

# The NHS research governance process: a researcher's experience

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## Abstract

*Health research that seeks the participation of patients requires ethical and administrative clearances through the NHS research governance process. This is a two-stage process which involves a central Research Ethics Committee (REC), and Research and Development (R&D) at specific Trusts. Reflection is undertaken from a researcher's perspective on their experience of negotiating NHS research governance, including R&D within six Trusts, to obtain clearance for a qualitative study. The REC offered a clear framework for the researcher, but the committee meeting focused on scientific merit to the exclusion of more distinctively ethical matters. Furthermore, while the committee was receptive to a qualitative proposal, the administrative apparatus of the REC is potentially more conducive to clinical/quantitative studies. While the REC offered a clear procedural framework, this was absent from Trusts' R&D processes. There is greater scope for NHS research governance to be undergirded by complementary ethical and administrative review processes.*

## Introduction

This paper presents the experience of a researcher who obtained clearance for their health-related project via the NHS Research Ethics Committee (REC), and subsequently Trusts' Research and Development (R&D) processes. The purpose of the paper is to offer a personal account that highlights areas where this overall research governance process might be improved, thereby enhancing outcomes for both researchers and the NHS.

So that I could undertake my qualitative PhD study with Staffordshire University (who were the sponsor organisation of this research) I applied to the REC for ethical clearance, and following this stage I initially approached five NHS Trusts to seek site-specific R&D clearances for my study to allow access to patients via these Trusts<sup>1</sup>. Shortly after this period I approached a further Trust, and it is my experience of working with these six Trusts that is under consideration in this paper. Undertaking a multi-site study presented an opportunity to formulate distinctive insights on the pursuit of endorsement for a study via a number of NHS organisations.

The intention is to focus on systemic elements of the process that might be improved; it certainly is not a critique of any particular Trust or department. The NHS professionals that I worked with throughout this process were consistently approachable and helpful. However, as with any system, there are areas that might be enhanced and this paper endeavours to highlight where such enhancements could be made.

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<sup>1</sup> These clearances were sought and obtained in 2011.

## Context

The role of NHS RECs is to protect research participants (including service users, relatives and staff) from harm and to ensure that research is compliant with recognised ethical standards. Nevertheless, it has been highlighted that researchers spend a substantial amount of time justifying their research to RECs and R&D departments, which erodes research time on projects (Watson & Gelling, 2012, p.2097).

In a reflective paper on studies that failed to obtain REC approval, Folstein & Quilligan (2011) recognise that the research ethics review is an important process. However, they report that the intensity of the committee meeting was challenging for inexperienced researchers. In addition, it was felt that the REC had a quantitative/clinical orientation and was therefore not sufficiently receptive to their qualitative and experientially-oriented proposal. This point is reinforced by Shaw et al. (2009) who undertook telephone interviews with researchers who had sought NHS ethical clearance. Those employing qualitative approaches felt that governance systems favoured clinical or laboratory studies. This forced researchers "to pre-empt things that they would prefer to keep more open-ended" (Shaw et al., 2009, p.917) thus undermining the foundations of their research principles. The authors therefore highlight that there is a tension between the required breadth and flexibility of approaches seeking to explore health-related domains, and narrowly defined administrative procedures "that stripped away these very qualities" (Shaw et al., 2009, p.918).

The particular mode of ethical scrutiny that should be applied to qualitative research is explored by Larkin, de Casterle & Schotmans (2008). It is argued that the constraints of ethical application systems might not be conducive to the evaluation of qualitative research proposals. A relational ethics perspective is required which recognises the process of how relationships are negotiated within research practice. This can prompt a more theoretical evaluation of research protocols, shifting emphasis to asking the ethical question rather than solving the ethical problem (Larkin, de Casterle & Schotmans, 2008, p.240). Such insights arguably have particular relevance within dementia research, as relationships substantially shape the experience of the condition and have the scope to sustain or undermine positive self-perceptions of personhood (Kitwood, 1997). This is not just a matter for detached research scrutiny: the importance of conducting oneself appropriately in research encounters, acknowledging the person with the condition's personhood and how it is shaped by social interactions, is of paramount importance for the researcher when reflecting on their own conduct (Cowdell, 2010).

