research nurses, it must be acknowledged that there are competing agendas that can impact on the nurse's ability to deliver such high standards of care consistently. From own experience as a former clinical research nurse, the agendas of a) recruitment targets, b) patient care and c) the need to carry out ethical research (and satisfy funders) can be demanding for the nurse. Such tensions between providing optimal care for individuals as a registrant while also being on the payroll of a financially sponsored research project can cause additional tensions, at times. The findings of this research have necessitated a great deal of reflection. For the clinical research nurse, there is need to identify such tensions and manage them positively as being a nurse and a researcher are not mutually exclusive, but constantly requires balance between the responsibility to patient care against maintaining fidelity to ethical research standards & outcome. Remarkably, the findings of this research are valuable and reassuring to the ever-evolving role of the clinical research nurse, and in helping clinical research nurses to cope with the crisis of identity that so often confounds the clinical research nurse role.

Summary

The purpose of this chapter has been to discover and make sense of the views and overall experiences of real-life clinical research participants during the process of informed consent after they had taken part in the informed consent process for clinical research studies. The focus was to gain more insight into the reasons why most real-life clinical research participants remain unable to understand or recall information about studies they had signed up for, considering the findings of this research and previous literature. The

discussion focused on the four themes that emerged from the findings; Study invitations, Researcher attributes, Study information; and Personhood.

Of these four themes, a trusting relationship between clinicians and patients, which borders on medical paternalism, continues to influence prospective clinical research participants' engagement in the informed consent process. Involving trusted clinicians prematurely in the informed consent process appeared to hinder meaningful engagement with detailed study information and may indicate why most clinical research participants are unable to remember detailed study information after consenting for studies.

The participants described their involvement as relying heavily on expert opinions and having little consideration for the detailed study information provided. It appeared that study information was seen by some participants to be irrelevant, lengthy and often with complex terminologies, and serving minimal purpose in the decision-making process. Instead, medical status, personal and demographic factors appeared to determine information needs, necessitating an individualised approach when discussing study information with prospective participants. Interestingly, nurses were identified as friendlier and more approachable in their dealings with prospective clinical research participants during the process of informed consent, making nurses the preferred staff for more meaningful engagement by the individuals that took part in this research.

The findings suggest that members of the public remain unaware and unwilling to ask about clinical research studies when attending clinical appointments. This indicates that more needs to be done about promoting public and patient involvement in clinical research, both as participants and potential collaborators in the development of clinical evidence. The implications of these findings for methodological, ethical, legal and healthcare professions education and research practice has been highlighted. The next chapter describes recommendations on how to take forward this evidence for future practice and further research.

Chapter 7

Conclusions and recommendations for future practice

Introduction

The aim of this chapter is to reflect on this research journey and to consider recommendations for improving the informed consent process for participation in clinical research. The recommendations are a direct response to the views of the clinical research participants as expressed in this research. This chapter makes a unique contribution to knowledge by demonstrating to stakeholders some practical and realistic approaches by which healthcare professionals may validate their knowledge and skills to meet professional standards and public expectations in the conduct of informed consent. It is hoped that the recommendations will serve to uphold or improve the experiences of those volunteering for research and by extension the essence of ethical research practice. Given that a positive experience by service users yields increased recruitment and retention, the hope is to raise the awareness of all stakeholders of the need to support and promote optimal engagement by ensuring consent for clinical research is valid, legal, and above all ethical. This chapter starts will a recap of the research focus, and reflections on the measures taken to establish quality of this this naturalistic study.

Theoretical underpinning revisited

The views of service users were sought to identify the real issues that impact on the informed consent process as they perceived them, and to seek out possible measures that may enhance the engagement of potential clinical research participants in the future. This focus was underpinned by the philosophical assumptions of this research, derived from Lincoln and Guba (1985), who believe that construction of meaningful realities must reflect

the real-life issues that people face. This research therefore aimed to come to grips with reality in a sense that mirrors accurately the concerns and predicaments that people see themselves facing of real-life encounters (Lincoln and Guba, 1985). The goal was to create fresh insight on the focus of inquiry based on the views of real-life service users.

Research Methodology revisited

In search of reality, this research engaged in individual face-to-face interviews with clinical research participants after they had taken part in an informed consent process for participation in clinical research. The participants were recruited from three NHS Foundation Trusts across the North East of England. The selection included participants with capacity, who spoke English, and had taken part in an informed consent process (for the purpose of taking part in clinical research) in the preceding three weeks. The interviews took place in locations of the participants' choice, included hospital meeting rooms and in some occasions at participants' homes. These settings reflected the natural environments in which consent processes for clinical research take place.

Guided by constructivist methodology, data was analysed with the intention of capturing quality and depth of the human experience, as well as the naturally occurring context. This resulted in co-production of knowledge in that findings emerged inductively from the data and through further discussions with the researcher (Guba, 1990). In line with the naturalistic orientation, knowledge was socially constructed and actively created through questions and answers, and by the interactions that took place during data collection (Kvale and Brinkman, 2015). Effort was made to represent the participants' views accurately, by way of quotes, capturing context, to reflect the meaning of the experiences shared.

Measures for trustworthiness revisited

Being a naturalistic inquiry, measures for credibility, dependability, transparency, confirmability, and transferability were observed at various stages of the research process. (Guba and Lincoln, 1989b; Long and Johnson, 2000).

Credibility

Credibility is concerned with the establishment of confidence with regard to the truthfulness of the reality constructed (Lincoln and Guba, 1985). Streubert and Carpenter (2011) suggested that one of the best ways to establish credibility is through prolonged engagement in the field with the participants. Prolonged engagement implies the investment of enough time to achieve the goals of building trust, getting to know the respondents and enhancing the quality of information obtained (Lincoln and Guba, 1985). Prolonged engagement was observed in the course of data collection, as the researcher engaged with the participants during interviews for as long as each participant required. There was no set time limit for each interview, with some conversations lasting a considerable time, while others were swift. Prolonged engagement enabled the participants to relax and get comfortable with the researcher, which enhanced naturally occurring interview conversations. The researcher intentionally allowed time for a period of bonding and initiated social conversations with each participant before moving on to start the interview conversations and audio recording. Although this measure meant that some participants often drifted from the focus of inquiry into other matters of interest to them, it yielded honest and in-depth views. The participants could lead the flow of conversations, with the researcher steering the conversations back into focus when necessary. Without a prolonged engagement in the field, the individuals may have felt uncomfortable relating to a perceived stranger, which could have affected the depth and quality of data obtained.

Peer debriefing was another measure employed to improve the credibility of the research findings. Peer debriefing is a process whereby the researcher invites an external check on

the inquiry process (Lincoln and Guba, 1985). The researcher engaged in peer debriefing sessions with the supervisory team, who reviewed transcripts and provided continuous guidance on interpretations. The Higher Education Post Graduate Research research advisory forum also reviewed and offered feedback on the research process and emerging data. These processes challenged and guided the research process, promoting authenticity of data gathered and the applied interpretations.

Dependability

Dependability refers to the degree of consistency with which an instrument measures the attribute it is designed to measure (Polit and Beck, 2012). Hence, having implemented the processes for ensuring the credibility of the findings of this research, it follows that there can be “no credibility without dependability” (Lincoln and Guba,1985; pg. 316). Hence, it is argued that the processes taken to establish the credibility of this research equally serve to assure its dependability. In addition, the researcher implemented an extensive list of measures, including regularly seeking the advice of her supervisory team on issues of significance throughout the research process. The supervisory guidance provided the opportunity to reflect on research activities and to ensure that congruence was sustained throughout the research process. Congruence in research is a process where the researcher invites an external reviewer to check that the product of the research is consistent and dependable (Cresswell and Poth, 2018). In doing this, the research observed and was guided by the underpinning principles of the NI paradigm, by ensuring that the activities of the human instruments were clearly documented by a clear research focus, and the selection of an appropriate tool, which allowed for the authentic voices of the human instruments to be heard. The use of an interview guide encouraged focus on the research objective during the interviews, alongside a comprehensive analysis of data guided both by a thematic framework and written quotes. This ensured an audit trail of the

methodological processes (Lincoln and Guba, 1985), demonstrating the appropriateness of the researcher's judgement and explaining the rationale for perceived deviations or methodological shift. Further, the use of quotes from transcripts ensured that participants' voices remained undistorted and not lost in the interpretations of data.

