The ethical conduct of nursing research

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Introduction

Health research is undertaken with the primary aim of improving the delivery of healthcare and/or to develop new interventions and treatments for the recipients of healthcare. Nursing research focuses on the multiple roles that nurses play in delivering that healthcare and explicitly aims to benefit patients and improve service user's experiences and healthcare outcomes. All research involving human participants requires that ethical approval is obtained before the research commences and nurse researchers also need to be aware that their professional conduct within research falls within the remit of national codes of practice, such as the Nursing and Midwifery Council's 'Code' in the UK (Nursing and Midwifery Council, 2018). Despite these ethical requirements and professional codes, it would be naïve to believe that all research with ethical approval will be conducted ethically. It is essential that the nursing profession seek to ensure that research is undertaken to the highest ethical standards and that every effort possible is made to identify and rectify research that falls below these standards.

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Research participants make a significant contribution to health research, often giving their time and exposing themselves to inconveniences and risks associated with the research in which they are participating (Sackett, 2005). If research lacks scientific merit the contribution of these research participants is wasted and if they are exposed to risks out of balance with the possible benefits then equipoise is also lacking and research participants are exposed to risks without reasonable justification. Research undertaken in such circumstances is not only unethical but also risks damaging important trust relationships between researchers and those who might participate in research.

Lessons learned from the history of research ethics have highlighted the potential harm that can result from research conducted in an unethical manner (Gelling, 2020). Research Ethics Committees (RECs) around the world have become the main means of protecting research participants from the possible risks of participating in research. In meeting this gatekeeper role, RECs are seeking to ensure that researchers meet fundamental ethical benchmarks as determined by society and as described in ethical guidelines, including the Declaration of Helsinki, and professional research ethics codes such as the British Psychological Society's 'Code of Human Research Ethics' (British Psychological Society, 2021). Despite lessons learned from history, and subsequent guidance/codes, there are still multiple examples of unethical healthcare research, with each such example risking harm to those participating in the research. RECs are at the forefront of minimising the possible risks associated with participating in research.

Risks v Benefits

When considering an application for research ethics approval, a REC will want to be reassured that the risks associated with a research project are proportionate to the potential benefits. Whilst risks associated with participating in research cannot be completely eliminated, it is important that possible risks are identified, anticipated and minimised and that processes are put in place should someone experience harm directly resulting from their participation in the research. This might require that researchers seek to ensure that potential research participants have the mental capacity required to give informed consent or that those at greater risk are excluded from participating in the research.

Some forms of research might be associated with greater risks, including clinical trials of investigational medicinal products (CTIMPs), but no research, including nursing research, is without risk. It can be frustrating for RECs when researchers don't identify clear and obvious risks in their research. Some of the clearest examples of this often come from qualitative researchers, or researchers using questionnaires, who often falsely assume their research is risk free even when participants are being invited to reflect on past traumatic experiences.

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Benefits from the research

RECs will also want to be reassured that the research has genuine potential to result in benefits for patients or to the generation of new knowledge. It is important that ethical approval does not give credibility to research that it does not deserve. RECs are required to make a judgement about the scientific merit of a research proposal but they often don't have the knowledge and/or expertise amongst their membership to make that judgement. It is for this reason that RECs seek peer reviews from those able to offer an expert opinion on the proposed research. It is essential that such reviews are both independent of the research team and external to the research team's home institution. For those undertaking research into the practice of nursing, it is essential that those forming an ethical opinion or offering a peer review have input from experienced nurses who can draw on their experience of nursing and can offer a meaningful insight into how new research might contribute new knowledge to the nursing profession.

Nurses possess a unique knowledge base so it is important that nurses use that knowledge by acting as REC members and as expert peer reviewers. Currently too few nurses engage in such activities because it is often not considered central to their academic or clinical role. The value of such roles should not be underestimated.

