Applying for ethical approval for research

Abstract

Common to all research involving human participants is the need to obtain research ethics approval. This approval needs to be on place before research participants can be approached and before data collection can begin. This paper offers a brief insight into some of the key issues researchers need to consider when planning an application for research ethics approval.

Key words

Research ethics

Research governance

Introduction

All research involving human participants, either directly or indirectly, requires those undertaking the research to consider the ethical implications of their research. The history of research ethics includes many repeated examples of unethical research that often resulted in harm to those involved in the research (Gelling 2011). There are many well-documented examples of unethical research conducted by several nations during the World War II that resulted in significant harm to large numbers of people. Such research was conducted in the name of medical science but with little, if any, regard for the harm to which participants were exposed. Another well-documented example of unethical research demonstrating scant regard for the safety of human participants was the Tuskegee Syphilis experiment study, which started in 1932 and didn't end until 1972 (Katz *et al* 2008). It is now accepted that researchers wishing to involve human participants in their investigations need to seek ethical approval before they can approach potential research participants and before they can begin data collection. This paper will offer a brief insight into some of the key issues for nurses engaged in research by seeking to answer six of the most common questions about applying for research ethics approval.

Do I need research ethics approval?

It has become a fundamental principle, for all research involving human participants, that researchers need to obtain research ethics approval, from an independent research ethics committee (REC), before they can begin their research. There are, however, different types of inquiry or clinical investigation including audits, service evaluations and research (Twycross and Shorten 2014). Guidance on differentiating between these investigative approaches is provided by the Health Research Authority (HRA) (National Research Ethics Service 2010) and the Medical Research Council (MRC) in the UK has produced tools to help researchers determine if their study is research (http://www.hra-decisiontools.org.uk/research/) and to determine if the project needs ethical review (http://www.hra-decisiontools.org.uk/ethics/). Differentiating between these different types of inquiry is important because research ethics approval is only required when the investigation is defined as research.

Service evaluations are usually 'designed and conducted solely to define or judge current care' (National Research Ethics Service 2010). No new interventions can be introduced as part of a service evaluation and the data to be analysed is often drawn from existing routinely collected data. New data can be collected through interviews, focus groups or questionnaires but the focus of data collection should be on evaluating the current service. The primary objective in undertaking a service evaluation is to identify ways in which current care and the patient experience might be improved. An example of a service evaluation would be an exploration of the support provided to the relatives of critical care patients where the outcome will be used to develop current practice.

Clinical audits are undertaken to generate information 'to inform delivery of best care' and to judge current care against pre-determined standards (National Research Ethics Service 2010). A clinical audit might be used to examine if patients attending Accident and Emergency Departments are seen within expected waiting times. The outcome of the audit will indicate if further action is required to meet the expected standard. For both service evaluations and clinical audits there can be no change in current treatment or care, by decision or through randomisation of available treatment options, and research ethics approval is not required before the investigation can begin. Despite research ethics approval not being required for these types of investigation, this shouldn't be interpreted as meaning that there are no ethical issues (Abbasi and Heath 2005). Many of the ethical issues considered important to researchers are equally as important to clinical auditors and service evaluators.

Research is defined as an 'attempt to derive generalizable new knowledge' and can include studies seeking to generate new hypotheses or seeking to test existing hypotheses (National Research Ethics Service 2010). Research can involve the introduction of new treatments, often through randomisation, and will usually involve the collection and analysis of new data. Most importantly, an investigation defined as research requires the researcher to seek research ethics approval before the research can begin.

Differentiating between the different types of investigation can sometimes be a little complex (Wade 2005) but it is important because not seeking ethical approval for research can have serious implications for the researchers. University based researchers will face disciplinary procedures and research students will fail their programmes if they undertake research without the necessary ethical approvals. A further consideration for researchers is the need to disseminate findings so that future patients might benefit from what has been learned (Stichler 2014). One of the most common means to disseminate research findings is through publication in peer reviewed journals but journal editors will not publish any research if the paper does not include a statement confirming that the research was ethically approved before the research commenced.

How many applications will I need to make?

As a result of the implementation of the 2004 EU Clinical Trials Directive and the subsequent Medicines for Human Use (Clinical Trials) Regulations 2004, it became necessary for researchers to seek research ethics approval for clinical trials of medicinal products from only a single REC. Prior to this, researchers would have needed to seek research ethics approval from every NHS organisation hosting their research. This meant that if a research project involved 20 research sites across the UK then the researchers would need to make 20 applications for research ethics approval. The 2004 changes were implemented for clinical trials but the principle of single ethical approval was generally applied to all research in the UK.