Confirmability

This research sought to demonstrate confirmability by presenting a clear link between the researcher's inferences and the appropriate category of labels, ensuring that the audience can determine for themselves the quality of the interpretations. Streubert and Carpenter (2011) believe that confirmability could be demonstrated by ensuring an audit trail that allows for the tracing of the researcher's account. In doing this, the quotes that support the findings are coded using labels that ensure anonymity, yet are traceable to the original transcripts. This process serves to differentiate the researcher's inferences and participants voices. Importantly, this research reinforces that all accounts, as expressed by the participants, are context-bound and remain true within the individual context. In line with the NI paradigm, the researcher functioned as a human instrument but remained conscious to control any potential bias. Objectivity of interview data was safeguarded by an interview guide to ensure consistency and neutrality in the probes and questions asked.

Transferability

Being a Naturalistic Inquiry, and given the purposeful nature of the sampling strategy and the unique yet diverse nature of the population, this research does not claim generalizable data. All accounts as expressed by the participants are context-bound and remain true within the individual context. However, the knowledge generated in this research adds a fresh insight and enhances understanding of the views of clinical research participants on the process of informed consent for participation in clinical research. The insight could be beneficial across platforms to support future interactions relating to ethical considerations in the design and conduct of research involving human participants.

Originality

There remains a scarcity of literature both nationally and internationally that has sought the views of clinical research participants on the process of informed consent after they had taken part in a clinical research study. This research is unique in the sense that by exploring the views of service users, it reports on the matters that are of real-life significance to services users in a manner that professional opinions are unable to achieve. This research has added to the body of knowledge relating to the process factors influencing service users' decisions to sign up for clinical research, and reveals that potential clinical research participants make their decisions based on human gestures as well as on needs. Most participants that took part in this research did not engage in depth with written study information, rather they were swayed by the interpersonal attributes of the professionals dealing with them. A clear recommendation from the findings of this research therefore is the need for a shift in the focus of ethical review processes to include more monitoring at the frontline, where it is believed that potential participants are impacted most in their decision-making processes.

Ethical considerations

This research followed through all the recommendations of both the Faculty Research Ethics Committees (FREC) and the NHS REC, as contained in the research protocol. The wellbeing of each research participant remained paramount.

Reflexive and reflective review

Reflexivity demonstrates the epistemological considerations of an inquiry in the way that the researcher reflects on the nature, grounds and limits of the human knowledge generated (Palaganas et al, 2017). In doing so, this research maintained a learning journal that captured what worked and what was of concern, to be shared and deliberated with the supervisory team in a timely manner. A reflexive but logical approach from the outset

allowed for unassuming discovery in favour of a genuinely sustained search for truth throughout the course of the research (Macfarlane, 2009).

Gaining Entry: Personal Capabilities and Feasibility Factors

The challenges of researching a considerably difficult to access group presented the researcher with a number of opportunities for reflection, both in-action and on-action (Tanner, 2006). First, the researcher's background as a former clinical research nurse allowed for an intellectual insight into what to expect with regard to the well-documented difficulties in navigating NHS governance procedures. The privilege of having experience working in the field enabled some level of optimism and hope. The researcher set out with hope that a meaningful and valuable study such as this would thrive and be supported by relevant stakeholders, especially at the grassroots levels where the driving concerns are well felt. The researchers' optimism served to minimise scepticism at the inception of the research proposal, without which the mountain may have seemed too difficult to climb.

As the research progressed however, the researcher was forced to confront her critical instincts around the governance processes, and the emotional demands of wanting to persist so that patients' voices be heard. The first challenge related to the delays in kick-starting valuable research due to some bureaucratic processes experienced in dealing with organisational gatekeepers, rather than the NHS REC, as had been anticipated. It was realised that while NHS REC had undergone significant improvement by way of considerations for proportionate reviews (Health Research Authority, 2020; NRES, 2011), governance approvals at the grassroots level remained a challenge. The research experienced significant amount of variation in the requirements between Trusts, as some Trusts appeared to function successfully alongside the REC procedures as stipulated within the Integrated Research Application System (IRAS) (HRA, 2020; NRES, 2011), whereas others demanded additional documents, causing undue delays in the process. Certain

departments were apparently lacking structures and processes as it often took a long time to respond to study inquiries.

Dealing with delays was challenging, given the time limitations with regard to field work. It was daunting to see that some research and development departments refused to engage despite knowing that the research had gained the support of clinical researchers at the frontline who had pledged to support it in principle. This response from a governance department, without any explanation, was a significant hindrance. On reflection, there remains some uncertainty around the guidelines from various organisations with regard to requirements, with some requiring the researcher to provide evidence of support from clinicians in principle before R&D approval could be considered, while others required that the researcher abstain from contacting clinicians until an R&D approval was in place. This presents an obvious challenge for a novice researcher setting out to navigate through the cloud. It remains unclear how one might tackle similar challenges in the future. A standardisation in the process across all NHS R&D departments could be advocated.

The researcher's experience could help to pre-empt and guide novice researchers daring to delve into NHS research involving patients in future. One useful lesson was the degree of resilience displayed by the researcher in dealing with the various gatekeepers. In particular, the success of access could be attributed to the researcher's ability to penetrate barriers to the community of practice (Perkins, Hughey, and Speer, 2002; Coburn and Stein, 2006). At first, some research teams displayed a certain level of territorialism and protectionism against a perceived outsider. However, the researcher, drawing upon previous skills and knowledge was able to gain the confidence of that community. With an insider knowledge, the researcher ensured constant engagement with the clinical research team, often sending regular email follow ups, telephone calls and regular site visits. The researcher remained cordial, friendly and approachable in the face of adversity. This allowed for trusting relationships with frontline staff and an expedited access to the participants after previous weighty bureaucratic delays.

This experience is not isolated and was similar to the accounts of a qualitative study by Tinkler et al (2017), in which they concluded that altered relationships within communities of practice appeared to have an impact on the divergence in core clinical research values. In the experience of this research, perceived identity clashes and apparent apprehension about the focus of inquiry contributed to the unease. Yet, Erlandson et al. (1993) note that although challenges may persist in the negotiations for access from those who have the authority to allow one to enter their world, it is vital that the researcher takes steps to develop relationships with the internal groups whose support may be required.

As fieldwork commenced, I engaged in continuous reflection after each interview. As a participant-observer, I supported the participants in the co-production of knowledge in the manner that the researcher probed and responded to questions as well as in the maintenance of a working relationship with the participants. As a former clinical research nurse with natural insight into the phenomenon being studied, I therefore cannot be considered an outsider. Such a position allowed for a more parallel understanding within the natural environment, which enabled the participants to offer deeper and genuine insights from their real-life positions as patients.

Intense Focused Conversations during Interviews

Despite their background and previous experiences in data collection, the researcher experienced some challenges in managing some of the concerns expressed by the participants during intense focused conversations (Mann, 2016). For example, issues emerged during data collection requiring the researcher to respond to matters outside of the traditional scope of the inquiry. In particular, some participants expressed unresolved concerns from their encounters in clinical studies, of the nature that required expert judgement. Having a depth of experience and competence, the researcher was able to reassure participants using common vocabulary (Mann, 2016; Gillham, 2000; Erlandson et al., 1993). Careful choice of words and an awareness of appropriate resources proved

reassuring to the participants. Such matters would have been difficult to deal with without an insider knowledge of the state of play in good clinical research practice. This is a valuable insight that could be beneficial to stakeholders, and that would serve the researcher in future considerations of ethical research design and conduct for academic researchers involving NHS patients in the future. Reflexivity of this nature that looks back on methodological issues in a meaningful manner is recognised as a crucial element in ensuring quality in qualitative research (Mann, 2016). It would have been unproductive to assume a distant and detached position in such matters of real-life focus with participants. Instead, the researcher effectively enabled the participants to open their worlds, yielding honest and genuine data from their experiences. Mann (2016) acknowledges that analysis of methodological interviews in relation to methodological choices, interests, subjectivities and the influence on the data collected is a crucial aspect of reflexivity.

Finally, a positive step in this research was conducting interviews in locations convenient for the participants. This enabled more diverse participation by individuals that may otherwise have been discouraged from signing up for research. As reflected in the findings, travelling and its associated inconveniences impacts on the successful recruitment of potential clinical research participants. It is advocated that every effort must be made to minimise the discomfort that study procedures may have on those volunteering to contribute to knowledge and science.