Articles also consider the R&D process specifically. Drawing on their experience of navigating the governance process, Jonker, Cox & Marshall (2011) highlight the challenges of seeking clearance via more than one NHS Trust. "The authors' experience is that gaining the approval of several trusts' R&D committees can be a contradictory, lengthy and tedious process" (Jonker, Cox & Marshall, 2011, p.262). This can delay research or even dissuade potential researchers from pursuing projects. Reflective accounts from other multi-site research studies endorse this point. Elwyn et al. (2005) stated that it took 150 days to gain ethical clearance. This is argued to be an underestimate by Walters (2005) who sought clearance from multiple Primary Care Trusts: it is argued that 9 to 12 months should be allowed for ethical approval when seeking this extent of research clearance. This point is reinforced in a journal editorial: "There is very often a lack of simplicity and consistency between Research and Development (R&D) departments at different NHS Trusts and, consequently, multi-centre research in particular, has become a logistical nightmare (Gill & Burnard, 2009:137).

## Reflective methodology

As highlighted in the introduction, this paper is based upon a researcher's reflective evaluations of the NHS research governance process. Reflection in this instance presents a multi-layered approach to analysis, based on *reflection in action* and *reflection on action* (Schön, 1983). Reflection in action accounts for how insights were actively formulated during engagement with the governance process through the application stage, interacting with administrators and participating in meetings. Reflection on action is predicated on a degree of temporal detachment and situates the 'reflector' as an observer of prior activity, as they reimagine and re-evaluate key interactions and occurrences. The reflective vantage point from which the governance process is evaluated will also be defined by later experiences accumulated within the research process itself.

This temporal extensionality produces a somewhat paradoxical situation, whereby the reflective researcher operates as an observer analysing themselves as a research subject. Two particular and disparate perspectives on the phenomena under enquiry are therefore unified under one multifaceted reflective approach. Although the integration of two or more perspectives leads to new forms of perception, each contributing perception is still situated, leading to a particular rather than a general perspective (Brueur & Roth, 2003, para 4).

Recognition of the situatedness of reflective insights does not, however, mean that these insights must be excessively circumscribed. A credible notion of interpretation can facilitate an expansive reflective orientation that accounts for the intersection between situated subjective judgements and more extensive/durable features of the social fabric. The *hermeneutic circle* helps to forge conceptual links between these levels of phenomena: this concept relates to grasping the iterative relationship between micro-units of experiential data and the research process as a whole (Smith, Flowers & Larkin, 2009, p.28). For example, when reflecting on the research governance process it is important to recognise that no stage exists in isolation from other stages. While a particular administrative feature of governance might be scrutinised, this feature should not be viewed as a discrete phenomenon: it will relate to the ethos and principles of the broader governance process and could thus have far-reaching implications by impacting upon research practices and the orientation and aspirations of researchers.

## The research ethics committee

### *A clear framework*

As my study sought the participation of patients with dementia (in semi-structured interviews) it was necessary for me to seek clearance from the REC. My application to the REC was unsuccessful at the first attempt. Whilst it is disappointing not to receive endorsement for a project, the experience of negotiating this stage of ethical clearance was generally positive. The REC provides clear timescales for the provision of responses; for example, applicants will receive a response within ten working days following the REC meeting, and an overall decision is made within 60 days from the initial application. The opportunity for additional feedback was also provided and I had a telephone conversation with the Chair about my presentation to the REC. It was therefore possible for me to understand where my application required strengthening and what measures I could take to ensure that it had a greater chance of obtaining clearance at the second attempt.

As a researcher seeking NHS ethical clearance for the first time, the experience was positive and instructive. The clarity over timescales and helpful feedback mitigated some of the anxiety

that can be induced by a potentially daunting process – a process that has the scope to hold up a project that the researcher is eager to commence. The feedback ensured that I addressed any aspects of my protocol that were insufficiently robust. As a result of taking the required measures, my application to the REC was successful at the second attempt<sup>2</sup>.

### *A focus on scientific merit to the exclusion of ethical scrutiny?*

A query that the REC process raised was whether questions focused on methodology/scientific merit to the exclusion of more specific ethical considerations. I have been presented with some particular ethical dilemmas during my research and reflected on whether these are the types of situation that could be addressed more directly at the REC. Such situations prompted me to consider whether the REC had primed me sufficiently with regard to ethical decision-making, or if the process was skewed slightly too much towards methodological scrutiny. For example, on one occasion during the fieldwork for my study I arrived for an arranged interview with a person with dementia and their carer and it appeared that they were not at home. While a relatively straightforward matter, it has potentially serious implications if the researcher opts to take no action and fails to raise the matter with their clinical contact.

