A practical guide to attaining research ethics approval in the UK

Tod AM et al (2009) A practical guide to attaining research ethics approval in the UK.

Summary
This article examines the permissions and approvals required for nurses and other health professionals to conduct research in the NHS in the UK today. A fictitious example of a research study conducted by a nurse who did not obtain NHS research ethics committee (REC) approval is provided. The current position regarding the REC approval process, including the role of ethics in research governance, is explored. The differences between research, audit and service evaluation are explained. Finally, the main ethical issues to be addressed in an application for REC approval are summarised.

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A larger study involving patients Pam decides to conduct an exploratory study. This initial study involves interviewing staff to obtain their views on the care needs of the patient group and what they think are the gaps in care.

As the study involves talking to colleagues and is being conducted locally, Pam thinks it does not require research ethics or governance approval. Her findings are illuminating. They raise a number of questions for practice and further research. Pam considers that they are worth publishing. However, on submitting an article to a journal she finds that it cannot be considered for publication because the necessary approvals have not been obtained. Her research is never published or disseminated.

Scenarios such as this result in knowledge being lost that is of great potential value and use to nursing practice. In addition, nurses who are just starting to engage in research may become dispirited and give up thoughts of further research. This will have a knock-on effect on nursing’s pool of evidence.

Approval to conduct research
Pam should have sought two types of permission:
- NHS research ethics committee (REC) approval.
- NHS research governance approval.

These are not the same, although they are often spoken about in the same way (Box 1). Research ethics approval is provided by an NHS REC. Research governance approval is provided by the appropriate NHS organisation(s), for example trusts and primary care organisations. The UK comprises four countries: Scotland, Wales, England and Northern Ireland. There are some variations in health administration between these
Research Ethics Committee approval

The REC approval system is run by the National Research Ethics Service (NRES), which is part of the National Patient Safety Agency. NRES seeks to maintain a UK-wide system of NHS ethical review. The actual review of individual research projects is conducted by RECs. The framework and standards for the membership and conduct of RECs are laid down in the Department of Health document Governance Arrangements for NHS Research Ethics Committees (GAfREC) (DH 2001). GAfREC is under review and a new edition is expected to be published this year.

RECs include clinical, academic, research and lay representatives. In England and Scotland the strategic health authority (SHA) is the appointing authority for RECs and is accountable for the establishment, support, training and monitoring of RECs. In Wales and Northern Ireland responsibility lies with the Wales Office of Research and Development for Health and Social Care and the Department of Health, Social Services and Public Safety respectively.

There are four main activities to consider in relation to REC approval:

- Establish whether REC approval is necessary.
- Identify which REC to submit the research to.
- Submit the application.
- Attend the REC meeting and address any issues raised.

Each of these tasks is discussed briefly using Pam’s study as an example. Further information and guidance on all the tasks can be found on the NRES website (www.nres.npsa.nhs.uk/).

Is REC approval required? To answer this question Pam would need to decide whether her project was best described as research, audit or service evaluation (Box 2).

Nurses may be confused about the difference between research, audit and service evaluation (Box 3). Where doubt persists about how to describe or define a project nurses should ask the local NHS R&D department or REC for an opinion, or email NRES (queries@nres.npsa.nhs.uk). If asking the REC for an opinion it is worth asking for a written response on headed paper so that you have a record of the decision. This means that documentary evidence of efforts to seek appropriate permissions to conduct your research is available for research project files.

Having decided that the project is research, the nurse then needs to decide whether it is NHS-based research. If it is, ethical approval from the appropriate REC is required. A project is NHS-based research if it involves (DH 2001):
Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient’s or user’s past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions such as care homes.

- Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above.
- Access to data, organs or other bodily material of past and present NHS patients.
- Fetal material and in vitro fertilisation involving NHS patients.
- The recently dead in NHS premises.
- The use of, or potential access to, NHS premises or facilities.
- NHS staff – recruited as research participants by virtue of their professional role.

In Pam’s case, the research project is NHS-based. Therefore it requires REC approval.

Whether Pam is conducting an audit, service evaluation or research project, she should ensure that it is good quality. As her project is research, this means that it should be good science. Essentially, it should be able to answer the questions it sets out to answer. RECs require that all projects they receive have had an independent scientific review before they review them. This can be done in various ways. If Pam was undertaking her project as part of a university course then that institution would usually have a system to provide such review for its students. If Pam was acting independently, the R&D office of her employing health body might provide it.