Limitations of this research

Sample size and selection bias

In common with many qualitative studies, this research has a few limitations. First, the sample size is comparatively small and was drawn from a unique population of patients in a selected region of the country. Second, the sample cannot be representative of the population despite prior intention to recruit across several specialties. Accessibility was very tightly controlled by research and development gatekeepers, so direct access to the

participants was problematic. The researcher was reliant on the recommendations of the clinical gatekeepers for access to participants. This posed a dilemma regarding selection bias in an already difficult to research group. With the participants being patients, these challenges were anticipated but could not be surpassed if the research was to be granted a favourable ethical opinion by the NHS REC. It was emphasised that the researcher should only recruit from clinical areas after a prior permission from each responsible clinician. This meant that some clinical areas could not be recruited in cases where the responsible clinician had refused access to potential participants. Due to these circumstances, the findings of this research are therefore not generalizable. Nevertheless, the knowledge generated adds a fresh insight and enhances understanding of the views of clinical research participants on the process of informed consent for participation in clinical research. The insight could be beneficial across platforms to support future interactions relating to ethical considerations in the design and conduct of research involving human participants. Also, the access difficulties present an opportunity for future research on how best to improve access for such difficult to access groups. However, 19 participants across three NHS Foundation Trusts is considered a very successful sample, given the difficulties involved.

Member Checking

Member checking is a process by which the researcher allows members of the stakeholding groups, including participants, to test the categories, interpretations, and conclusions drawn from a study (Erlandson et al., 1993). The purpose of member checking is to enhance the credibility of naturalistic research by ensuring accurate representation of participants' views (Thomas, 2014; Koelsch, 2013). However, due to the nature of this research involving patients, some of whom were battling life-changing medical conditions, this research had a duty of care to minimise the impact of participation on the individuals that volunteered, so a decision was made to reduce the burden of participation to a single occasion. Therefore, member checking by participants could not be implemented. Instead, member checking

was implemented throughout the interview conversations and at the end of each interview by way of the researcher summarising the data at intervals and allowing respondents to immediately correct errors or challenge the interpretations expressed. Also, in the course of data analysis and interpretation, the researcher engaged in peer debriefing sessions with the supervisory team, who reviewed transcripts and provided continuous guidance on interpretations. The Higher Education Post Graduate Research advisory forum also reviewed and offered feedback on the research process and emerging data. These processes challenged and guided the research process, promoting authenticity of data gathered and the applied interpretations.

Key findings revisited

This research found that participants' decisions were be influenced by a range of process factors. It is evident that potential clinical research participants inform their decisions based on some interpersonal humanistic philosophy, rather than on their reading of written information. In particular, the process of informed consent appeared to be influenced by how information was delivered, rather than the extent of the content; on the nature and relevance of information; rather than the amount; and on the unique circumstances of each individual need. There also appeared to be some conflict between the perspectives of real-life patients, and those of policymakers relating to the necessary steps to an informed decision.

First, this research indicates that potential clinical research participants continue to be influenced by the power of trusting relationships between clinicians and those in dependent relationships with them. Findings suggest that participants tended to perceive study invitations as recommendations and calls for action when a study was introduced by a trusted clinician in a position of authority. Hence there is a concern that potential clinical participants may be unable to assume total responsibility for an autonomous decision if influenced by a person perceived to be in a place of authority to help them. There is an implication for practice with regard to the nature of their relationship to the person

introducing the proposed research to prospective participants, this being that REC reviewers and researchers alike are urged to be mindful of the influence of power differentials when designing and reviewing study invitations in clinical research. A level of trust and respect for a physician appeared to breed dependency by prospective clinical research participants.

Second, the findings indicate that most participants in this research were persuaded to sign up for a research study by how much they liked the professional, and the charisma and interpersonal qualities of those professionals involved in their care. Across all of the themes, there were indications that participants were swayed more by a welcoming and considerate approach than by the written information being presented. The way both clinical and research staff related to participants was seen to influence prospective clinical research participants' willingness to engage in the process of informed consent for research. It appeared that a positive and nurturing professional demeanour encouraged engagement and participation, whereas a condescending and inconsiderate personality discouraged engagement and participation.

With regard to the above, it was interesting to note that prospective clinical research participants were particularly encouraged to sign up for research by the professionalism and support shown to them by the clinical care team that looked after them. The participants' accounts point to a significant interdependence between clinical care teams and clinical research teams, of the sort that is yet to be acknowledged in both healthcare and clinical research literature. This knowledge was particularly insightful given the implications for the recruitment and retention of prospective clinical research participants. The implication being that recruitment and retention success did not appear to be solely dependent on the activities of research teams but was instead linked and reliant upon the healthcare experiences of patients during their clinical care.

Third, some prospective clinical research participants did not engage adequately with the content of written study information because they had already made up their mind. Others

did not have time to go through the information, while others still perceived the content to be lengthy, irrelevant, and serving medico-legal purposes. For these reasons, most participants did not read the written information provided. Those that read it appeared to do so minimally without due attention to details, thereby consenting for studies without due consideration of study information.

Fourth, some prospective clinical research participants were persuaded to sign up for research by a range of patient-related factors and personal constructs. This included altruistic ideas around supporting science for the greater good, although it emerged that many participants did so to benefit their own health or their own relations. Other influencing factors included age, burden of illness and search for a cure. These factors served to influence participants' decisions to take part in clinical research. The decisions were therefore not particularly underpinned by rational consideration of all the details of information provided.

Finally, and of novel insight, the participants of this research took the opportunity to add to the knowledge on the information that real life clinical research participants consider to be important or of relevance. They made suggestions about the information that real life patients would like to see included in Participant Information Sheets for participation in clinical research. They also identified perceived barriers to participation. In doing so, the participants candidly shared their individual perspectives but also appeared mindful of the perspectives of the larger community of clinical research volunteers.

Recommendations

The participants' ideas are pondered upon further in the recommendations section, and form part of the suggestions being put forward for improving future practice.

Recommendation Group One: Invitations

1. *It is recommended that study advertisements / invitations are sent to prospective participants by post to allow them to consider whether to take part.*

2. *It is recommended that the person introducing the study should not be seen by the patient as 'recommending' participation.*
3. *Multiple approaches and follow up should be avoided.*

Study invitations, being part of the process of informed consent for clinical research, ought to be initiated by an individual that will not be perceived to be recommending the study to service users. This leads to a dilemma around the assumed independency between trusted clinicians and the studies they recommend to their patients, where some studies may be in the best interests of patients and clinicians would be right to make that recommendation.

This research suggests that a change of terminology needs to be considered, to reflect the purpose of study invitation as an *introduction* rather than a *recommendation* at such a time of vulnerability for real life patients. The position for a change in terminology is further considered given the circumstances in which such study introductions currently take place. It was identified that study invitations did not always allow for the disclosure of the depth of study information that is required for potential clinical research participants to make decisions on participation.

Given that some participants felt pressurised into participating in the research due to being requested several times, research teams should guard against multiple approaches.

Recommendation Group Two: Recruitment beyond the initial contact

4. *It is recommended that all staff seeking consent and participation should be appropriately trained to ensure they have relational and inter-personal skills.*
5. *It is recommended that potential participants are introduced to studies in an environment away from busy clinical settings and where interruptions can be avoided.*
6. *It is recommended that potential participants are spoken to by nurses unconnected to the research or clinical teams to avoid any response desirability bias.*
7. *It is recommended that potential participants are recruited via an advertisement / introduction rather than an invitation, as this reduces the likelihood that the patient will deem it as a request.*

In undertaking the informed consent process, it is the view of this research that genuine effort needs to be made to prioritise the right to an autonomous and informed decision by those that volunteer to participate in clinical research. This could be aided by facilitating an independent decision in the sense of genuine freedom of choice. It is suggested that all those involved in the research must take every step to avoid direct, paternalistic, or subtle coercion. Steps that enable prospective clinical research participants to engage meaningfully in the process of informed consent are encouraged. One such step is to ensure that proposed clinical research studies are introduced to potential participants by a more neutral designation of staff, rather than by clinicians who are in a dependent trusting relationship with patients. This may include experienced nurses, such as specialist nurses, or nurse practitioners who are deemed to have an equivalent level of knowledge and expertise but are a less authoritative influence on patients. This suggestion is made on the recognition that professional trusting relationships of the kind that exist between patients and clinicians appeared to significantly influence prospective participants' readiness to sign up for a particular research study on the basis of trust in the clinician's 'recommendations. Although a patient may not directly perceive an act of coercion, the Coalition for Collaborative Care (C4CC) acknowledged that people must have the right support in terms of knowledge, skills, power and confidence to work co-productively with experts in an engaging and informed manner (C4CC, 2018). The findings of this research suggest that most prospective clinical research participants found nurses to be more approachable and were more confident to engage in interactions with nurses than with doctors.