In addition, the REC meeting could be utilised to help the researcher consider how research interactions will be managed in practice; for example, if a participant exhibits emotional discomfort or distress. Documenting principles of appropriate practice in the REC application is just one stage of this process; managing actual emotional situations in the presence of others is substantially more challenging. It is also important to recognise that methodology and ethics are not independent realms: technical and ethical matters will intersect (Carson & Fairbairn, 2002). Ethical review should take in to account this intersection, evaluating both the scientific feasibility and ethical dimensions of a proposed approach to enquiry.

In this study a joint interview approach was selected, with the person with dementia and their carer interviewed together. This introduces the requirement for particular evaluations to be undertaken if a person exhibits any distress during the interview. The researcher has to be mindful of how the process is impacting on both the person with dementia and the carer, and also with regard to how any ethically-based decision will affect the relationship between these two people. The decision as to whether to continue or terminate an interview is therefore rendered more complex by this interactional complexity. It has been highlighted that a potential disadvantage of the joint interview process is that it has the potential to stir up antagonisms and conflict (Arksey, 1996). This in itself presents a challenge the interviewer, but there could also be a lack of consensus between participants as to whether it is appropriate to continue with an interview. Under such circumstances the researcher is negotiating a decision-making process that has the scope to impact negatively upon both participants.

Health research is an interactional process often involving contact with vulnerable people: it could therefore be efficacious for the ethical clearance process to prepare the researcher as much as possible for engagement with this setting. Whilst it is obviously not possible for a REC to cover every eventuality that might be encountered, some scenario-based questions focused on particular ethical matters might help to establish that the researcher has the capacity to effectively negotiate certain dilemmas. This would also help to orient the researcher towards the ethically complex situations that could occur, such as those discussed above. Contemplating challenging scenarios can help the researcher to anticipate the process of ethical decision-making and to mentally situate themselves in complex empirical settings, prior to undertaking

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<sup>2</sup> From the initial application to clearance, the REC process took approximately four months.

their research. This is reminiscent of the approach to relational research ethics discussed in the 'Context' section above which focuses on raising questions rather than problem solving (Larkin, de Casterle & Schotmans, 2008).

Furthermore, a system could be put into place whereby researchers can offer feedback on ethical matters that have been encountered during the research process. The REC currently requests a 12-month update from researchers: this seeks information on a number of topics including the sample obtained, whether there have been any protocol breaches, and whether the researcher requires any advice on ethical issues. However, it does not request feedback on any ethical dilemmas or issues that the researcher has encountered and addressed. A system to receive feedback on such matters could enable the NHS to be better informed with regard to the ethical issues that arise during research with patients. This system could also inform the REC process by offering examples of ethical matters that researchers should be able to evaluate before they commence a project.

### *Administrative exactitude versus flexible research*

It is highlighted in the 'Context' section above that RECs might be more attuned to the assessment of quantitative/clinical research to the detriment of more open-ended qualitative approaches. I found the REC receptive to my qualitative proposal and any overt preference for quantitative/clinical approaches was not discernible. Nevertheless, further to the perspective of Shaw et al. (2009), assessing research with reference to a particular set of administrative principles is arguably more suitable to the scrutiny of quantitative research designs. There does seem to be a tension between seeking precision from the researcher with regard to their research proposal and the requirement for flexibility when undertaking qualitative research. It is perfectly reasonable that the REC should seek clarity on the intentions of researchers with regard to their protocol. What can perhaps be scrutinised is what degree and format of clarity can be established prior to undertaking research, and if an inapplicable standard is likely to hamper rather than facilitate effective empirical study.

For example, in this research I sought a sample of younger people with dementia and initially set the upper age parameter at age 60, although I stated in my application that this could increase to 65 if recruitment proved too difficult. This was deemed too imprecise by the REC, and in my resubmission to the panel I removed reference to potential revisions and merely stated the initial age parameters that I was setting. Upon commencing the research, it did prove excessively challenging recruiting a sample within this age range. I therefore submitted a formal amendment to the REC for the age parameter to be raised to 65, as per their requirement to notify the committee of any substantial revision to the protocol (i.e. an adjustment to the design of the research). This amendment was subsequently approved.

