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# Student research in the NHS: an educational research case study

Katie Gathercole
Post-Graduate Researcher
School of Education
University of Leeds
Leeds LS2 9JT
Email for correspondence: ed09kag@leeds.ac.uk

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**Abstract**

The ethical and Research and Development (R&D) sections of the NHS must approve all research that is to take place in clinical settings. The process of gaining NHS approval for student studies is identical to that of more experienced researchers such as medical consultants. This raises a number of issues and challenges for doctoral students; particularly those that are located in non-medical fields. This paper offers insights from my own experience of negotiating the NHS governance framework for a doctoral study focused on the educational experiences of children and young people with the medical condition Cystic Fibrosis (CF).

## Introduction

In order to conduct research in clinical settings in England, it is necessary to gain approvals and permissions via the ethical and Research and Development (R&D) layers of the National Health Service (NHS) (Thompson and France, 2010). In recent years there has been considerable criticism of the NHS system for the ethical review of research. In response to the concerns of previous arrangements for ethical review, an overhaul of NHS research governance took place in 2009. Despite this, according to Thompson and France (2010), further changes to the management of the governance process are necessary as the new system fails to be consistent and streamlined. The ethical review of student research in the NHS has received particular criticism. As research governance has much to gain from the increasing knowledge of applicants to the system (Wilkinson, 2008), this article presents a case study that reflects on seeking NHS ethical approval via the revised system, for a Doctoral project located within the social sciences.

## Student research in the NHS

Health and social care research undertaken wholly for educational purposes within NHS settings must adhere to the Department of Health's (DoH) Research Governance Framework (2005) . The Governance Arrangements for Research Ethics Committees (GAfREC) (DOH, 2011) do not distinguish between student research and other types of research such as clinical studies. In practice, this creates tensions because as Wilkinson (2008) argues, NHS Research Ethics Committees (RECs) usually apply the same standards to student research as to studies with significant risk such as complex phase one clinical trials[i]. It is true that many experienced social and clinical researchers find NHS research governance challenging (see for example Stalker et al. 2004; McDonach, Barbour and Williams 2009; van Teijlingen, Douglas and Torrance 2008; Thompson and France 2010). Therefore, it is important to consider this process in relation to less experienced researchers, particularly because some argue that NHS governance can be a barrier to student research (Brindley, 2012; Tan, 2004; Oakeshott, 2006).

The National Research Ethics Service (NRES) acknowledges that student research has significant educational value, including the training it provides for those who will go on to become the professional researchers of the future (NPSA & NRES 2010). However, Woolham (2011), in his review of research governance in the adult social care field, argues that some universities actively discourage students from conducting live research in this area due to the relatively short timescales for completion. Nevertheless, it is important to train students about their role in setting and maintaining ethical research standards (van Teijlingen et al., 2008). Furthermore, training in research not only increases students' understanding of

ethical issues, but it also allows them to more effectively interpret the evidence base that should underlie most developments in their chosen field (Wilkinson, 2008). Significantly, for many doctoral students, the acquisition of research skills is likely to be a compulsory element of an educational award.

Despite the importance of learning about research, it is evident that some students experience major challenges where their research proposes to involve a clinical setting. For example, Tan (2004) reports the difficulties associated with the rejection of an ethics application and its subsequent resubmission. In Tan's (2004) case, different ethics committees reviewed each application which meant that each one raised new and different concerns. Consequently, Tan (2004) was unable to gain ethical approval for the study proposed. Any amendments to an application required following ethical review can also be time consuming which is an additional problem for student projects. As Oakeshott (2006) argues, her study was rejected for reasons specifically relating to the time-constraints associated with her course. She explains that a research governance manager reviewed her application and stated that it could not gain approval due to the lengthy time delays associated with gaining an honorary contract, a criminal records check and occupational health clearance (Oakeshott, 2006).

Brindley (2012) also cites difficulties with the approvals process linked to the timescales of his course. Although his ethics application was provisionally accepted, approval was dependent on a number of changes being made. While Brindley (2012) argues these changes would not have been achievable due to time restrictions, he also suggests they would have impacted upon the quality of the data collected. As an alternative to his research plan, Brindley (2012) decided to explore Trainee Clinical Psychologists' experiences of the NHS research ethics process. Perhaps somewhat alarmingly, participants in the study reported a sense of being overwhelmed and powerless, along with feelings of anxiety and isolation when negotiating the process (Brindley, 2012). The study also found for the majority of participants, NHS governance was experienced as an inherently complex and mysterious entity, with this uncertainty being compounded by the obstacles and time pressures they encountered (Brindley, 2012).