Nationally coordinated v university review

Nationally coordinated ethical review, such as that overseen by the Health Research Authority (HRA) in the United Kingdom, has contributed to the development of an ethical review system that offers independence and is constantly striving to ensure a high-quality service to researchers and wider society. The HRA requires that REC members undertake regular training on the multiple aspects of ethical review and keep themselves up to date with developments in research and research ethics. University RECs, usually referred to as URECs, lack the same co-ordinated approach, do not have the same requirements for training and often lack the same rigorous approach to peer review. Ethical review in universities has improved considerably over the past couple of decades but has not moved on in the same way as ethical review in the National Health Service (NHS). It is wholly appropriate that research undertaken by nurses and/or about nursing is exposed to the same level of ethical scrutiny as all other types of research involving human participants. Much nursing research does not require research ethics approval through HRA processes, but it remains essential that those undertaking the research, and those who might later read the research in journals, are able to have faith in all ethical review processes and can, subsequently, have greater confidence in the quality of the research.

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Developing future ethical review and monitoring

With RECs performing such an important gatekeeping role, it is essential to consider how well they are performing this role. Are RECs preventing the conduct of unethical research and meeting the expectations placed on them by society? Whilst all RECs have the same function, how that function is delivered can vary widely. In the UK the HRA has demonstrated the considerable benefits of a nationally co-ordinated approach to the ethical review of research. Might the time be right for universities and other higher education institutions to consider a similar national or international approach or agreed standard benchmark in seeking to more clearly demonstrate the quality and transparency of ethical review?

A second, but usually underdeveloped and often neglected, role for RECs is their ongoing monitoring of approved research studies. Initial ethical review seeks to establish how the research will be conducted and, as highlighted previously, that the research has meaningful potential to result in benefits and that the possible risks are proportionate to the possible benefits. Through thorough ethical review it is possible to determine a researcher's intentions but after a study has been ethically approved it is more challenging for RECs to monitor a researcher's conduct. This is an area needing further consideration, both by researchers and by RECs.

It is a common experience, even amongst seasoned researchers, that research seldom goes to plan and frequently requires protocol amendments to adjust how the research will be conducted. It has become a common international requirement that researchers undertaking randomised controlled trials (RCTs) prospectively register their protocols on publicly accessible databases. Such databases make it possible to ensure that research is conducted as originally planned and ethically approved. Other forms of research can also prospectively register their protocols on publicly accessible databases, but this is not always required or expected. There would be considerable advantages if there was an international expectation that all research be prospectively registered in this way, regardless of professional discipline or methodological approach. Advantages might include standardisation of ethical standards, a wider awareness of current research and greater potential for future research collaborations. Such prospective registration would also contribute to ensuring that papers being considered for publication meet standards for publication (Moher, Altman, Schulz, Simera, & Wager, 2014; Smith et al., 2018). Many journals now seek to publish registration reference numbers, contributing to greater transparency.

Researchers still often treat the need to seek ethical approval as a chore or a hurdle they need to overcome prior to commencing their research. This disappointing view might now be less common but undoubtedly still exists. Improved training in research ethics on nursing and research programmes has largely changed attitudes in nursing but there might remain an absence of clear guidance for nurses engaging in research. Earlier in this editorial, the British Psychological Society's 'Code of human research ethics' was held up as a good example of guidance on research ethics being provided to a professional discipline (British Psychological Society, 2021). It is notable that no similar code exists for nurses in the UK and they are challenging to find in other parts of the world. The Royal College of Nursing (RCN) published 'Research ethics: RCN guidance for nurses' in 2009 but this is now out-of-date and does not reflect recent legislative developments or current ethical review practices (Royal

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College of Nursing, 2009). The time might be right to consider developing national, or even international, guidance on research ethics for nurses.

Conclusion

Trust is important in all aspects of research, especially during the ethical review process where RECs need to trust that researchers will behave in an ethical manner and researchers need to trust that the RECs will behave in a thorough but fair manner. Strong research needs a partnership between researchers and RECs but neither can expect that research will always be conducted as originally planned. Research should always be conducted as described in the original ethically approved protocol or as subsequently ethically approved through protocol amendments. How RECs perform their gatekeeping role needs to be strengthened to help ensure their ability to meet the expectations placed on them by society. Currently RECs may not always be fulfilling this role. Nurses in their roles as researchers, REC members and as users of published research, have a key role to play in seeking to ensure that research about the practice of nursing is always undertaken and utilised ethically. Much more could be done to ensure this happens.

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