This research makes a further suggestion about the use of the term 'study invitations' when introducing proposed clinical research studies to potential research participants. Instead, a more neutral term such as a 'study advertisement or introduction' is proposed, especially when studies are being introduced by clinicians who are in an authoritative relationship with prospective participants. The term 'invitations', defined as 'a written or verbal request inviting someone to go somewhere or to do something' (Oxford English dictionary, 2020)

may be deemed as a call or request for action. Such terminology may therefore be deemed as requesting that potential participants participate in a study. It is concerning that such a connotation does not reflect an independent approach. Instead, it may explain how some patients appear to feel indebted to honour clinicians' recommendations without prejudice.

Sitting down with potential research participants on a one-to-one basis in a private setting appeared to improve patients' experiences of their care during the informed consent process for participation in clinical research. Participants felt reassured when research staff made efforts to protect their privacy by drawing bedside curtains during informed consent consultations – although this may not be adequate given that the person in the next bed could also hear the conversation. This suggest that a private room could be preferred by patients for a person-centred approach to the consent process.

Recommendation Group Three: Disclosure

8. *It is recommended that disclosure focuses on what matters to the individual (as suggested by this research (see Figure 10, below) as well as disclosure of risks, advantages and disadvantages. This can be achieved by asking the patient what they want to know.*

Reasonable expectations of research participants in relation to information disclosure

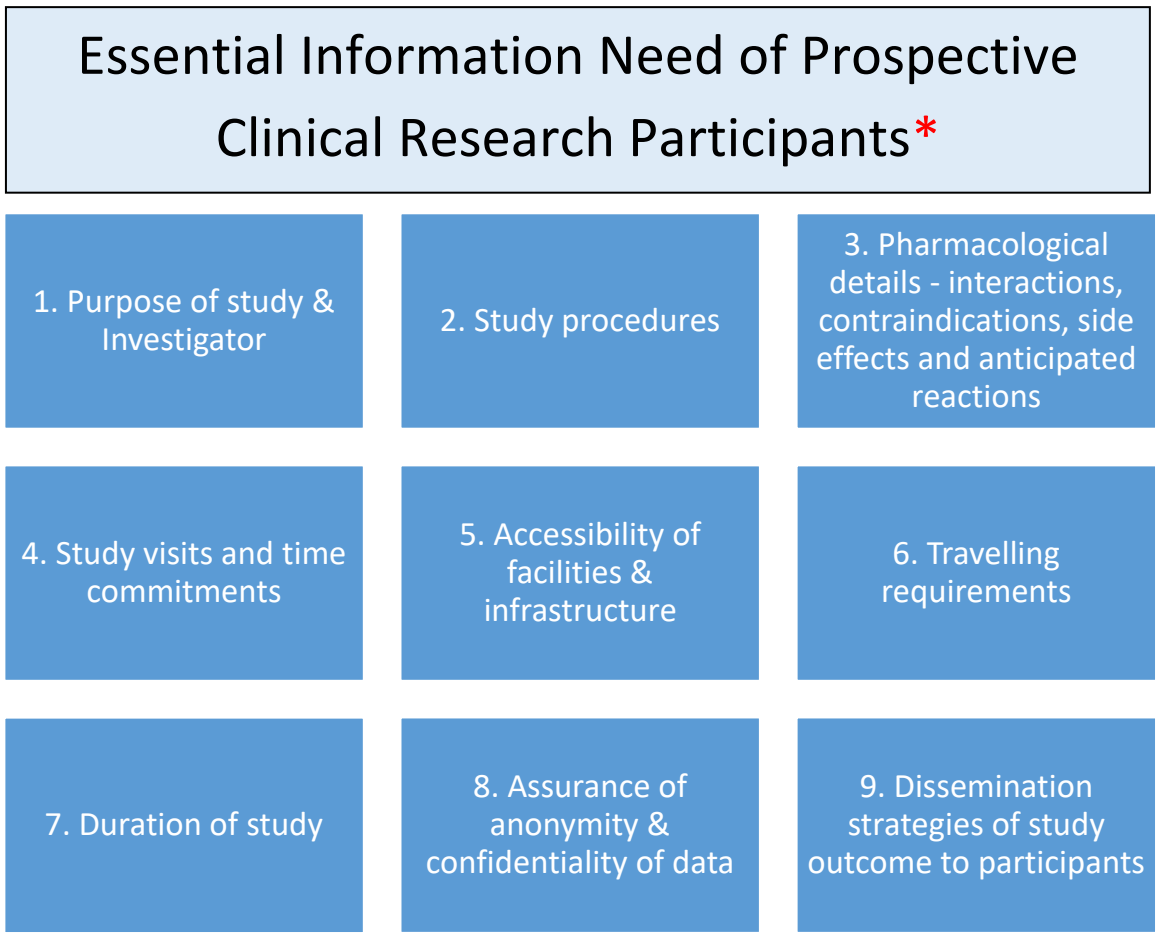


Figure 10 Diagrammatical representation of the essential information need of prospective clinical research participants (outlined originally in figure 5 but reproduced here for ease of reference).

**as identified during this research*

9. *It is recommended that the Patient Information Sheet should be viewed by Research Ethics Committees as a secondary source of information, with the primary source being face-to-face human dialogue.*
10. *It is recommended that disclosure of study information takes into consideration the areas outlined originally in Figure 5 but reproduced here as figure 10 for ease of reference.*
11. *It is recommended that the dialogue between researchers and participants is ongoing through their involvement and should include updates on the research outcomes*

Another suggestion for future practice regards issues of honesty in the manner that prospective clinical research participants are supported to consider what taking part in a

study may mean for them. There were a few instances where participants felt that research staff did not fully disclose necessary information regarding study procedures. For others, this was compounded by perceived therapeutic benefits of taking part in clinical research. To most, the motivation for signing up for clinical research was to benefit themselves in the hope for a medical check-up, treatment or cure. Such motives often appeared to cloud participants' judgement in their considerations of the risks and the perceived benefits of participation.

It is the view of this research therefore that researchers in their duty of care must ensure that prospective clinical research participants are supported to understand what taking part in the study entails, especially relating to the risks and benefits involved, in a manner that is personalised. This is an obvious criterion for a valid and ethically informed decision making (GMC, 2013; BERA, 2011). As mentioned in previous chapters, recent legislative changes require that the informed consent process for research is responsive to the needs of service users during the informed consent consultation (Montgomery v Lanarkshire Health Board, 2015). Hence, it must no longer rely on pre-written information that may not necessarily represent the individual needs of each real-life patient. Montgomery v Lanarkshire Health Board (2015) determined that informed consent disclosures must be considered from the perspective of service users and not from the perspective of the responsible clinician (as used to be the case with the Bolam test). The current standard requires that information and dialogue considers the expectations of reasonable persons in the patient's position and what such a person would be likely to attach significance to (Montgomery v Lanarkshire Health Board, 2015). A competent clinician (European Medicines Agency (EMA), 2016) therefore could be said to be one that is aware of and able to reasonably respond to any significant issues from patients' or potential clinical research participants' perspectives, in a manner that puts wellbeing first and foremost.

For example, this research indicated that prospective clinical research participants struggled to make sense of the terminologies used to describe information regarding risks and benefits. It was pointed out that the expression of risks in percentages for example did not mean much, which meant that prospective research participants may have consented for research without understanding the essential information disclosed to them.

It is the view of this research that more needs to be done to ensure that information is explained to prospective participants in everyday plain language (EMA, 2016). One such example may include the expression of risk in relative terms such as 'I in every 50 people', instead of in percentage ratios. Researchers need to be consistent in their use of plain and understandable language for service users.

Dissemination

NHIR (2019), citing the Government's Chief Scientific Adviser, Professor Chris Whitty, states that "research is of no use unless it gets to the people who need to use it". It also recommends that effective dissemination involves engagement with stakeholders such as research participants, research staff, commissioners, patient and professional groups (NHIR, 2019). It is through such stakeholder engagement that the purpose of research may be realised through raising awareness and enhancing understanding.

