

Chapter

NAVIGATING THE UK NHS ETHICS AND GOVERNANCE APPROVAL PROCESS: THE CASE OF JUNIOR RESEARCHERS

Kimberly Jamie*

Science and Technology Studies Unit,
University of York, Heslington, York, UK

ABSTRACT

The process of applying for research ethics and governance approvals to conduct research in the UK's National Health System (NHS) has been subject to some scrutiny by social science researchers. Whilst the process is, generally, experienced as cumbersome, bureaucratic and at a disjuncture with the nature of social research, the benefits for researchers and their projects have also been recognised. This chapter argues that representing the NHS ethics and governance approval process as either an experience that enriches research or an experience that hinders research is too simplistic as it does not take account of the degrees of expertise of the researchers navigating through it. Drawing on the author's own experiences, the chapter argues that the UK NHS ethics and governance approval process challenges the research of junior, particularly doctoral, social scientists on three primary levels. Firstly, the necessity of finalising a research design early on in the project is at odds with the developmental nature of a PhD and the serendipity of fieldwork. Secondly, the need to dedicate six months of a PhD programme to obtaining ethics and governance approvals means junior researchers working within the NHS are disadvantaged in terms of the time that they have available for fieldwork and data analysis. Finally, the heterogeneity of governance application policies means that junior researchers can be required to negotiate authorisation to access directorates with busy senior clinicians, which is challenging due to their lack of academic capital (publications, potential future collaborations). Due to these, and other, challenges faced by junior researchers, a multi-level support system seems imperative.

* Corresponding author: Kimberly Jamie., Research Fellow Science and Technology Studies Unit, University of York, Heslington, York, YO10 5DD, United Kingdom. E-mail: kimberly.jamie@york.ac.uk

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INTRODUCTION

The need for research to be subject to review by a research ethics committee (REC) has been a central part of medical research since the World Medical Association's Declaration of Helsinki in 1964. This declaration brought together numerous reports and guidance documents into a comprehensive overview, which, although not a globally legally binding document, has been described as 'the most widely accepted guidance worldwide on medical research involving human subjects' (Christie, 2000, p. 913). Social research has tended to be more self-regulating than clinical research and, as such, has generally required less researcher engagement with RECs. Despite this, the need for qualitative social research to be subject to ethics review has become more commonplace since the 1960s when the US Department of Health and Human Services issued guidelines stating that *all* research involving human subjects should be subject to ethics review (Guillemin and Gillam, 2004). Since this time, ethics reviews of qualitative social research have become fairly standard in many universities and research institutions. In the main, such reviews are generally carried out at the local level of the researcher's department or faculty (Haggerty, 2004) but for social researchers recruiting participants from within the UK NHS this review process involves contact with ethics and governance bodies beyond those at the institutional level.

This need for additional ethics approval was enshrined in 1991 with the publication of the Department of Health's *Local Research Ethics Committees* (1991) report, which stated that the ethical implications of all research, both social and clinical, taking place within the NHS should be subject to review by a local REC. In this report, these ethical implications were largely concerned with eight key areas; scientific merit of the research; effects on the health of the research subjects; potential hazards and strategies for dealing with them; potential distress or discomfort; the adequate supervision of the research and training of the researcher; monetary incentives that are offered to participants; procedures for obtaining informed consent; and the development of appropriate information sheets for participants. Although the Department of Health has updated its policy documentation, the principles underpinning the purpose and role of RECs remain the same with the protection of research participants' 'dignity, rights, safety and well-being' being the primary concern in the ethics review process (Department of Health, 2011, p.14).

The need for social researchers to undertake the NHS ethics and governance approval process has been subject to much academic debate, most of which centres around the question of whether committees help or hinder social research. This chapter argues, however, that this binary construction of the process as presenting either promise or peril (McCormick, 1984) for researchers is too simplistic as it does not take account of the expertise of the researchers undertaking it. As such, this construction of the process does not acknowledge the possibility that a senior researcher may experience the process in wholly different way from a junior researcher with relatively limited experience and expertise. Drawing on the author's own experience as a doctoral researcher undertaking the NHS ethics and governance application process, this chapter argues that there are three key ways in which junior researchers may experience the process as more of a challenge in comparison to their more experienced

colleagues. Firstly, the necessity of finalizing a research design early in the project is at odds with the nature of a PhD and the serendipitous nature of social science fieldwork. Secondly, the length of time that researchers are required to dedicate to ethics and governance applications disadvantage junior researchers in terms of the time available to them for fieldwork and data analysis. Finally, heterogeneity of governance policies across NHS sites and R and D departments means that junior researchers may have to negotiate authorization for access with senior clinical personnel with limited experience or academic capital. In order for junior researchers to fully benefit from undertaking the NHS ethics and governance application process, current support provision needs to be improved.