While it was possible to adjust my research framework it would perhaps be preferable if flexibility could be accommodated more readily at the outset of the governance process. A substantial amendment to a protocol requires the completion of additional paperwork for clearance from the REC (via Chair's action), which then had to be forwarded by the researcher to Trust R&D departments. This therefore generated more work, both for the researcher and NHS staff.

Scrutiny does therefore need to be applied to reconciling the REC's requirement for stated procedural clarity and the reality of research processes that are not so readily coerced into predetermined parameters. The imposition of a particular fixed notion of administrative clarity is not particularly conducive to the actual processes of research which should be built on flexibility and awareness of contingencies. It has been argued that RECs are excessively bureaucratic

(Robinson, Murdoch-Eaton & Carter, 2007) and it could also be the case that this lends itself to a mode of binary 'tick-box' exactitude. This is therefore pursued at the expense of nuanced definitions of research effectiveness, which are particularly applicable to certain qualitative approaches (Riessman, 1993, p.64).

This process also has the potential to perplex an inexperienced researcher, who is obliged to package their research neatly for the bureaucratic requirements of the REC, only for this packaging to become unravelled when presented with the complexities and irregularities of empirical study. The argument is not that research should be predicated on rootless, 'anything goes' grounds. What is being claimed is that a 'category mistake' (Ryle, 1969) is being committed in imposing a misplaced definition of rigour upon the empirical process. Genuinely rigorous research is not defined by fixed and narrow *a priori* parameters, but is built upon clear and flexible foundations upon which meaningful data can be generated. If RECs are increasingly able to relate to this actuality then they can help to facilitate and promote effective, rigorous research which is predicated on openness and adaptability.

## Research and development

As highlighted above, the REC process was underpinned by clearly outlined procedures which help the researcher to navigate the process. The R&D process lacked this sense of clarity overall. Although this might be expected to some degree when dealing with six organisations rather than one central committee, this paper considers how certain aspects of the procedure might be rendered more effective and consistent. All Trusts require the REC documentation and supporting information to be sent prior to initiating their clearance mechanisms. Nevertheless, my ongoing involvement in this process varied across the Trusts. Of the six Trusts, the key differences in experience can be categorised as follows:

- At one Trust, the administrative process had some key differences in comparison with the other Trusts
- At one Trust, I had to seek additional management endorsement before clearance was obtained
- At two Trusts, clearance was obtained following a further committee meeting
- At two Trusts, R&D clearance was received with no further input required from me

These differences are also addressed in the following table:

**Table 1.** Variations in R&D process across NHS organisations

Organisation	Committee	Additional management clearance	GCP training	NHS signature on SSI	Clearance available within (no. of months)
Trust 1			✓	✓	5
Trust 2		✓			1
Trust 3	✓				2
Trust 4	✓				6
Trust 5					2
Trust 6					1

This paper will now deal with the key matters over which the R&D procedures diverged. (The Trust numbers in the table above are used within the text).

### *Administrative differences*

R&D offices are required to implement mechanisms and processes that complement the particular Trust, or Trusts, that they support. As NHS organisations differ in their structures and services, it is therefore likely that there will be differences in the approaches of different R&D functions. It would be unreasonable for a researcher not to expect divergent processes to be present to some degree across different R&D offices. However, it can be argued that procedures should be as consistent as practicable across the NHS to facilitate the effective navigation of R&D protocols. The divergence in timescale was also quite pronounced: two R&D offices were ready to clear the application within one month; another two were ready within two months; but two Trusts took over four months to grant clearance. Having already navigated the REC process, waiting several further months for R&D clearance could substantially impede a project, particularly if a researcher is dependent on only one or two sites.

Within one R&D office approached for this research project [Trust 1], a number of administrative procedures were quite markedly different from the other five offices. For example, it was necessary for the researcher to have obtained Good Clinical Practice (GCP) training prior to receiving clearance. I had attended this training so it did not delay my application, but under other circumstances it may have impeded a researcher from commencing their project. Whilst GCP training may be a reasonable requirement for a researcher seeking to work with the NHS, this point has been raised to highlight a divergence in stated requirements from different Trusts; only one Trust treated GCP clearance as mandatory. Such divergences could be disorienting for a researcher seeking clearance from multiple R&D offices, and a variety of stipulations across organisations could also delay the progress of a project.