For research undertaken in the NHS this is relatively straightforward with researchers needing to make a single application for ethical approval to an NHS REC, which can be any NHS REC in the UK. Although universities may have slightly different policies, most universities also expect their researchers to make a single application for research ethics approval, either through the NHS system or through the university's own process for the ethical review of research. It would be unusual for a university-based researcher, undertaking their research in the NHS, to need research ethics approval from both organisations because such a requirement would create unnecessary work for both the researchers and the RECs. It is important to note, however, that students undertaking ethical review for their research through NHS processes will also need to comply with their university's processes, which might include scientific or methodological review.

This single ethical review policy might differ slightly between organisations and there are exceptions to this single review principle. UK based researchers undertaking data collection outside the UK might be required to seek ethical approval at their university and also to meet the ethical review requirements where the data collection is being conducted. Meeting local requirements could vary from making another full application for research ethics approval to seeking permission from a single person. It is this inconsistency in local review that means that universities need to maintain an oversight on the ethical conduct of the research. Despite this exception to the rule, there is now a general principle that researchers need only seek ethical approval for their research from a single REC.

Where should I apply for research ethics approval?

It is important that researchers seek the research ethics approval they need from the most appropriate REC. The challenge for researchers can sometimes be to identify to which of the multiple types of REC they should be applying. Research involving NHS patients and property will usually be submitted to one of the 70 NHS RECs in the UK. However, if the research only involves NHS staff then ethical approval from an NHS REC might not be required. This does not mean that research ethics approval is not required but does mean that researchers might need to seek approval from a REC outside the NHS, possibly from a university REC.

The NHS and the HRA have established a thorough process for ethical review of research that is applied across the UK. The Integrated Research Application System (IRAS) application form is

accessed, completed and submitted online (www.myresearchproject.org.uk) and is an intelligent form that adds or removes questions according to the type of research and responses to questions. This means, however, that it is important that researchers ensure they answer questions correctly to avoid the risk that required information is not included in the application. The application and all supporting paperwork (see below) are submitted online before being reviewed by the REC. Although it is possible to submit the application to any of the UK's 70 NHS RECs, researchers will always be invited to attend the REC review meeting so it is always a good idea to apply to a REC that meets within easy travelling distance. In attending the meeting, researchers can help the REC members to understand what the research is about and answer any questions they might have. This can help ensure there is no misunderstanding and can help the application to progress smoothly through the review process. There is considerably more information about applying for research ethics approval through this route on the HRA website (www.hra.nhs.uk).

Every university in the UK has in place a process for the ethical review of research. The policies and processes might differ between institutions but each will have a rigorous process for the ethical review of student and staff research. Most, but not all, universities also adhere to the principle of single ethical review and would not require student or staff researchers, undertaking their research in the NHS, to make multiple applications for ethical approval. It has become common practice for university RECs to accept the ethical opinion of an NHS or other external REC, needing only to receive written confirmation that ethical aspects of a research project have been considered and approved. Because there is some variance between practices in different universities, researchers should seek advise about local requirements within their own institutions.

There are also other types of REC, outside the NHS and universities, that might be the most appropriate REC to review an application for ethical approval. Many county councils, private health providers and hospices have formed RECs to deal with the growth in research involving their users, clients and patients. Early in the planning stage of a research project, researchers should investigate with the research sites which process for ethical review they would consider most appropriate.

What do I need to include in the application for ethical approval?

In addition to the research ethics application form, it is usual to submit the following documents in support of an application for research ethics approval:

- *Research ethics checklist.* An application for research ethics approval can include a large number of documents so it can be helpful, for both the researcher and the REC, to have a checklist of all the documents being submitted with the application.
- *Information about researchers.* RECs will want to be reassured that the researchers undertaking the research have the experience and qualifications required to complete the

research successfully and safely. This is why NHS RECs expect to see CVs for the researchers making an application.

- *Participant information sheets.* These documents provide potential research participants with the information they need to make an informed decision about participating in a research project. The amount of detail will depend on the type of research and who will be involved in the research but they are usually written in a question and answer style, which helps potential research participants to understand the information. Participant information sheets need to be written specifically for the intended participants so that information sheets for children and young people will be very different to those intended for adult participants. There is useful guidance on preparing information sheets on the HRA website (http://tinyurl.com/nncnyhr).
- *Consent forms.* These are used to record an individual's freely given informed consent to participate in a research project after they have read the participant information sheet and been able to ask any questions they might have.
- *Recruitment material.* If researchers plan to use posters, leaflets or any other material to support recruitment these will need to be provided to the REC as part of the approval process. The REC will want to know that the wording of the material is appropriate and in no way coercive.
- *Questionnaires.* Any questionnaires or surveys being used to collect data will need to be submitted for review and the REC will want to be reassured that the researchers are not asking for unnecessarily sensitive information and that the questionnaires have been well designed. If well established, reliable and valid questionnaires are being used it might not be necessary to make these available to the REC.
- *Interview schedules.* Qualitative researchers planning to use interviews or focus groups will need to provide the REC with a copy of their interview schedule for the first interview. It is not usually necessary to inform the REC each time the interview schedule is revised because they will be familiar with the idea that interview schedules develop as the research progresses.
- *Research protocol.* Although not always necessary, many RECs will want to have a copy of the full research protocol, which often includes considerably more detail about a research project than can be included in a REC application form.
- *Evidence of sponsorship and indemnity.* Whatever the type of research, it is essential that appropriate indemnity is in place should anything go wrong during the conduct of the research.

