

Research made simple: ethics committee approval

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Nursing research often involves collection of data from human participants. Participants involved with research may be vulnerable, acutely unwell or even lack capacity to make decisions. Protecting the safety and well-being of all participants is a requirement and nurse researchers need to ensure the ethical principles of autonomy, non-maleficence, beneficence and justice are maintained throughout the research process.¹

To protect participants, research studies are subject to approval by research ethics committees (RECs)—sometimes called research ethics boards or institutional review boards.¹ Securing REC approval can be a complex process, requiring nurse researchers to demonstrate that the proposed study meets the necessary ethical and research governance requirements for research involving human participants. This paper will provide an overview of the role of RECs and offer guidance to nurse researchers applying for REC approval.

Research ethics committees

RECs came to prominence in the second half of the 20th century. The internationally recognised Declaration of Helsinki—first adopted in 1964, but amended several times since then—states all researchers need to secure REC approval before commencing research involving human participants, in order to safeguard the health and well-being of those involved.² RECs can be part of national research authorities (such as the National Office for Research Ethics Committees in Ireland), and/or sit within organisations such as hospitals and universities. Their role is to provide independent scrutiny of research and to determine whether proposed studies can be given ethical approval.

RECs usually consist of several people with different roles and expertise. RECs often include members with research, statistics, ethics and/or clinical expertise. The public and people with lived experience are also members of the REC panels and provide essential insight into the value of the research, the acceptability of the study for participants and whether the written documents are accessible.

REC approval is a formal process that nurse researchers complete before commencing research involving human participants. An initial step is to establish whether the study needs REC approval. Usually, research involving human participants requires REC approval, but deciding

whether a study is research can be difficult. The lines between research, audit and evaluation are blurred, so it is useful to think carefully about whether the study meets the criteria for research (table 1).³ Some tools exist to help make this decision, including the 'Do I need REC review' tool provided in by the Health Research Authority in the UK (<http://www.hra-decisiontools.org.uk/ethics/>).

What do RECs consider when scrutinising research protocols?

RECs consider a wide range of issues related to research ethics and integrity. REC applications can be lengthy documents including a detailed protocol, participant information sheets, consent documents and data collection tools. There may be different criteria or templates used across different RECs and variation does exist in the process and outcomes of REC review.⁴ Despite this variation though, there is some agreement about what is important and the areas that need addressed in their REC applications.⁵

- ▶ Scientific value: does the study ask important questions; is the proposed methodology appropriate; will the research produce useful findings?
- ▶ Resources: are there adequate resources available for the research; is the research team sufficiently competent and experienced to complete the research?
- ▶ Risk assessment: does the risk assessment show a favourable risk-benefit ratio for people involved in the study and wider community?
- ▶ Independent review: has an independent review of the research happened? What patient and public involvement has occurred?
- ▶ Recruitment: will recruitment be fair, free from coercion, and are the risks and benefits of the research shared equally within society?
- ▶ Consent: will participants provide informed voluntary consent, and will participants be able to withdraw their consent and remove themselves from the research should they wish to do so?
- ▶ Privacy: does the study protect participants' privacy and personal data?
- ▶ Protection: does the research have adequate safety and welfare measures to ensure participants' well-being?

Table 1 Evaluation, audit, research

	Evaluation	Audit	Research
Aim	Evaluate quality of current practice	Measure current practice against agreed standards	Generate new knowledge
Initiated by	Service provider	Service provider	Researcher
Involves new treatment	No	No	Sometimes
Randomisation	No	No	Sometimes
Allocate participants to different groups/treatments	No	No	Sometimes

Table 2 REC decisions

Decision	Outcome
Approved	The REC have approved the study. The nurse researcher has ethical approval and can commence the study. The REC will often provide an approval code for the study, which is used for publication and proof of ethical approval.
Approved with conditions	The REC have approved the study but have provided specific conditions for the study. The nurse researcher has ethical approval but must ensure they meet all the conditions of approval to the REC's satisfaction before commencing work.
Revise and resubmit	The REC have not approved the study and the study should not commence. The REC want the nurse researcher to revise their research protocol and resubmit it to the REC for further consideration. The REC will normally provide a detailed summary of the revisions needed before it is ready for resubmission.

REC, Research Ethics Committee.

- ▶ Supporting documents: are research documents accessible enough for the intended audience, and do they provide enough information about the research, so participants can make an informed decision about participating?

What happens after the REC review?

Once the review process is complete, the REC will decide on the most appropriate outcome for the research. Though some different terminology may be used in different countries, REC decisions usually fall into one of the following: approved, approved with conditions, or revise and resubmit (table 2).⁶

What can help get an REC application approved?

Securing REC approval can be a lengthy and stressful process. Approval times vary between RECs, but some RECs can take several months to provide a decision on an application.⁷ It is important that nurse researchers factor in the time taken to secure REC approval when planning research projects; even the most experienced researchers often need to revise their REC applications before being approved, and the process can take longer than expected.⁶ This could have implications for funding or—in the case of student projects—for meeting academic deadlines. Taking simple steps before submitting the REC application can help minimise the chances of having to resubmit the REC application and can help expedite the research process.

Steps to take when applying for REC approval

- ▶ Find out about the application process for the REC you will be using (eg, submission process, documents required, timelines involved). Some RECs use online submission systems, so it may be necessary to create an account and/or learn how to navigate the system.
- ▶ All nurse researchers need to allow enough time for the REC review process and should assume they will need to revise the REC application because even experienced nurse researchers may have to revise their REC applications.
- ▶ Involve stakeholders when designing the study and preparing an application for REC approval.

- ▶ Consider the ethical principles of autonomy (respect of persons), non-maleficence, beneficence and justice when designing the research.¹
- ▶ Complete a risk assessment and evaluate whether the potential benefits outweigh the possible risks associated with the research.
- ▶ Write the research protocol using the structure recommended by the REC or an established framework such as the 'Ethics Tool Kit'.⁸
- ▶ Ensure the participant-facing documents (such as information sheets) are comprehensive and that the language is accessible for the intended audience.
- ▶ Get peer feedback on the application from an experienced researcher who is not involved in the study.
- ▶ Use version control to manage the different versions of key documents.
- ▶ Check all documents before submission to avoid unnecessary delays in the review process.

Conclusion

RECs are crucial in protecting the health, safety and well-being of research participants. In order to receive approval from these committees, nurse researchers need to ensure that their proposals are clear, comprehensive, informed by stakeholder input and focused on the well-being of those who will take part in their study.

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References

- 1 Heale R, Shorten A. Ethical context of nursing research. *Evid Based Nurs* 2017;20:7.
- 2 World Medical Association. World medical association declaration of helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;310:2191–4.
- 3 Twycross A, Shorten A. Service evaluation, audit and research: what is the difference? *Evid Based Nurs* 2014;17:65–6.
- 4 Trace S, Kolstoe SE. Measuring inconsistency in research ethics committee review. *BMC Med Ethics* 2017;18:65.
- 5 George AJT. Research ethics. *Medicine* 2016;44:615–8.
- 6 Brandenburg C, Thorning S, Ruthenberg C. What are the most common reasons for return of ethics submissions? an audit of an Australian health service ethics committee. *Res Ethics* 2021;17:346–58.
- 7 Glasziou P, Scott AM, Chalmers I, et al. Improving research ethics review and governance can improve human health. *J R Soc Med* 2021;114:556–62.
- 8 Li RH, Wacholtz MC, Barnes M, et al. Incorporating ethical principles into clinical research protocols: a tool for protocol writers and ethics committees. *J Med Ethics* 2016;42:229–34.