**Where should the research be submitted?**

If a research project falls into one of the following categories the research application should be submitted directly through the NRES website; the NRES central allocation system will then allocate the proposal to a REC:

- Studies that involve a clinical trial of an investigatory medicinal product.
- Studies that involve a medical device.
- Research involving children.
- Research that includes participants who are prisoners.
- Research that involves adults with incapacity to give consent.
- Research that involves a human tissue bank application.

**NURSING STANDARD**

**Guidance on research, audit and service evaluation**

1. When deciding whether a project is research, audit or service evaluation it is necessary to be guided by the underlying purpose of the project and question to be answered. It is important to choose the process that has the best fit for the required project. Novice researchers may describe and define a project as audit or service evaluation because it is seen as an easier option in terms of approval processes.

2. Where the decision is to conduct audit or service evaluation and not research, the NHS organisation in which the project is conducted will still have to approve the project for management purposes.

3. The same or similar ethical issues need to be considered when designing and conducting audit, service evaluation and research. The project protocol should address issues such as informed consent and confidentiality, the rights of participants to withdraw from the study and how study data will be used for dissemination and publication.

4. If a research project is being conducted as part of a higher education degree then nurses might have to satisfy additional university research ethics and governance processes. The supervisor at the university should provide advice.

- Research that involves gene therapy.
- Research taking place in more than one site or domain. A domain is the area covered by an SHA in England, health board in Scotland, regional office in Wales or the whole of Northern Ireland.

All single site research should be submitted directly to the local REC. This will be the case for most small studies conducted by nurses, like that conducted by Pam. However, if in doubt, contact the administrator of the local REC or NRES for advice.

**Submitting the application**

A number of documents need to be submitted as part of an REC application. NRES provides a checklist to help. For clarity the documents have been divided here into four parts.

First, a research protocol needs to be completed. The protocol should describe fully the research aims and methods. It should also justify why the research is necessary, why the particular methods have been chosen and demonstrate that they are adequate to answer the research question. Any ethical implications of the research should be outlined and addressed.

Second, the form on the NRES website should be completed. Application for REC review is through an online process called the integrated research application system. You will need to register before completing the application and there are instructions on how to do this on the NRES website. This can seem daunting but the process is straightforward and help and guidance are available on the NRES website. The online
form is programmed to filter unnecessary questions once the filter page at the beginning of the form is completed. For example, in a small interview-based study researchers will not be asked questions about drugs or statistics.

When completing the form keep the language simple and do not be tempted to use academic or clinical jargon. Where the form asks for lay language, use lay language. All members of the REC receive a copy of the application form and it is important that the contents are accessible to and understood by the range of committee members, including lay members.

Third, all documents relating to research participants will need to be developed and submitted. These include participant information sheets, consent forms, interview schedules, questionnaires, any covering letters or recruitment advertisements or posters. Guidance on the content and structure of participant information sheets and consent forms is set out on the NRES website. Note that you might be asked to provide participant information sheets in different languages if you are working in a multicultural environment. In Wales, it is a legal requirement that information is provided in Welsh and English.

Finally, other supplementary documents will be required. These include letters from sponsors, any funding body, a statement guaranteeing indemnity and copies of any independent scientific review that the study has undergone (this may have been arranged as part of the research governance process or an application for research funding). The sponsor for a study is the individual or organisation taking overall responsibility for the conduct and standard of the research. For nurses the sponsor will usually be either the NHS organisation or university if the study is conducted as part of a course. The ability to provide these documents is a good illustration of how early contact with the R&D department can pay dividends. These aspects of research governance can be addressed immediately.

Attendance improves the efficiency of the process as minor issues can be addressed immediately. By the end of the meeting the REC should be adequately reassured about the following issues, as applicable (DH 2001):

- Scientific design has been adequately peer reviewed.
- Proposed conduct of the study.
- Recruitment of research participants.
- Care and protection of research participants.
- Protection of research participants’ confidentiality, anonymity and privacy.
- Informed consent process.
- Local community considerations, for example translation of patient information sheets.

The REC has four options when making a decision:

- A favourable opinion.
- A provisional opinion with request for further information.
- An unfavourable opinion.
- No opinion. This is rare, but would occur where the REC has decided that no opinion can be given until a specialist referee has been consulted.

The REC is under an obligation to provide a decision within 60 days of submission. However, in the event of a provisional opinion the clock is stopped while waiting for further information or clarification. An appeals system exists for researchers who are unhappy with the decision given. Once ethics approval is obtained, annual progress reports are required along with an end of study report. The researcher is also obliged to maintain a site file which documents the conduct of the study and contains key papers.