THE UK NHS ETHICS AND GOVERNANCE APPLICATION PROCESS

The NHS ethics and governance application process can be divided into three phases; the ethics application; the Research Passport application; and the governance applications.

NHS Ethics Application

The initial phase of the application system requires researchers to complete and submit, along with supporting documentation, a standardised online form. The supporting documentation that is submitted includes CVs for all of the researchers on the team, interview guides, participant information documents, recruitment literature, consent forms, project protocols and any other documentation that may be relevant to ethics decisions. The extent of this documentation and the length of the online REC form means that historically the paperwork for this phase of the application process has been as long as 150 pages (Oliver, 2006)

Once this documentation has been compiled, researchers book to attend a REC meeting where they are given the opportunity to discuss the research with the 18-person (maximum) committee, at least one third of whom are drawn from the lay public (O'Reilly, Dixon Woods, Angell, Ashcroft, and Bryman, 2009). Following this meeting, RECs offer one of three opinions on the work- favourable (research can commence), provisional (queries raised by the REC need to be addressed) or unfavourable (application needs to be resubmitted), which make up around 15%, 64% and 8% respectively of the decisions made by RECs (O'Reilly et al., 2009). Since 2004, the final favourable or unfavourable opinion has been required to be given to researchers within sixty days of their application being made.

Research Passport Application

Research Passports were introduced in 2009 following a Department of Health report in 2005, which condemned the amount of bureaucracy and duplication that was involved in researchers applying for temporary honorary contracts at each NHS site in which they conducted research.

This ‘bureaucracy buster’ was imagined as a way of streamlining the application process and reducing its time burden (Kielmann, et al., 2007, p. 237). Researchers who do not have a contractual relationship with the NHS are required to obtain a Research Passport which can be used to obtain letters of access for individual NHS sites. The application form for the Research Passport can be completed at the same time as the REC form and is submitted, along with a Criminal Records Bureau certificate and an Occupational Health certificate, to the project’s lead R and D office (usually that within the NHS Trust at which most, or all, of the research will take place). Once this form has been validated, the Research Passport is then taken forward into the governance application process.

Governance Application

Much writing which examines the relationship between social research and NHS ethics and governance process presents obtaining a favourable REC opinion as the end of the researcher’s ethics journey. This, however, is usually only one of the first steps on the road to being able to commence field research. Once researchers have been issued with a valid Research Passport and have obtained a favourable outcome from the REC, they must then apply for governance approval from each of the NHS sites (hospital trusts, Primary Care Trusts or care homes) in which they plan to conduct research. This application involves submitting two standardised forms, along with supporting documentation, to each site’s R and D department. These forms are designed to assess the practical and financial demands of the research on the given site (Smajdor, Sydes, Gelling, and Wilkinson, 2009). Unlike the first phase of the application process where a centrally-set timescale is in place for providing researchers with an opinion within sixty days, at the governance application stage, each R and D department has different policies and time-scales in place, which has been widely critiqued and highlighted as a fundamental flaw in the NHS ethics and governance process (Al-Shahi, 2005; Reed, 2007; Richardson and McMullan, 2007).

REFLECTIONS ON THE NHS APPROVALS PROCESS

Social scientists have reflected extensively on the NHS approvals process and the potential impact that it has on their research. Largely, these reflections can be divided into two ways of understanding the process; as a process which is beneficial for social research, or as a process which is a hindrance to social research.

The process has been highlighted as a beneficial endeavour for social researchers and their projects as it obliges researchers to interrogate their research design to a greater extent than researchers who are not required to undertake the process. Since NHS ethics and governance committees require the research design to be presented in its minutiae, and a large quantity of documentation to be submitted in support of the application, researchers are able to highlight potential ethical, methodological or analytical problems with the research at an early stage of the project.

This means that these issues, which may have otherwise have been overlooked, can be addressed and the quality and rigor of the research can be improved as a result (Kent,

Williamson, Goodenough, and Ashcroft, 2002; Van Teijlingen, 2006; Van Teijlingen and Cheyne, 2004). Moreover, this approval process is understood as beneficial for identifying potentially hidden ethical issues in research that may otherwise have been classified as 'low risk' (Van Teijlingen, Douglas, and Torrance, 2008). Guillemin and Gillam (2004) argue that all social research involves some level of risk to participants, although these can get overlooked in research projects that do not involve highly sensitive topics or vulnerable people. By requiring researchers to extensively evaluate their research design for potential ethical issues, the NHS ethics and governance application process can highlight relatively minor ethical issues that may otherwise have been overlooked (Van Teijlingen, 2006).