As set out in the proposal for this research, the plan is to disseminate the findings to relevant stakeholders through publications, presentations at conferences and at various workforce events. This will include support group networks, peer group meetings and researcher training events for clinical research professionals at grassroots levels. To enhance impact, the researcher will present findings to the relevant NHS trusts that supported this research at their team meetings. All organisations indicated interest in being notified of the findings of this research. Attendance at team meetings will be coordinated through research matrons, team leads and the R&D departments of the relevant Trusts.

Another dissemination channel to enhance impact will include presenting at the university's research seminars to early career researchers and at the Faculty Research Ethics Committee meeting. Early career researchers who may not yet have the level of experience and insight on matters of significance to real-life clinical research participants in relation to the informed consent process will benefit from the knowledge that this research provides. This is especially the case for novice researchers who may be planning to engage in research involving healthcare patients and organisations (Kendal and Halliday, 2014). Targeting and disseminating findings of this nature to early career researchers is fundamental to the championing of a meaningful informed consent process as it matters to real-life clinical research participants. The hope is that such insight may empower early career researchers to willingly engage in the process of informed consent from planning to execution and to pass on the knowledge to their mentees in time to come.

At a macro level, the findings of this research will be shared through presentation at professional conferences and publication in subject-specific peer-reviewed high impact journals. The intention is to submit manuscripts to The Lancet, The British Medical Journal (BMJ), The Journal of Medical Ethics, BMC Medical Education, Nurse Researcher, The International Journal of Qualitative Methods, The Journal of Continuing Education in the Health Professions and Bioethics. It is of course anticipated that this list of high-impact journals may prove challenging to publish in, but the hope is that the meaningful research questions answered in this research and the recommendations made will be attractive to all well-meaning reviewers and publishers. Also, abstracts will be submitted for either poster or oral presentations at the forthcoming International Conference on Nursing Science and Research in Singapore, January 2021 or London, August 19 – 20, 2021. The conference is an interdisciplinary platform for researchers, practitioners and educators to discuss practical challenges and opportunities for solutions in the fields of Nursing Science and Research. Other realistic opportunities for dissemination will be sought continually.

Summary of chapter

This PhD research has looked at the views of clinical research participants on the process of informed consent for participation in clinical research. It has provided evidence of the process factors that influence prospective clinical research participants' engagement in the process of informed consent for research. It is evident that patients sign up for research for reasons other than their use of the study information provided to them. This knowledge was particularly insightful given the implications for study design, ethics reviews, recruitment and retention of prospective clinical research participants. This research has also given insight into the information that participants may wish to know about, making a further contribution to existing knowledge.

As the saying goes, he "who dares to teach must never cease to learn" (John Cotton Dana). As an educationalist and developing researcher, I have made a real effort to reflect on this unique research journey, which highlights areas of professional and methodological strength, as well as areas where further development is required. It is my goal to share the findings of this research with peers and wider stakeholders at various levels including via publication in a peer-reviewed journal and presentations at local and international conferences, to inform future healthcare professions education and clinical research practice.

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Appendices

Appendix 01: Study Invitation Letter

INVITATION TO TAKE PART IN RESEARCH

Mrs Nwanyieze Nwali

Postgraduate researcher

Department of healthcare

Northumbria University

Dear Patient,

My name is Nwanyieze Nwali. I am a postgraduate researcher at Northumbria University, Newcastle upon Tyne.

I am currently carrying out a study to find out the views and opinions of patients on the process of informed consent for clinical research participation.

As you have recently been involved in an informed consent process for taking part in a clinical research study, I am writing to ask if you would be interested in taking part in this study.

This will involve about 40-60minutes of your time for individual interview with the researcher which will be recorded.

Your response will be completely anonymous and will only be used for the purpose of this study. All the data will be collected and analysed by the researcher and no reference will made to your name or person whatsoever.

Should you wish to take part, may I take this opportunity to thank you for your interest to participate in this study. You can contact me on 07939031348 for further information and involvement in this study.

Yours sincerely,

Mrs Nwanyieze Nwali

Postgraduate Researcher

Appendix 02: Reply Slip for participants

REPLY SLIP FOR PARTICIPANTS

I..... (Participant's name), wish to express my interest to take part in this study;

Title of Study: An exploratory study of service users' perspectives of the process of informed consent for participation in clinical research.

I have read the information sheet, and would like to discuss the information further with a member of the research team.

I can be contacted on the following contact details at the times specified;

Mobile telephone number…… ……..

Morning □□□□□□Afternoon □□□□□□□Evening □□

Home telephone number…….. ……..

Morning □□□□□□Afternoon □□□□□□□Evening □□

Email……..

Postal address…….

.....

Participants Signature.....

Date......

The researcher wishes to take this opportunity to thank you for your interest in this study.

Appendix 03: Patient Information Sheet

PARTICIPANT INFORMATION SHEET: FACE-TO-FACE INTERVIEW

Version 1: 30th May 2014

Title of Research Project: An exploratory study of service users' perspectives of the process of informed consent for participation in clinical research.

Investigators: Nwanyieze Nwali; Supervisor: Dr John Unsworth

Invitation:

You are being invited to take part in a research study. Before you decide if you would like to take part it is important to us that you understand why the research is being done and what it will involve for you. Please take the time to read this information sheet; you can discuss anything you like regarding the research with the researcher or person of your choosing. Please ask if there is anything that is unclear or if you would like more information.

Take some time to decide if you would like to take part after discussing the information about this research.

What is the purpose of this study?

The process of informed consent is of utmost importance in the ethical conduct of clinical research. The purpose of this research is to find out about research participants' viewpoints on the process of informed consent for clinical research participation.

We are going further by seeking the views of patients on the process of informed consent after they've taking part in a clinical research study. **We set out to do this by the way of a one-to-one face-to-face interview with patients that have been involved in an informed consent process for a clinical research study.**

Findings from this study may help clinical researchers to guide their future practise and ensure that the needs, preferences, rights, safety, dignity and wellbeing of prospective research participants are to be duly considered throughout the research process. It may also help to identify areas that may need further research.

Why have I been invited to take part in this research?

You have been invited to take part because you had been involved in an informed consent process for a clinical research study of recent. Your viewpoint of the informed consent process for clinical research participation is therefore important to us.

Do I have to agree to take part?

Your choice to take part is entirely voluntary. It is up to you to decide whether you want to take part or not. If you do agree, you will be asked to sign a consent form. Even if you do decide to take part and then change your mind, you are free to withdraw at any time without giving any reason whatsoever. This will not affect the standard of care that you receive in any way.

What will happen to me if I agree to take part?

This study is a non-interventional research as there will be no treatment or medication involved.

If you agree to take part, we will ask you to sign a consent form granting us permission to seek your views on the process of informed consent by the way of a **one-to-one face-to-face interview with you.**

We will make arrangements with you for a time and place that will be most convenient for you for a chat over your experience of the process of informed consent. The chat will take no longer than *two (2) hours* of your time.

To enable us to remember and mirror your views to others, we will ask *your permission to audio-record our interview with you*. We must reassure you that any information you give to us will be *anonymous and confidential***.** No identifiable reference will be made to you or your identity whatsoever.

What will happen to the information collected at the interview?

The evidence from this research will be considered and used to report findings but your personal information will not be revealed and your opinions will not be identified at any point.

We have a duty to protect your information by the way of ensuring that no identifiable reference will be made to you or your identity whatsoever.

What are the possible risks of taking part in this study?

There are no known risks for you of taking part in this study other than the sharing of your time with us.

What are the possible benefits for me of taking part in this study?

There will be no direct benefit for you of taking part but the findings of this study may encourage a more effective, appropriate and considered approach to the process of informed consent.

Your agreement to take part is entirely *voluntary* and there will be no financial reward for you or the researchers whatsoever.

What sort of research will be undertaken using my information?

By seeking and considering patients' views, we will collect evidence in the form of data to help inform developments, support claims or justify proposals for action or change in the informed consent process.

What happens if I change my mind?

You can change your mind at any time by contacting the investigator or any member of the research team (Contact details are given below). You do not need to give any reason and there is no consequence whatsoever. Remember, your participation is entirely voluntary.

What if I wish to make a compliant about the research or researcher?

You may wish to speak to Dr John Unsworth the supervisor on the contact number below at first instance.