The next section examines research governance, clarifying the difference between it and REC approval, and explaining their relevance in the research governance framework.

Research governance approval

The focus of this article is REC approval. It is, therefore, not possible to discuss extensively the research governance framework. Further detail is provided by the DH (2005). However, two key points are made here. First, research governance and REC approval processes should be followed simultaneously by researchers. Second, ethical approval is part of research governance approval. Research governance approval will...
not be given by an NHS trust or primary care organisation unless REC approval is granted.

The research governance framework document outlines the principles, requirements and standards of research in health and social care (DH 2005). It addresses the five domains of research governance:

- **Ethics** – ensuring the dignity, rights, safety and wellbeing of research participants.
- **Science** – ensuring that the design and methods of research are subject to independent review by relevant experts.
- **Information** – ensuring full and free public access to information on the research and its findings.
- **Health, safety and employment** – ensuring at all times the safety of research participants, researchers and other staff.
- **Finance and intellectual property** – ensuring financial probity and compliance with the law in the conduct of research.

The framework seeks to promote a quality research culture and a safe research environment in health and social care organisations. It sets out the responsibilities and accountability of all those involved in the research process. These are:

- The researchers (from chief investigator to the person collecting data).
- Clinical staff involved in research or care of a participant.
- The NHS organisation hosting the research.
- Universities and other employing organisations.
- The research funding body.
- The sponsor.
- The participant.

The legal and professional requirements of people and organisations involved in health and social care are all embraced by the research governance framework. It is a core standard for healthcare organisations and a core requirement of all people conducting research in the NHS. A nurse employed by an NHS organisation, for example a trust or primary care organisation who undertakes research without research governance approval, will be liable to disciplinary procedures by the employing organisation and may be in breach of the Nursing and Midwifery Council (NMC) code of professional conduct (NMC 2008).

Before submitting a research study to a REC it is necessary to register the project with the relevant research office or department in the relevant NHS organisation(s). They will give you a number that the project is registered under. This number will be entered onto the NRES form. Increasingly, there are calls to standardise and streamline research governance procedures (Dumville et al 2004, Elwyn et al 2005), but until that happens a study should be registered with and seek approval from each NHS organisation where the study will be conducted.

A range of issues need to be addressed as part of the research governance process. These relate to the five domains of research governance and include:

- A research protocol which has been subject to independent scientific review, for example by a funding body. If the protocol has not had independent scientific review the NHS organisation will have a system in place to conduct the review.
- A form with the basic information required to process a research governance application. Some NHS organisations have their own form but there is a move towards standardising the form. A commonly used research governance form is available on the NRES website.
- Indemnity – a statement is required either from the NHS organisation employing the researcher or from the supervising university to guarantee that it is in a position to compensate someone in the event of negligent harm.
- Finance – evidence is required that the financial implications of conducting the research have been reviewed and approved by the NHS organisation: for example, is there adequate research funding to carry out the research or are there implications for NHS resources as a result of the research being conducted?
- Health and safety – any risks to the health and safety of patients, participants and staff need to be identified and information provided on how they will be addressed.
- The researcher needs to demonstrate that data protection legislation and obligations will not be breached.
- REC approval is required.

Research governance approval will not be granted until all the above have been reviewed by the relevant NHS organisation. Some of the main ethical issues that all researchers should consider when designing a research study and submitting it for REC approval are now examined.

**NURSING STANDARD**
Ethical issues

The principles approach is a useful ethical framework (Gillon 1994). This states that healthcare interventions should attend to four principles. These are general rules that should be followed where possible and that require strong justification to break. The principles are:

- Respect autonomy – make sure people’s rights and ability to make decisions for themselves are not compromised.
- Beneficence – make sure that your interventions benefit patients or others.
- Non-maleficence – make sure that your interventions minimise any harm or risk of harm to the patient or others.
- Justice – make sure that your interventions are fair, that you do not, for example, discriminate against anyone.

Respect autonomy At the core of this principle is the belief that people should generally be allowed to make their own decisions about what they do, what happens to them and to information about them. In research, this can be ensured in a number of ways.

The first is through the mechanism of informed consent. You should ensure that proposed research participants take part freely and with adequate information and understanding. Participant information sheets are one way to ensure this. However, bear in mind that people often do not read these or may have literacy needs so it may be necessary to talk through them when asking for consent. When developing documents for potential research participants it is necessary to be aware of language issues. This means avoiding technical jargon and writing in a language appropriate to the target group, for example the Welsh Language Act 1993 requires equal provision of information in Welsh and English in Wales.