In contrast, reflections on the NHS ethics and governance application process as an endeavour which hinders social research are, arguably, the most common. Within this, the most frequent complaints about the process are based around how excessively bureaucratic and time consuming the process is; the disjuncture between the clinical-bias of the process and social research; and the lack of standardization between NHS sites in terms of the governance application system. Firstly, the quantity of documentation that is required for an application to the local REC to be submitted is understood as excessive for relatively low risk social research projects. Oliver (2006) notes that REC forms, and their supporting documentation have historically be as long as 150 pages. In the clinical context, Al-Shahi and Warlow (1999) found that their ethics and governance applications generated 5,789 pages, weighing 26.9kg. Notwithstanding the time taken for ethics and governance committees to review applications, the assembly of such large quantities of documentation means that the process of ethics and governance approvals is time intensive for researchers. Tysome (25/05/2007) and Reed (2007) argue that the process of obtaining NHS ethics and governance approval is approximately six months, although some governance committees may take significantly longer.

NHS approvals primarily exist as a way of protecting patients from the potential risks of biomedical research as per the Nuremberg Code and Declaration of Helsinki. This means that the process is heavily geared towards clinical research, despite the fact that social researchers are also required to use the same approvals process (Reed, 2007; Richardson and McMullan, 2007). Richardson and McMullan (2007) argue that whilst the approvals process is cumbersome and time consuming for clinical researchers, it presents an even more challenging undertaking for social scientists due to the disjuncture between its clinically-informed nature and the realities of social research. This, they argue, has a number of potentially harmful consequences for social research in the fields of health and medicine such as a reduction in the amount of health research being undertaken; limitations on the scope of health research; unethical research being carried out; poor research design and the loss of valuable research opportunities during the lengthy review process. Moreover, Reed (2007) notes that critiques of the NHS ethics approval process which construct it primarily in terms of being a 'bureaucratic nightmare', risk overlooking the more complex problems associated with it, such as it being heavily gate-kept by NHS personnel who constitute the majority of the REC members which positions social scientists as 'outsiders'.

Much of the academic debate around the purpose and experiences of the NHS approvals process deals with issues of the first stage of the process, obtaining REC approval. In contrast, the lack of standardization of governance application procedures between NHS sites often causes more issues for researchers than the first ethics application phase as the forms, information and expectations at the governance phase are highly variable between sites (Al-

Shahi, 2005; Mallick and O'Callaghan, 2009; Munro, 2008; Reed, 2007). While all sites require researchers to submit two standardised forms at this stage, the additional information and supporting documentation that is also required varies greatly. Unlike at the first ethics phase of the application process, once these documents have been submitted, very few R and D departments have standardised time-frames for approvals which means researchers are unable to accurately plan their fieldwork activities due to being unaware of when their governance approvals will be given. In 2005, the UK Department of Health published a report which labelled the governance application process 'cumbersome' and argued for the introduction of a research passport, an amalgamation of application forms in order to reduce duplication (Department of Health, 2005). Whilst the introduction of the Research Passport has gone some way to reducing such duplication and the related time concerns, the heterogeneity of governance application processes remains a concern for researchers (Dumville, Watson, Raynor, and Torgerson, 2004; Haynes, Bowman, Rahimi, and Armitage, 2010; Mallick and O'Callaghan, 2009; Munro, 2008; Reed, 2007).

REFLECTIONS ON THE NHS APPROVALS PROCESS: THE CASE OF JUNIOR RESEARCHERS

Whilst social scientists' reflections on the process of NHS ethics and governance applications are useful for understanding the advantages and disadvantages of the process for social research in general, the literature gives no attention to the way in which the process may be experienced differently by researchers occupying different positions within the academy. Previous writing in this area tends to homogenize the experiences of social scientists and fails to analyse the particular challenges faced by researchers who navigate the NHS ethics and governance process at different stages of their careers. The remainder of this chapter offers an analysis of the particular challenges faced by junior, particularly, doctoral researchers navigating the NHS ethics and governance process. The chapter focuses on three challenges which repeatedly occurred throughout the author's ethics and governance application; (i) the need to finalise a research design early on in the project; (ii) the large amount of time dedicated solely to ethics and governance applications; and (iii) the heterogeneity of requirements at the governance application phase, particularly around obtaining authorization signatures.