If you are still not happy, you may wish to express your concern with INVOLVE, a national advisory group for the public on health and social care research. Tel: 023-8065-1088; Email: admin@invo.org.uk.

If you require any further information, please contact:

Investigator: Nwanyieze Nwali

Postgraduate Research Student, Faculty of Health and Life Sciences, Coach Lane Campus East, Northumbria University, Newcastle upon Tyne NE7 7XA. Telephone: 07939031348; Email: nwanyieze.n.ihesiaba@northumbria.ac.uk

Supervisor: Dr John Unsworth

Principal Lecturer & PHD Supervisor, Faculty of Health and Life Sciences, Coach Lane Campus West, Northumbria University, Newcastle upon Tyne NE7 7XA. Telephone: 01912156548; Email: john.unsworth@northumbria.ac.uk

Appendix 04: Consent form

PARTICIPANT CONSENT FORM: ONE-TO- ONE INTERVIEW

Version 1: 30th May 2014

Title of Research Project: An exploratory study of service users' perspectives of the process of informed consent for participation in clinical research.

Investigators: Nwanyieze Nwali; Supervisor: Dr John Unsworth

Participant Details

Study Number: Study ID:

Please tick **Yes** or **No** in the column if you agree with each of the statements:

	Yes	No
I confirm that I have read and understand the information sheet dated 30th May 2013 version 1.0 for the above study. I have had the opportunity to consider the information it contains. I have had the chance to ask questions		
I understand that my taking part is voluntary. I am free to withdraw at any time, without giving any reason and without affecting my present or future medical treatment.		
I understand that my personal information such as contact details may be looked at, where it is relevant to my taking part in this study. I give permission for the research staff to have access to my contact details.		
I agree to take part in a one-to-one face-to-face interview at a safe and convenient location of my choice		
I understand that my personal information or views will be treated confidentially, and no identifiable reference will be made to my personal views or identity at any point		
I understand that my taking part in this study will not bring any direct benefit for me, or financial reward.		
I consent to taking part in this research		
I agree to my GP receiving notification that I am taking part in the study		
IF YOU ANSWERED 'YES' TO THE ABOVE QUESTIONS YOU AGREE TO TAKE PART IN THIS STUDY.		

Name	Date	Signature
Person taking consent	Date	Signature

Appendix 05: Semi-structured interview questions

INTERVIEW GUIDE

1. Can you describe to me what you remember about being asked to take part in clinical research study?
2. Do you recall what the study was about?
3. Who first spoke to you about the study? Was it your doctor, a nurse or any other?

4. How did you find the interactions during the consent process?
5. Did you find it useful?
6. What was it that you found most interesting about the informed consent process?
7. What then was least useful?
8. How did you make up your mind on whether to take part or not?
9. Were you informed of certain rights that patients have when deciding to take part in clinical research? Are you able to talk me through the rights that you were told about please?
10. If you were to do it again, would you change anything about the process of informed consent as it matters to you?

Appendix 06: Sample transcribed interview [uncoded]

I – Interviewer

R – Respondent

I

So, again, thank you very much for coming today, [Respondent]. And I will just start by asking you to describe to me what you remember about being asked to take part in the clinical research study.

R

Right, I've been asked to take part in two. So I'll just go for the recent one?

I

Yes, or you can draw from both of them really, yeah.

R

Well, the first one – I can't even remember how I got involved. It was… It was to do with the diabetes new tablet. And I can't remember how I got involved. But the second one I do know because it wasn't that long ago. I was asked by a podiatrist if I was interested, and then a nurse or a sister – I don't know what the ones are with the purpose uniform – came in and explained everything thoroughly to me. When I said I would be interested. And she came down, she explained things, I was told exactly what would be going on. What the

clinical study was. How it would going to work. And then I agreed to it. That's how I agreed to it.

I

Do you recall what the study was about?

R

I was called Leukopatch – and it was taking parts of the blood, like the leukocytes, probably, to make a patch which healed… Pulled ulcers on diabetic people. It was a new process some firm had invented in Sweden, I think. And they've given… Was it Nottingham University? They'd given some machines to them and they had handed them out to the diabetic foot clinics. And they then… The one in Gateshead in Trinity Square got one, and they were taking part. And they asked some people – I know I agreed and I believed some… One other person – I don't know how many they actually got. And then I was due to take part and I got the blood test and then I got an infection in my ulcer. And I got another infection. So I couldn't take part for a long time. And then they did let me take part after the ulcer had healed up. And I was told I wasn't going to get the patch itself, I was going to get… I was going to be the control. One of the controls. But I didn't actually get the treatment, but I had to go and be treated every fortnight or every week. So I had to go and get my normal treatment. Well, I knew I wasn't getting the proper treatment because I couldn't… Because they had to take blood to do that, and they had to let you know. So they couldn't take blood without giving you any treatment because it's unethical. So that's where I was told. So… So that was it.

I

Right. So you knew… It was clear to you that you were going to be control? Not receiving the actual…?

R

Yes. It seems strange to me because I'm used to… When you do trials like that you always keep everything secret. But they said they couldn't. That was the only thing.

I

So what were your thoughts on the nurse's approach to you, when they approached you for the study?

R

They said that the study would… It was just like this – it was consents and all that were written out. And there was a pile of work I had to do to take home to check over. And then they were told I would be getting a blood test… If I went on the study I would be getting the blood… Not a blood test, a blood sample taken every fortnight, or every week, when it was. Whenever it was. And that would be used as a patch on to cover the wound. And that was about it, I think. I can't think of anything else being mentioned.

I

So from your view, how was the information explained to you?

R

Oh, very good. Very, very well. I understood straight away when they were talking.

I

The explanation – you said you understood straight away. Was that from the information that they gave or was it from, I mean, the information sheet? What we call the participant information sheet? Or was it from talking?

R

Mostly from the information, because the sheet, I… You know, I don't know if anybody is like me but they just read sheets and they don't really get the full idea from it. But it was from questions and asking the sister who was running the test – running the study – it was from her. And she was just great, as far as I was concerned. She told you everything you wanted to know and stuff you didn't need to know. But what she thought was important.

I

So what was most useful in helping you to understand the study? Was it the participant information sheet, or was it the interaction with…?

R

The interaction, definitely. Yes. You can ask questions, can't you? If you don't understand. You can't with a sheet.

I

Yeah. And did…? Did you ask any questions at the time?

R

I would imagine I did. Yes, I did – I asked questions on the way the test was going to be run. Because, as I said, I noticed that you were going to find out that you weren't… Which, to me, seemed strange. Because they usually have double blind tests – that's the way they run clinical tests. She just said… And that's when she explained they couldn't do it, because they couldn't take blood. It's not ethical to take blood for somebody and not to use it. So if they're taking blood from somebody it has to be used for something. So they had to… So you would know straight away you weren't getting the test. So that's the reason they weren't doing double blinds.

I

Were you satisfied with that explanation at the time?

R

Yes, I think I was. Yes.

I

My next question was going to be, you know, how was your question answered. Yes, so obviously your…

R

Yes, she just told me exactly why it was. Because of taking blood – it's not ethical.

I

So, to you, how clear were you on what the study was about before you took part?

R

I think I was very clear. Because… Because I know that ulcers are… Diabetic ulcers are hard to cure or clear up. And this was one way that somebody had thought of, of doing that. You know, it might speed it up a bit. So I knew exactly what it was. And they were just using

parts of your… Other parts of the body that helped, sometimes, clearing disease, to clear this one on the external diseases. So it's… Or internal diseases. So I was quite clear about what was going on, I think.

I

And, again, you already mentioned that it was the interaction that was the most useful in making that clear.

R

Yes.

I

So, then, do you have any suggestions on how researchers could improve the way we…? We provide or discuss information?

R

Well, as I said, I've been on two of these trials. I wasn't overly happy with the first one – but it wasn't run by a nurse. It wasn't a researcher. It wasn't a nurse or a medical… It might have been a medical researcher – I don't know. But she wasn't a nurse. And I wasn't too happy with the way that was run. And it ended rather… I was rather upset, the way it ended. It involved taking a massive tablet. And they… Because it was during the trial stage. And at the end, my throat was so swollen with these big tablets. So after I had been going for quite a while – it must have been half… 6 weeks or so. 6 sessions, I should say. Not 6 weeks. And I mentioned… She happened to mention, "Did you have any trouble?" I said, "Yes, those tablets are terrible to swallow. I've got a bad throat." "Oh, right then," she said. "I've got an 85-year old woman has no trouble doing it." "What?" So that was the end of that. She just wrote me off. And I thought, "Well, that's not a nice way to end it."