The difficulties experienced by student researchers discussed here are located within the medical sciences. There is an absence of discussion of the experiences of students from non-medical areas of research in the literature. Therefore, I now turn to a personal account of negotiating the NHS governance process for a doctoral study within the field of educational research.

## Case Study

This case study highlights an application for NHS ethical review which took place in 2013, for student research investigating the educational experiences of children and young people

with the medical condition Cystic Fibrosis (CF). The study intended to adopt a mixed-methods approach with two phases of data collection. The first phase planned to administer a questionnaire with children of compulsory school age in one of the largest CF centres in the UK as this would enable the recruitment of a relatively large sample of participants (approximately 100). The 35 item questionnaire consisted of questions about the impact of CF on education. Questions were written sensitively to avoid drawing attention to difficult situations in education that children may not previously have perceived to be problematic. The questionnaire did not ask for any clinical or personal information about the participant, nor did it include any intrusive questions.

The second phase of the study planned to select three children for interview based on a number of factors of interest within a dimensional sampling approach. In addition to children, interviews were proposed with key stakeholders, such as those involved in the education and medical care of children with CF. Given I also have CF, a potential risk of the study related to the possibility of cross-infection[ii] between myself and the child participants. However, the research methodology was written to remove this risk completely; administration of the questionnaire could be conducted by a research nurse on my behalf and interviews with children could take place virtually via an online platform to avoid physical face-to-face contact.

**NHS Approvals**

Given that the study was to recruit children and their parents via a CF centre, it was necessary to seek ethical approval via the NHS governance system. As a student researcher in the field of education, I was acquainted with the procedures for gaining ethical approval via the university governance arrangements. However, I was unfamiliar with NHS procedures and in particular, the permissions I would require in addition to ethical approval. Therefore, I was ill prepared in terms of the amount of work and time needed to negotiate the process. Table 1. on the next page illustrates the NHS requirements, associated supplementary documentation and time-scale, which exemplifies the complexity of the approvals task. Discussion of every approval and permission needed for the research is beyond the scope of this paper. Therefore, the main focus is on the process of gaining ethical approval for the study.

Table 1. NHS approvals needed for the research to begin

| **Approval Needed** | **Documentary evidence submitted** | **Time-scale** |
|---|---|---|
| Sponsor review | NHS ethics application form<br>Research protocol<br>Research flow-chart<br>Information sheets<br>Consent forms<br>Questionnaires<br>Interview schedules | 10 working days |
| Peer review | As above | 10 working days |
| Directorate approval | N/A | 10 working days |
| NHS ethical approval | *All sponsor review documentation and:*<br>Evidence of sponsor insurance/indemnity<br>Sponsor review approval letter<br>Directorate approval letter<br>CV student (researcher)<br>CV academic supervisors<br>Lone worker policy<br>Evidence of peer review | 57 calendar days |
| Disclosure and barring service check (DBS) | N/A | 6 weeks |
| NHS honorary contract/letter of access to hospital trust | Research passport application form<br>DBS enhanced certificate<br>Evidence of qualifications<br>CV (researcher)<br>Two references<br>Exploration of gaps in employment<br>ID with photograph<br>Verification of permission to work in the UK | 25 working days |
| Research and development approval (NHS permission for the research) | *All ethical approval documents and:*<br>R&D application form<br>Site specific information form<br>Clinical nurse CV<br>Clinical nurse evidence of research ethics training<br>REC correspondence<br>REC favourable opinion letter | (As above: Time-scale running concurrently with NHS honorary contract) |

Before I was ready to submit my application for NHS review, I experienced a great deal of difficulty in gaining information about the specific processes I should follow in the context of the project. For example, I did not know if I needed both NHS and university ethical approval for the study. I was particularly concerned about whether it would be within the NHS remit to review parts of the study involving participants who were not NHS patients or relatives (i.e. teachers). Therefore, to avoid compromising the project and to ensure that all aspects of the study were reviewed by a REC, a decision was made to apply for ethical review via

both the university and the NHS. While ethical approval was given by the university, this later proved unnecessary as I found that the NHS could review all aspects of the study. Consequently, this resulted in a delay to commencing the NHS approvals process. However, once this issue was resolved I was able to submit my application to NRES.