Finalising a Research Design

The NHS ethics and governance application process requires researchers to provide relatively precise details of their research design before fieldwork commences. NHS ethics and governance approvals are then granted based on this information, which is provided in standardised, clinically-biased forms. Researchers are, then, bound to these details by the conditions of their approvals and any deviations from them contravene these approvals. Hence, the ideal scenario for a social researcher would be to have their research design and participant list finalised prior to beginning the ethics and governance process so that unanticipated changes would not risk contravening ethics and governance approval.

However, social research does not lend itself to this scenario and the NHS ethics and governance process fails to take into account the chaotic and serendipitous nature of social science fieldwork. Perhaps the best example of this chaos and serendipity is snowball sampling. Although snowballing is widely used in social research and advocated as a way of accessing hard-to-reach populations (Faugier and Sargeant, 1997), the requirement for researchers to have separate permissions for a particular number of participants from each NHS site curtails the snowballing potential. As an example, the author received permission from one NHS site to undertake no more than five interviews with pharmacy personnel. During the first interview within this directorate, the clinical lead recommended seven pharmacy personnel and numerous practitioners working outside of the pharmacy department for the author to interview. In this instance, then, the snowballing capacity of the researcher was curtailed by the restrictive permissions of the NHS ethics and governance process and a number of potential participants were not contacted for inclusion in the study.

Constraining the extent to which serendipity and chance play a role in field research is particularly problematic for junior researchers, who may rely on serendipitous encounters with gatekeepers to access networks that would otherwise be closed off to them. To demonstrate, Harvey (2010) notes how important network building and snowball sampling was to him during his doctoral and post-doctoral work interviewing CEOs, vice-presidents and directors. Discussing serendipity in ethnographic research, Fine and Deegan (1996: 439) note that researchers regularly create 'favour banks' whereby they offer services in exchange for participation. For junior researchers accessing medical communities, the development of such a 'favour bank' is difficult due to the comparative lack of services (such as publications and potential collaboration opportunities) that they can offer participants. Hence, junior researchers may access participants more easily through gatekeepers.

Another challenge presented by the need for early finalization of research designs is that it leaves very little scope for changes to the research. For senior researchers working on a grant-funded project with clearly defined work packages, objectives and participant populations, this may not be as problematic. However, doctoral research is primarily an educational and training undertaking (Collinson, 1998) during which researchers develop their own epistemological perspectives, methodologies and academic voices through conducting research which is flexible in line with their development. Hence, Brause (2000, p. 38) notes that 'the identification of "what to study" evolves slowly' as researchers become immersed in their field and identify areas of particular interest. In this way, doctoral researchers constantly 'redirect their journeys' by changing their research topics and methodologies (Pansiri, 2009, p. 84). For junior researchers who are bound to relatively strict NHS ethical approval conditions, the scope to change the methodologies being used and the populations being researched are severely limited, which means that the purpose of doctoral training to develop independent academic perspectives through fluid research risks being neglected.

Time Taken for Approvals

Full-time doctoral research programmes in social sciences in the UK usually involve a three year registration period as per the Swinnerton-Dyer Report (1986) and most institutions provide doctoral researchers with a further year in which to write up their theses. For doctoral

researchers who are funded by a funding council or body (most commonly the Economic and Social Research Council), their stipend covering tuition fees and living expenses is usually paid for the three years of registration and the fourth year is self-funded by the doctoral student (McQueen, 1994). This three year registration period tends to be divided into three phases of research work comprising desk-based theoretical ground work; field work and data analysis; and writing up and dissemination (Harrison, 2010). These phases of work roughly map on to the three year registration period and form parallels with the personal development of doctoral researchers from undergraduate students to independent researchers (Gardner, 2008). In addition to research, doctoral students are also increasingly expected to take on teaching responsibilities and extensive skills training (Park, 2005; Roberts, 2002)

For doctoral researchers recruiting participants from within the NHS, the lengthy approvals process is a large administrative burden that has to be factored into this already strained timetable and heavy workload. The process of acquiring NHS ethics and governance approval takes an average of six months, although unforeseen delays at some NHS Trusts can mean that the process takes much longer (Reed, 2007; Tysome, 25/05/2007). Since no empirical fieldwork with NHS personnel or patients can be undertaken until these approvals have been received, doctoral researchers requiring such approvals cannot as easily schedule their work within the three year registration period. Willis (2010) notes that lengthy ethics procedures risk junior researchers not having enough time to collect their data and complete their PhDs within the registration period. This risk would appear greater for researchers working in the NHS.