This is not an exhaustive list of the material submitted with an application for ethical approval but does include the most common items. Each REC will provide detailed advice about the information and documents they need to accompany an application for research ethics approval.

What do research ethics committees look for?

RECs have an important role in balancing the risks and benefits of proposed research projects and it can be helpful for researchers to understand the key issues that RECs will consider during their deliberations. RECs will focus on a) the potential risks to research participants, b) the

potential risks to researchers, c) the need for freely given informed consent and d) the potential of the science to generate findings of values.

Risks to research participants

As noted previously, the history of research ethics has been a repeated series of unethical research resulting in harm to participants in research. It should not be surprising, therefore, that RECs want to know about the possible risks to research participants, how these have been minimised and what will happen if a participant is harmed during a research project (Watson and Gelling 2012). There is almost no research that is without risk to the participants in that research, no matter how unlikely the risks might be. Individuals invited to participate in data collection through interviews could be exposed to the risk of upset during an interview if they are invited to recall potentially upsetting events from their past. Researchers need to recognise this and ensure that plans are in place should this happen.

Risks to researchers

Whilst most researchers will recognise the need to provide information about the possible risks to research participants, they often neglect to consider the risks to those conducting the research. RECs will want to be reassured that researchers have given adequate consideration to their own safety. If a researcher plans to interview participants in their own homes then there is an inherent risk so the REC will want to know that appropriate lone worker policies are in place.

Freely given informed consent

The first principle of the *Nuremberg Code* and the *Declaration of Helsinki* (World Medical Association 2013) is the need to ensure that research participants have been able to make an informed and free decision to participate in a research project. As a consequence, the REC will want to know how potential participants will be a) identified, b) informed and c) recruited and throughout this process the REC will want to be reassured that no participants will feel coerced into participating in the research. Such coercion need not be deliberate and there will sometimes be situations where clinicians responsible for a patient's care might also invite them to participate in their research. In such circumstances a potential research participant might feel obliged to participate in the research so researchers need to manage such situations very carefully.

The science

The REC needs to know that a) the research question is one worth asking and that b) the proposed design will allow the researchers to answer the research question. Researchers need to demonstrate that a research project has scientific value and has the potential to contribute new knowledge and understanding to patient care or clinical practice. If a researcher cannot demonstrate such value then it would be unethical to allow the research to proceed, based on the principle that 'bad science is bad ethics'. This is an important ethical issues because research that has no potential for benefit risks wasting research participant time, researcher time and, ultimately, valuable and limited resources.

What other approvals might I need?

In addition to seeking research ethics approval before any research project can begin, researchers are also required to seek approval to access sites where the research will be conducted (Gelling 2015). In the NHS, this research governance approval is usually managed Research and Development (R&D) Departments in individual Trusts or healthcare providers. This means that researchers conducting their research at multiple sites might need to seek multiple R&D approvals. Fortunately for researchers, research ethics and R&D approvals are usually prepared and submitted using the same Integrated Research Application System (IRAS). Depending on the type of research being planned, researchers might need to seek additional approvals. Clinical trials of investigational medicinal products (CTIMPs), or clinical trials of new medicines, will require researchers to also seek the necessary approvals from the Medicines and Healthcare Products Regulatory Agency (MHRA). Because of the frequent collaboration between NHS sites and universities there are now examples of joint working between these organisations.

Conclusion

Seeking research ethics approval has become an important step in the process of planning any research project involving human participants. The process of planning an application for research ethics approval often has great value for nurses engaged in research because they need to consider, in some considerable depth, how they will conduct their research. This paper has offered a brief insight into some of the issues for researchers by answering some of the most common questions asked about applying for research ethics approval. It has been only been possible to consider some of the main issues but there is considerably more information and guidance on the HRA website (http://www.hra.nhs.uk), within universities and in guidance documents provided by the Royal College of Nursing (Royal College of Nursing 2009, Royal College of Nursing 2011) (http://tinyurl.com/ppkcbyw). Regardless of who be undertaking the ethical review, much of what has been described in this paper will be common to ethical review in all circumstances.

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