I

So it wasn't you that chose to stop it?

R

No, no. But it was just when I happened to mention the tablets are hurting my throat – maybe that wasn't an important part about it. And she just said, "Oh, right. Well stop doing it. An 85-year old woman can swallow them no problem."

I

And with that study, did they explain what they problems…? You know, would have been?

R

Yes, yes. It must have been five years ago now, I think. So I can't remember exactly what went on. But, oh yes, it was explained. Because I… Yeah. Because I went up there before I started and had a word with the woman and… So I had no problem in understanding what it was about, because they explained it. As I say, you ask… You ask questions when… And then you go home, and you think, "Oh, I should have asked that." And you can ask it the next week.

I

Yeah, yeah… That's right. Because as you say it's a continuous process. And then, moving on to enabling informed and autonomous decision-making. How did you make up your mind on whether to take part in the study or not?

R

Well, it just seemed… There's no reason why I shouldn't have taken part. I was going to be heard in any way. I wasn't going to be damaged. They weren't going to make it painful. And I was there every week anyhow, so it just seemed why not help out, you know?

I

And what's your motivation for getting involved in research? As the…?

R

Well, I like to know how things work. I'm interested in science. And, for instance, I'm a blood… I used to be a bloody donor. I've also got my donor card. So I think you can help… Just helping people is probably a motivation. So they can help me and help other people as well.

I

And then for that study – that particular one – what were your thoughts on the importance of the study?

R

Well, it… I was told that if it worked with be of great benefit to people with ulcers on their… You know, foot ulcers and the like. So I was told that that was what it was. They still weren't sure how it was… When I was told, they weren't sure if it was going to work properly or not. And this was just to find out if it was going to work. So they could carry on and maybe go further one way or another.

I

And… And for the study again – because I'm saying that because I know you've been involved in two studies – with the information sheet, did you have any concern? Was there any aspect of it that made you uncomfortable?

R

No, nothing. It was quite straightforward. And it's even like anything that you would expect from medical, where things are kept quiet. Your name wasn't involved. They even photographed my foot – you know, the ulcer – but they couldn't have a photograph with my face in it. So every photograph they took they had to make sure there was no face in it, and nobody else in it. They had to scrap one because somebody else had managed to get a bit of a head in. So they had to scrap it. So it was that… That sort of secret, or confidential. Confidential.

I

So you understood why that was done the way it was done? Yeah. And then the wording of the form and the… Was that easy to understand for you?

R

Yes, because they didn't use any of the technical terms. They just said they would separate the blood out and use part of the blood to, yeah, form the patch. They didn't say what it was. It was just a part of that blood that helped healing. So it wasn't complicated, it wasn't technical.

I

And did you feel the need, at the time, to discuss the participant information sheet or things that you were told with someone else outside of the team?

R

No, I don't think I've got… As long as I have somebody answering my questions, and I thought they fair enough, it's just that was good enough for me.

I

And I'm just going to ask you a question – an issue to do with the influence of power relationships and coercion. Which is important when we ask people to take part in research. How did you feel about your ability to express your honest feelings on whether to take part in the research?

R

I know what you mean, because sometime, like, you know, it's… Dr Whatnot is a consultant, but the consultants really, really don't want to talk to you at all. And they don't listen for a start. But nurses – I find nurses and the podiatrist… They're very friendly and they'll listen to what you say, and they don't try and do any, like, bossy business or try and pretend that they're better than you. So they're very good at it. And I think nurses… And I've always found it's nurses and the podiatrists I go to are very good at listening. So they don't try and pretend they're anything other than just a normal person. Whereas you can't say the same for some doctors.

I

So comparing nurses to doctors, which of them would you feel more comfortable in expressing your views, your…? Your fears or your thoughts or any hesitation – will it be different?

R

Well, I think nurses, in general… I can talk to… For instance, my diabetes person – the person who looks after me – is a nurse and I can talk to her no bother. But the other problem is I've got new doctors – all the doctors have changed recently – so I don't know any of them in my surgery. But I think I definitely feel more comfortable talking to nurses than I do to doctors. Because they seem to be, you know, more friendly.

I

Apart from the issue of friendliness, is there any other factor that might affect your ability to express views with, say, the doctors? If they were going through this with you?

R

No, I don't think so. Well, if it was something important, I would talk about it. But it's just that, I think, you see to talk… Well, nurses seem to have a little bit more time and they'll get you involved in the conversation – rather than being… Telling you what to do. Or they ask, you know… That sort of thing.

I

And I'm going to ask you on the issue of choice. And having a fair say. From your position as a patient, how did you feel on…? When working out your choice to accept or decline any involvement in the study?

R

Well, there was no pressure put on either way, as far as I was concerned. I was just given the information, asked to do it, and from what I understand there must have been some people refused it because they only had two clients doing it, as far as I know. Two patients. So some must have felt… And I felt… I didn't feel that I had to take it or had to decline it. I wasn't put in that position at all, by anybody.

I

So did you have any hesitation?

R

No. Just… Once I'd got my questions answered, that was it.

I

And… In doing this, for nurses and for whoever is doing it, really, it is important to also… It should be important to us that we maintain dignity and respect throughout, you know, our involvement with patients. How do you feel that your dignity and respect was catered for?

R

Well…

[Phone rings]

R

My phone? It’s never switched on. Very well. I had no problem. I never thought I was being looked down on or… I was being told what to do or being forced to do anything. So I think I was respected by them and my dignity wasn't affected one little bit, I don’t think.

I

And for you, what does dignity mean to you, in a situation like this? What would you…?

R

Well, I think dignity is that I’m involved in what’s going on, rather than being told what’s going on. And I think that’s what they do. That’s…

I

And the environment for the process of informed consent that you took part… What were your thoughts in terms of privacy, safety and comfort?

R

They made it clear that I would expect the same privacy as you would get from any medical person. Is that what you mean? Yeah. And the comfort? Well, I was on a bed at the time, so…

I

You were…

R

One of the ones that they use for the… When you do your feet on the podiatrist… You know, a proper bed. So I was pretty comfortable.

I

Did you feel you had the privacy to listen and be heard and express yourself?

R

No, that's one thing you don't get there – because there's about 3 or 4 people in at the time. They've got… They usual have two podiatrists in. And the other nurse came in and they were all chatting on. Not that I bother, but… But that's the only thing. The only thing I could fault them on is that I'm sitting there with my foot getting done and then the receptionist comes in and has a chat. And, "Oh, that looks bad." But I don't mind.

I

And… In signing the form – obviously you had this problem with your feet at the time – did you feel comfortable enough with the, you know, facilities that you had to write on and be comfortable and sit comfortably and things?

R

Yes, I was. It's a brand new centre. They've only been opened, what? Less than a year. So everything was top rate in there.

I

How do you feel about time available for you? That was made available for you, to make up your mind on whether to take part or not?

R

Well, what they did was when… They doubled the session length – so instead of quarter of an hour it was half an hour to give me time to look… To look at things. And every time I saw the nurse about this, I got a double session of half an hour. So there was plenty of time to talk about it.

I

The double session – why did they make it a double session?

R

Because they had to get my foot treated and to give the nurse time to come down and have a word after the foot was treated. So there was…

I

And that met your needs?

R

Oh, yes, definitely.

I

Okay. And what were your thoughts on the timing of this body invitation and going through the process of informed consent?

R

Well I was there every week, so I was asked the one week to consider it, and then the next week I was asked if was interested. Which is fair enough by me.

I

So how long did they allow you to digest the information and make up your mind?

R

It was about a week. Or it might have been a bit more. I don't… I can't remember now. Because it was quite a while ago – it was before Christmas. But there was plenty of time. I wasn't… In any way felt hurried. So it was no bother to me.

I

Uh-huh. And during the… The informed consent process, how did you feel about being listened to during the…? The interactions?

R

Oh, yes, they do. They were listening very well. So if I had something to say they would listen. They weren't interrupting or anything and trying to answer the question before I'd finished or that sort of thing that goes on quite often. But, yes, they listened very well – and then they would answer the question the best they could. Or find out. If they didn't know the answer they would find out later for me.

I

And that's really – what you've just said – is moving on… Moving us on to the next, you know, bit of things that I would like to chat with you. And that's what are your thoughts on the knowledge of the research staff about the research study?