*Proportionate review.* Once the NHS ethics application was complete, the No Material Ethical Issues Tool (NMEIT) (NRES, 2013) was consulted to establish the most appropriate form of ethical review required. There are two types of review; an expedited system of proportionate review or review by a full REC. Research involving children may be considered for proportionate review (PR) where there are no 'material ethical issues' (NRES, 2013) and the proposed research methods include questionnaires and interviews. Therefore, the study was deemed eligible for the expedited system of PR by the NRES Central Allocation System. The application was reviewed by a PR Sub-Committee within eight days of it being received without the need for my attendance at a meeting. Unfortunately, 'no opinion' was reached by the Sub-Committee as they felt that the application did in fact have material ethical issues, thus requiring review by a full REC. However, the Sub-Committee did not identify exactly what the material ethical issues were although they did suggest some changes should be made to my application. For example, they recommended the use of an assent form for children completing the questionnaire rather than relying on implied consent as proposed in my ethics application. This proved useful as it would help children to recognise their right not to participate.

However, another suggestion seemed particularly misplaced. Reinforcing a medical model of research, the Sub-Committee stated that participants should be directed to their GP should they require support if they became distressed during the study. The Sub-Committee stated that my application was not clear about whether I was necessarily trained to deal with any potential distress and they did not appear to consider the role of the CF Research Nurse or my PhD supervisors in this regard. Unfortunately, as there is no provision for applicants to attend the meeting of the Sub-Committee, this meant I was unable to explain why this suggestion was inappropriate in the context of my research. In the case of patients with CF, close healthcare relationships between them and their GPs may be uncommon as the majority of care is provided by specialist CF units (Huq et al., 2011). I would also question the idea the GP is best placed to provide support in an educational research project should the participants become distressed. The contrasting positions on this issue parallel with concerns raised by other social researchers that there is an attempt to assert medical dominance on research that may stem from paradigms outside the traditional REC remit (McDonach et al., 2009; Williams-Jones and Holm, 2005; Dyer and Demeritt, 2009).

Following the PR process, it was not clear how I could respond to the recommendations made by the Sub-Committee as the application would be automatically passed on to the full REC. I decided I would address each of the suggested changes in a letter to the full REC. This was deemed necessary so that I could evidence I had considered the Sub-Committee's advice and gain approval as quickly as possible. However, writing this letter proved to be unhelpful as it constituted a change to my original application. I was informed by the REC Co-ordinator that any change to my application would mean I would need to withdraw it and resubmit via IRAS. Withdrawing and resubmitting my application would not have been possible as it would have brought further time constraints to the project which had already increased with the news that my application should be reviewed by a full REC. Therefore, given I was unable to respond, there seemed to be little purpose in the Sub-Committee providing feedback following the PR stage.

*Full REC review.* The full REC meeting was arranged relatively quickly following the notification of no opinion from the Proportionate Review Service (PRS). The full REC did not raise the same concerns as the PR Sub-Committee, although they did suggest that some changes to information sheets and consent forms were needed. The PRS suggestion that GPs should be informed about children's participation in the research was not felt to be necessary by the full REC, therefore evidencing an inconsistency in the decisions of the two committees. Being invited to attend the full REC meeting was incredibly useful as I was able to explain the reasons why this particular suggestion was inappropriate in the context of my study. My attendance at the meeting also enabled the full REC to clarify any issues and concerns they had in light of my application. In contrast to the PR, the full REC review was very helpful in this regard. They made some useful suggestions relating to all phases of the research including the aspects that did not involve the clinical setting, thus enhancing the ethical quality of the study.

Following the full REC meeting, a provisional opinion was received. The committee were content to give a favourable ethical opinion of the research on the basis that amendments were made to some of the research materials. Subsequently, a favourable opinion was given 18 days later, 57 calendar days after my initial ethics application was submitted and deemed valid (within the obligatory maximum 60 day time period). The process for gaining R&D approval and access to the hospital trust was very straightforward and took place immediately following the notice of ethical approval from the full REC. Both were granted 25 days after submitting the applications. However, the time taken to complete all the NHS approvals process was well over three months. This placed me at a substantial disadvantage to other students conducting social research projects in non-clinical settings who were able to gain necessary approvals more swiftly via university procedures. Nevertheless, the involvement of the NHS was deemed vital to the recruitment of a relatively large sample of children with CF that would enable a broad range of voices to be explored and analysed.

**Discussion**

There are major concerns as to whether the current NHS governance arrangements are appropriate to the task and able to provide timely and genuinely supportive systems to investigators (Thompson and France, 2010). In order to reduce some of the challenges associated with the review of student research, some argue that greater education and training in the area of research ethics is needed (Wilkinson, 2008; van Teijlingen et al., 2008). However, I would suggest it is vital that students are also given support with the process of gaining NHS approvals and permissions for their research. In my own study, the uncertainty and unfamiliarity with the approvals process, along with the difficulties experienced in locating relevant knowledge and information far outweighed any concerns about the ethical issues that might have arisen from the project. This mirrors similar difficulties experienced by the participants in Brindley's (2012) research. He argues that support is often sought from those who are unfamiliar with NHS ethics arrangements as student researchers experience a separation between the university setting and NRES (Brindley, 2012). The situation is compounded by the differences in structures and functions of Research Support Offices in the NHS or the Higher Education Sector, resulting in few common standards, systems or processes in place to support research and researchers (Perkins, 2011). It is also notable that the Health Research Authority (HRA) offers no training specifically for student researchers. Consequently, the absence of appropriate support and partnership working between universities and research ethics offices renders the process of completing ethics applications and gathering appropriate documentary evidence a complex and challenging task for students.