For funded doctoral researchers, this means that they are often forced to complete their PhDs during their fourth year when they receive no financial support from research councils and are not necessarily guaranteed supervision or office space by their institutions.

Hence, for doctoral researchers working in the NHS who rely solely on this funding, there is a need to ensure that the project is completed within the three year period. This could mean that the quality of their fieldwork, analysis or dissemination is reduced or that the additional training or teaching activities that are beneficial for future careers could be forgone in order to complete the PhD within three years. An anonymous student reflection on the NHS approvals process notes that the requirement to dedicate the majority of the first year of the PhD to this process 'was to the detriment of doing more in-depth, wider reading' (Anonymous, 2009, p. 2). As such, since no extended registration period exists for doctoral researchers who spend around one sixth of their project time dedicated to NHS approvals, these junior researchers risk finishing their PhDs with poorer quality data or publications and not having engaged in the extra-curricular activities that are now commonly demanded of them.

Heterogeneity of Governance Applications

Whilst the ethics approval phase of NHS permissions has been standardised, the governance phase is characterised by heterogeneity of policies and practice. There are two key areas in which this lack of standardisation is particularly manifested; the quantity of documentation required and the responsibility for obtaining authorisations. Firstly, the amount of documentation that different sites request from researchers varies significantly.

In some Trusts, two standardised forms outlining the practicalities of the research for that Trust (for example, staff numbers and time and spatial requirements), correspondence with RECs, documents previously approved by the REC and insurance information are all that is required. In others, financial implications details, criminal records checks, researcher health information, dissemination plans and additional training courses are also required to be submitted. This can have the effect of trapping researchers into a ‘byzantine labyrinth’ of bureaucracy (Alberti, 2000) where for each document that is submitted, further information is requested. For junior researchers, the request for financial implications details is particularly problematic. Financial implications usually request that researchers provide an estimate of the cost of each research encounter based on the participant’s salary and reimburse the Trust for this amount from a research grant. For doctoral researchers the only funding attached to their projects is their maintenance grant, which is not intended to cover research costs and can mean that research is not approved by some departments.

Moreover, despite the fact that this maintenance grant is not for research costs, doctoral researchers are still required to detail the finances of their project, which is an intrusive request that is not always placed on more senior researchers working on a grant-funded project.

Secondly, the lack of standardization in the process of obtaining authorisation signatures from the clinical leads of the directorates in which research will take place is particularly challenging for junior researchers. In some instances, Trust R and D departments request that researchers leave blank the section of the governance form which asks for a clinical lead’s authorisation, which is then obtained by the R and D department. In other instances, however, this signature has to be obtained by the researcher before they submit their governance application. This means that researchers have to contact busy clinical staff and negotiate authorisation with them. For social science researchers, this can be a challenging task as many clinical personnel are unfamiliar with the principles, objectives and methodologies of qualitative research (Richards and Schwartz, 2002). This means that researchers need to draw on their full academic capital and cultivate a tone and vocabulary that represents the importance of the research, and the centrality of their directorate to it, as well as the calibre of the researcher. For junior researchers, such negotiations are extremely challenging since they have limited experience in cultivating a discursive style which conveys their competence and the significance of their research.

Moreover, due to their comparative lack of academic capital qua publications, international standing in their field and potential for future collaborations, junior researchers have fewer bargaining tools to mobilise in these negotiations than their senior colleagues. For these reasons, junior researchers rely quite heavily on the interest and goodwill of these senior clinical signatories, which varies dramatically between institutions.

CONCLUSION

The challenges of the UK NHS ethics and governance application process have come under considerable scrutiny from both clinical and social researchers. Previous work in this area has, however, neglected to examine the particular challenges faced by junior, particularly doctoral, researchers navigating this process. Here, drawing on the author’s own experiences

as a doctoral researcher undertaking the NHS process, three of its most pervasive challenges have been identified as the need to finalize the research design early on in the project; the length of time that the approval process takes; and the heterogeneity of R and D policies.

Notwithstanding these challenges, undertaking the NHS ethics and governance application process can be an excellent opportunity for junior researchers to develop their time and project management skills. Increasingly health research job specifications in the UK detail experience of this NHS process as a desired characteristic of applicants and, therefore, the benefits of having undertaken the process during the doctoral registration period are apparent thereafter. In order to ensure that junior researchers appreciate the benefits of undertaking the process and are not overwhelmed by the challenges, it is imperative that universities, departments, funding councils and RECs understand the particular challenges faced by junior researchers navigating this process and offer the necessary support through initiatives such as group, individual or electronic mentoring, extended funding options and document sharing.

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