R

Well, seeing as it was a brand new study, I think they had a really good grasp of what was going on. Because it just… Things that have been going for a long time, you would expect somebody in the medical profession to know about. But this… They knew quite well what was going on, and even knew the mechanics of how they were separating blood and things like that. So I think the… They seemed to know, as far as I was concerned, what they were talking about.

I

And, you know, in knowing, how good were the research staff in explaining the study information?

R

Very good. You see, they knew exactly what was happening and what would be done and when it would be done and how often it would be done. And the expected outcomes. So all that was explained.

I

So at no point did you feel uneasiness in their competence for what they were…?

R

No, not at all. Not at all, no.

I

And in the past, I think you mentioned earlier on – because this time it was a research nurse. Comparing the research nurse and the time that a medic or, you know…

R

Yeah, a researcher of some…

I

Talked to you about it. In terms of their knowledge and competence, what are your thoughts?

R

I don't think… It was only because I found out that she wasn't a nurse or any medical… Just a researcher, it was because she told me that. She made no… I think she was a proper medical… Training. She might have been medically trained, but she was a medical researcher on the… I didn't notice any difference. It was just the last week when she was… She said that to me. I couldn't believe it. It just came out of the blue. Because until then she was being quite friendly and quite… Explained everything I needed to know. So I didn't think there was any difference between them.

I

Take me back to what you… How she… The researcher for that study approached you on that occasion?

R

To go on the study or when I...

I

No, at the time when… The incident that…

R

Well, just the same as any other meeting and I just happened to mention that the tablets were a bit big and they were hurting my throat and I had a bad throat through them. And

she said, “Oh well, we’ll take you off the study, then. And we’ve got an 85-year old woman who has no bother swallowing them.”

I

So, from that, really, another thing that for us as nurses is important was this impact and compassion. Did you feel that need was met?

R

Not compassion, definitely. I was really… Really mad when I left.

I

And it must be clear that this was the study before the last one.

R

Oh, the last one – I had no problem, I think. As a matter of fact, I’ve been going that often I’m getting very friendly with everybody up there.

I

And… How did the study information in the participant information sheet, as we call it, meet your informational needs and expectations?

R

Well… At the end of every session, the study nurse would ask the podiatrist to go through the wound – is this what you mean? That sort of thing?

I

What I’m referring to is the paper or the information sheet – you know, that they gave to you to read?

R

Oh, at the beginning? Yes, right, sorry.

I

That you mentioned before took about a week for you to digest, yeah.

R

To read through, yes.

I

And what was in it? The content of it? How did it meet your expectations and what you needed to know?

R

Well, it was a bit like that sheet you just… You gave me, was a bit like… I think it was actually a bit bigger. It had three or four sheets. And it went through everything as far as I could see. And there was enough there for me to be able to ask questions. So I could see what was right, what I wasn't certain about. So it was good enough to do all of that. So I could ask questions and accept things as being what was said on the sheet. So I think it was quite comprehensive, to be honest.

I

And if you can recall, was there a certain aspect of it that you probably felt not relevant to you or…? Or wasn't bothered about or…?

R

Well, I think with most of this stuff there's a lot of information on it. I think it just has to be put there, but there was some of it wasn't relevant. You're right, yes. Not a… Not a lot, but it just seemed to… It does hide out… I think if they have too much – the words… Too many words on the sheet, it hides the bits you want to get to. So it's got to be… It's got to be more concise, I think. The sheets, for things like that. But then again, I've got a science background, so I'm not so bad at this. But people who haven't got science… Might need it. I don't know. So I couldn't speak for them.

I

So, for you, if you can revisit that, what is your opinion of your use of the participant information sheet?

R

I think it did what it needed to do. It was good. Fairly good, yes.

I

And for you, what was the use?

R

Well, it had been explained to me. Well, talking to me… You may as well not bother, because I forget it within ten minutes. Unless I've really been concentrating or I've been in a situation where I can concentrate. So it was… Look at it… Oh, yes… And the key words that would remind me what was said. And there would be things that I hadn't really comprehended on the original one. So it was good that way.

I

On the… On the day, did you feel the need to…? If you needed… Forgot anything, would you rather someone explained to you…? Had a chat with you? Or did you feel the need to revisit the form at different times?

R

No, once… Once the study had started, I didn't need to do that.

I

And how important was the participant information sheet in helping you make your decision?

R

I don't think it was at all, because I think I'd already made my decision before I'd seen the sheet. You know, I was given the sheet to take home. Because I thought it would be a good idea to take part in it. After it had been explained to me.

I

And if you can recall, what…? Was there any part of the study information that you were not bothered about or didn't need to know about?

R

There was a little bit in it, but I can't remember what it was. But there was one or two things that seemed to be… Go beyond what you needed to know. But not a lot.

I

And you can't be able to…?

R

I can't remember what it was, but I can remember having to read through a lot of stuff before I come to the important bits, you know. That was the problem.

I

Can you recall what the important bits were for you?

R

Yes, explaining who was doing the study, what the study involved, and what the expected outcomes of the study would be. And why the study was taking place. So they were the important bits for me.

I

And… You know, from the informational needs – which is what we're talking about now – was there anything else that you would have liked the researchers to tell patients about beforehand?

R

I can't remember anything. It was pretty precise in what it was doing. It was comprehensive, as far as I was concerned. Nothing ever came up later on, and I thought, "That should have been on the sheet" – no. I can't think of anything.

I

And can you talk to me about the…? Like the bothersome…? For you, of the consent process? Was it…? How convenient was it for you?

R

How, sorry?

I

How convenient?

R

Oh, convenient.

I

Yeah, was it for you? The whole process of the information…?

R

Well, very convenient because it was all… Mostly all done at… While I was at the surgery. At the podiatrist. Because they would… The nurse, who was running the test, was in the office upstairs. So she would come down and have a word. So I didn't need to go up there or go to any other… Any other meetings or… It was all done during the… During the treatment times or as an extension to the treatment times.

I

And, for you… You were already there for treatment.

R

Yes.

I

Yeah. Would it have been different…? What could hinder you from being involved in research or the information sharing?

R

This particular time or in general?

I

Not this time. In general. Yeah.

R

I can't think of anything that would hinder it. I wouldn't like to be involved with something really dramatic, you know. An operation just for the sake of it – that sort of thing. But as long as it was… Properly supervised, I wouldn't… I wouldn't say there was much that would stop me doing it – unless there was some tablet that was having terrible side effects. But apart from that, as long as it was a simple test or a simple procedure that didn't involve anything nasty, I don't think I would have any problems taking part in the test.

I

And, you know, to sum it up for me, how would you sum up your experience of the process of informed consent for that study?

R

First class, I would say. But, yes, no bother. Everything went well and there was no problems at all.

I

And from the experience of your involvement in the consent process, would you be keen to take part in clinical research in the future?

R

Oh, yes.

I

And do you feel that it…? You feel able to ask about research when you…? You are in contact with…?

R

Yes, yeah.

I

Is that something you would do, or would you…? In wanting to know about research, you know, would…? Would you be comfortable to just ask about it or would it be that someone had to approach you for…?

R

I think somebody would have to approach me, because I don't know what's going on in this field. So… Somebody was… If somebody approached me, I would consider it definitely. As long as it wasn't involving going to hospital or…?

I

Because I'm asking you that question because there's a campaign that researcher and the NHS are running that it is okay to ask your… Your healthcare staff to take part in research. And, of course, we don't know so much what the thoughts of patients are on their ability, and willingness, to just ask. So… You're saying that…

R

Well, if it was up to me I would say definitely. Just ask. I don't know about other people, but in my opinion I've got no problem. You can always refuse, can't you?

I

And… And if you take me back again – what about your view and… For you. How do you feel about just asking? Because that's what we're saying – is that we know we ask you, but we would like patients in general to ask.

R

So if they can take part in trials? Oh, right. I'd never thought of that. I wouldn't know what's going on. That's the problem – I don't know what's going on. So, yes, if… If I thought there was a trial going on something I would definitely take part in it. If I was suitable, yes.

I

Thank you very much. And is there anything else that you want to ask or that may help, you know, nurses or researchers to improve this process for patients from your experience or…?

R

I think you should get up to the diabetic foot clinic and find out what they did. Because they did a good job.

I

Thank you very much. I so much appreciate your… Your coming. Thank you.

R

Right.