In addition, a section of the Site-Specific Information Form (SSI) requires a signature from the supervisor supporting the project and it is highlighted that a university signatory might be appropriate if there is a partner arrangement between the university and the Trust<sup>3</sup>. For five Trusts it was deemed appropriate for my University supervisor to sign this section. However, one particular R&D office [Trust 1] requested the signature of the NHS manager who was supporting the research within the Trust. It could have been more clearly established who was required to sign the application, and there is perhaps some ambiguity with regard to what constitutes a partner relationship between a university and NHS organisation. As highlighted above, it might be reasonable to demonstrate support from within the Trust by way of the relevant manager/clinician signature. However, as an external researcher it might prove quite difficult to obtain this signature, and it did hold up this particular process. It could be argued that internal checks undertaken by a R&D department could establish that support measures for the research are in place within the Trust, as stated by the researcher in their SSI application.

### *Management clearance*

With all R&D applications it is necessary to list the key Trust contact who will assist with this research. With all six of my applications I listed the Consultant Psychiatrist as a designated contact: these links had been facilitated by my University supervisor. I also listed in the

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<sup>3</sup> Section 23 of the form 'Authorisations required prior to R&D approval' addressed authorisations by managers within NHS organisations. However, guidance for this section also stated 'Where university employers have arrangements in place with partner NHS organisations, authorisation from the university to the NHS organisation can be provided in this section.'

applications any details of additional professionals I had spoken with who were likely to assist with the research. In five cases this was deemed sufficient, but with one application the R&D department sought additional confirmation from the team manager who would be helping with the recruitment [Trust 2]. This manager then felt that it would have been prudent if authorisation had been obtained from their line manager first. This required me to seek additional clearance. Eventually the Director of Operations provided an email to confirm that the research could proceed. I had contacts within this Trust so was able to seek out this confirmation, but if the same situation had arisen at another Trust then this process could have become quite tortuous as I sought the relevant level of management clearance.

It is certainly appropriate that each R&D office should seek to obtain relevant assurances from within the Trust that research can be supported without this negatively impacting upon service delivery. Nevertheless, with five R&D applications the endorsement of the listed Consultant was deemed sufficient. (If further checks with other professionals were undertaken then these took place without my involvement.)

There could therefore be some clearer guidelines for researchers with regard to the level of clearance that is required. Does the Consultant overseeing the research offer sufficient endorsement, or is the manager actively assisting with the research also required to offer their independent confirmation of their service's capacity to assist? It may of course be reasonable to establish feasibility with more than one professional, but in terms of the R&D process for the researcher, guidance could perhaps be clearer with regard to the extent of clearance they need to obtain to support their application.

### *Additional committee stage*

The key divergence across the R&D processes from a researcher perspective was the convening of a committee within two of the Trusts. One of these took place without my attendance required, but for the other (in a similar situation to the REC) I was invited to attend and present on my research protocol. At the majority of the Trusts to which I applied, no further input was required from me with regard to the scientific merit of my protocol and it did not appear that a formal committee was convened before clearance was obtained. My understanding of the R&D process is that it sets out to establish that the organisation can accommodate the project, that the researcher is appropriately supervised, and that the costs of the research will be covered by the sponsor organisation. Nonetheless, it appeared from the Trusts that convened a committee that checking on scientific merit and research methods remained a feature of the process, despite these being addressed comprehensively at the REC.

At the Trust where I was not required to attend [Trust 3], a member of the committee emailed following the meeting as they required further clarity on my research protocol, in particular with regard to the methodology. This led to an email exchange which spanned two weeks until the required clarifications had been provided. An additional aspect of the R&D process is the Research Passport which the researcher has to have signed off by their nominated lead Trust. This covers checks, undertaken via the sponsor organisation, such as Occupational Health and criminal record. The Trust I had nominated as lead undertook this aforementioned committee stage and I had received clearance from two other Trusts whilst waiting for this process to conclude. I was therefore unable to commence my research with the Trusts that had offered clearance, as the Research Passport can only be signed off by the lead Trust at the same time they complete their own R&D process<sup>4</sup>.

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<sup>4</sup> The length of time from my initial REC application to the stage where I was able to commence my research was approximately six months.