In terms of participants deciding freely, you need to think about whether they might feel pressured to give consent. This applies, particularly if you are a nurse caring for patients. For example, patients might feel scared to say no or feel a sense of obligation to participate. Role conflict, where the nurse is clinician and researcher, is a commonly discussed ethical issue in the nursing literature. This can affect patient autonomy if a participant feels obliged to take part in a study conducted by the nurse caring for him or her (Holloway and Wheeler 1995). The participant information sheet should emphasise the voluntary nature of consent. This applies equally to NHS members of staff. If you are someone’s line manager and you ask him or her to take part in your research project is he or she not likely to feel obliged to agree? Finally, consent may be a major concern with some research participants. This is the case with children, the mentally ill and those who may not have the capacity to consent at that time; see the Mental Capacity Act 2005 for further information. Where this is so, you will need to seek specialist guidance, such as that provided on the NRES website.

Privacy and confidentiality are other means of respecting autonomy. Privacy concerns those areas of participants’ lives that they wish to keep private; confidentiality concerns those private areas to which participants grant you access, but on condition that you will treat them as confidential. In general, this means that you will keep information in a particular circle: the research team and those charged with auditing that team. This should be made clear on the participant information sheet so that participants know where their details are going. RECs will want to be assured that you have measures to safeguard information: for example, you might keep data on a password-protected computer. Researchers using in-depth interviews sometimes have particular problems in relation to privacy. Interviews might stray into topics that interviewees would prefer to keep private. The interviewer needs to be sensitive to this and to say, for example: ‘Do you mind if I ask a bit more about that?’ and provide an option for the interviewee to say ‘Yes, I do mind.’

Beneficence Nurses are used to most of their interventions being aimed at benefiting patients. This changes when nurses are undertaking research. Your primary aim as a researcher is to find things out, perhaps with a view to benefiting patients in future. It is not part of their treatment and is not being done with their good in mind. If they choose to help you then that is good of them, but they are under no obligation to do so.

Non-maleficence Nurses are also used to the possibility that their interventions might harm patients. Injections may be painful, drugs may have side effects and blood transfusions might kill patients. These harms or risks are justified by the possibility of benefit to patients. In research, this is much more difficult. Much research stands little or no chance of directly benefiting patients. However, some research might benefit patients, as in a trial of a new drug treatment. Usually the REC will apply a broad principle: that any risks to research participants should be balanced by potential benefits. A risky research treatment might be justified if it might benefit participants who are in a risky state. A second rule the REC will apply is that...
the researchers should do all they can to offset any risk. Take the example of in-depth interviews. People wrongly believe that these do not carry any risk but if the topic is sensitive or embarrassing then they might. Measures that will reassure the REC include that you have experience of discussing this type of issue with people, that you have had training in interview techniques, and that you will have in place suitable arrangements to support participants should they become upset or require further support after the interview for example, contact details for a counselling service.

Justice

The inclusion of different groups in the sample is the main issue in relation to justice. This is a complex area (Allmark 2004). You should show at least that you have considered the issue. It might be that your study will be aimed at a particular group for example, you might be especially interested in health issues related to local Bangladeshi youth. No REC would turn down such a study because it failed to consider the health issues of other groups. However, in large and well-funded drug studies RECs might expect to see measures to ensure that, for example, a range of ethnic groups is included in the sample. It is not possible to give a hard-and-fast rule here; just remember to think about it and include your rationale on the REC form.

Conclusion

Anyone who wishes to conduct research in the NHS is obliged to obtain REC and research governance approval. The procedure is as follows:

- Decide the best way to answer the question: is research the best approach or would audit or service evaluation be a better way to answer the question?
- If it is research, register the project for research governance in all relevant NHS organisations and submit all necessary documentation.
- Complete the REC application form online via the NRES website form and submit all necessary documentation (NPSA 2007).
- If the study is conducted as part of a higher education course or qualification, check with the university or organisation regarding its ethics and governance approval processes. Note that university regulations do not supersede NHS requirements for REC and research governance approval.
- Attend the REC meeting and address any questions or problems raised.
- Having obtained REC and research governance approval, conduct the research while maintaining the required site file.
- Report any adverse events to the relevant NHS organisation and REC.
- Provide annual and final reports.

For the nurse who is a novice researcher these processes can appear daunting. However, if a stepwise approach is taken, sufficient time allowed and help and advice sought it can be a straightforward process.

References