Despite the recent changes to the NHS governance process, for student research projects, the system remains excessively bureaucratic and time consuming. There is much discussion of delays and time constraints pertaining to ethical approval and NHS permission for research (Stalker et al., 2004; Thompson and France, 2010; McDonach et al., 2009). However, the time taken to understand and negotiate the system correctly and complete the necessary paperwork makes for a more extended process. Recognition of this issue is of great importance for research students who may be required by their university or funder to begin their research within specific timescales. Proportionate Review may go some way to resolving some of the challenges experienced by student researchers. Student projects are often conceptualised as relatively 'low risk' (van Teijlingen et al., 2008; Wilkinson, 2008) and it has recently been acknowledged that the introduction of PR has resulted in the delivery of impressive timelines for the approval of low risk studies (House of Commons Science and Technology Committee, 2013). However, my experience suggests that the PRS are unable to review all types of student research because the concept of low risk is difficult to quantify (Edwards and Omar, 2008).

It would appear from my case study that it is problematic for both RECs and researchers to distinguish between projects with material ethical issues and those without. Consequently, it has been argued that the only appropriate means of identifying risks and ethical issues is consideration by a full REC committee (Hunter, 2006), although in contrast, some have reservations about a 'one size fits all' approach to ethical review (Brown et al., 2007; Bedward et al., 2005; Wilkinson, 2008). The swift ethical review of research has obvious benefits for students. However, at present this is only possible via the PR process and in its current form this is not ideal for the review of all student research. Given that researchers are not invited to attend the PR Sub-Committee meeting, there can be an absence of researcher involvement in their discussion. In my case, the PRS did not make any contact with me until their decision was reached. This meant that I did not benefit from the learning experience that attendance at the full REC meeting gave me and I was unable to defend the ethical and methodological decisions of my project that were scrutinised by the Sub-Committee. This created a sense of being voiceless during the review process, which is a concern also raised by other student researchers (Tan, 2004; Brindley, 2012).

Creating opportunities for dialogue between ethics committees and student researchers during review meetings is important and offers one way to overcome such challenges. For this reason, the full REC review given to my study offered greater advantages to PR. Nevertheless, it remains questionable as to whether student research should be subjected to the same level of ethical scrutiny as other types of high risk clinical research. The current NHS governance system needs improvement in order to suitably accommodate student projects. Greater tolerance of the imperfections associated with the applications of less experienced researchers is required. As Wilkinson (2008) explains, RECs should show less concern about student studies that do not meet the standards expected of senior researchers. He argues that such studies would be acceptable on the basis that they constitute overall benefit by increasing knowledge of research design, the ethical practices underlying research and of the ethical review process (Wilkinson, 2008). This position is acknowledged by NRES, who state RECs should recognise that student research may not be of the same scientific quality or importance as other professional research, though it may still contribute to knowledge (NPSA & NRES, 2010). The voices of students are largely underrepresented in the literature on NHS governance. This case study offers an account of the inherent difficulties facing students who require NHS approvals and permissions for research. While a limitation of the study is that it may not be generalizable to other student researcher experiences, many of the difficulties I have reported are not unique and have been described elsewhere.

## Conclusion

The issues raised by this case study should not overshadow the debate about ethical principals in research. However, it is important to recognise that students face a number of issues and challenges in attempting to conduct research in clinical settings. NHS review of student research is identical to that of more experienced colleagues. The application process is both time consuming and complex and there is a lack of support for students to successfully negotiate this. The situation is compounded for those in non-medical areas. Perhaps an unintended consequence of current NHS governance arrangements is that rather than protecting the vulnerable it represents a significant barrier low-risk student projects (van Teijlingen et al., 2008). The consequence is that some students abandon or radically change their project plan and may not stand to benefit from the learning experience that research in a clinical setting can provide. Therefore, investment in the provision of support and advice to student researchers and partnership between universities and local research ethics offices is greatly needed.

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[i] Phase one trials aim to test the safety of a new medicine (NHS Choices, 2014)

[ii] Cross-infection risks prevent those with Cystic Fibrosis from meeting face-to-face. This is because people with CF are vulnerable to specific bacteria that grow in their lungs.