This actually led to a situation whereby two Trusts were contacting me with regard to the status of my Research Passport, as they were ready to sign-off my R&D application. As REC clearance had been granted and I had received R&D endorsement from other Trusts I was ostensibly ready to commence my research. Whilst the Research Passport is an essential part of the administrative clearance, it could perhaps be considered whether it needs to be tethered to the overall R&D process of a particular Trust. The Research Passport and site-specific clearance are to some extent separable parts of the process: whilst both are required to work with a particular Trust they relate to a different range of checks, with the former linking to checks on the individual researcher and the latter relating to the research project. Conceivably when working at more than one site, a lead Trust could establish that they are unable to accommodate a particular project for site-specific reasons, which accordingly would appear to mean that the Research Passport cannot be signed off by them either. This could lead to some complications and delay with another Trust then needing to be nominated to sign off the Research Passport. These complications could be engendered despite the clearance of the Research Passport being otherwise straightforward, with all checks having been undertaken by the sponsor organisation.

With regard to the second Trust that convened a committee [Trust 4] I was invited to attend this meeting. At this meeting I addressed a number of questions, the majority of which related to research methodology. The period from R&D application to clearance was the longest with this Trust. This indicates the potential for delays when a supplementary committee stage is employed.

It must be recognised that Trusts are obliged to follow the procedures that they feel are necessary to ensure that they are able to accommodate research. However, the key query with regard to utilising a committee at the R&D stage is whether it duplicates evaluations that are undertaken at the REC: a second forum that reviews a project's scientific merit in detail is replicating the scrutiny applied at a prior stage of the process. The convening of a committee at the R&D stage has the scope to delay the clearance process as it is dependent on a fixed meeting date. In addition, in contrast to the REC, no clear timescales are offered for when a particular stage of the process will be completed e.g. when a researcher will receive confirmation of the committee's decision following a meeting.

The relationship between the REC and R&D processes perhaps needs to be documented more clearly so that duplication of effort can be avoided. As acknowledged above, Trusts will need to ascertain whether research applications are viable, but the REC has already taken on some of this task by checking on the ethical and methodological dimensions of the project at a meeting attended by a range of professionals and laypeople. Drawing on the notion of 'lean', an effective system should ensure that the parts of a process are complementary rather than repetitious, and thus add value (Fillingham,2007:232-233). By the R&D stage a research application has been rigorously checked with regard to methodological and ethical matters at the REC. Such a system enables the R&D stage to focus on more site-specific matters, such as whether the organisation has the scope to accommodate the research. The aim of this paper is not to prescribe the tasks that R&D functions undertake, but merely to suggest that, under any system, if the orientation of separate stages is very similar then this might lead to a less than optimal focusing of resources.

## **Conclusion**

This paper has presented a researcher's experience of the NHS research governance process, and offered insights into how REC and R&D stages of this process interrelate. It can be argued

that an effective system will employ complementary stages, present clarity of process, and also demonstrate consistency of practice from those engaged in delivery. The REC/R&D system is well equipped to offer complementary evaluation of the ethical and practical values of a research application.

My experience, however, suggests that more faith could be placed in the ethical and methodological assessments of the REC, to ensure that NHS professionals are not duplicating efforts in assessing projects. Furthermore, researchers would benefit from a process under which later stages of the process do not repeat the orientation of earlier stages. Scrutiny could also be applied with regard to whether more emphasis could be placed on preparing researchers for the ethically complex situations that they might encounter. In addition, it can be queried whether the requirement of RECs to pursue a specific mode of procedural clarity complements the flexibility of process required for effective research practice. This arguably has particular implications for qualitative research which is oriented to the exploration of experience and relationships.

It has also been demonstrated that the REC assists the researcher by offering clear timescales for its stages and responses. R&D processes lack this clarity. The argument is not that R&D processes should be precisely the same across all Trusts, as differences in approach may be necessary to meet a particular organisation's local configurations and requirements; but this paper has indicated some key areas of practice that could be clearer and more consistent across Trusts. The experience of this research is commensurable with that of other authors discussed in the 'Context' section of this paper who encountered delays and inconsistencies when seeking clearance for multi-site studies.

It has to be recognised that Trusts are obliged to ensure that they can accommodate research that is ethically sound and must take the measures they feel are necessary to make sure that the required evaluations are undertaken. This paper does not set out to challenge this principle, but suggests that scrutiny could be applied to aspects of the REC/R&D process to ensure that the NHS is able to undertake such evaluations more effectively.

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## **Acronyms**

GCP: Good Clinical Practice

SSI: Site-Specific Information

R&D: Research and Development

REC: Research Ethics Committee