

# Demystifying the ‘E’ word

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This is the third article in a series of practical guides aimed to help medical radiation practitioners get started in research. In this article, we focus on the ethics requirements and processes associated with a research project.

## What is ethics?

In Australia, all research studies involving human participants, human tissues and clinical data must adhere to the National Health Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research Involving Humans.<sup>1</sup> The Declaration of Helsinki also provides strict guidance on research involving human participants.<sup>2</sup> All such research projects must be approved by an accredited Human Research Ethics Committee (HREC). This is known as ‘ethical approval’.

## Why and when do you need ethics approval?

Depending on the jurisdiction, ethics approval may be required for any research or quality assurance activity. As medical radiation practitioners we must always seek ethics approval before commencing projects where we plan to disseminate the results via published manuscripts and at conferences, especially when patient data is used (even when de-identified). It is always important to contact your ethics office before starting any project to clarify your local requirements.

## Who are members of the HREC?

The HREC comprises of members representing aspects of the hospital and community. Additional members may be invited to participate as required to assist with scientific review and ethical decision making.

## Who is responsible for ensuring research abides by ethical requirements?

It is the researcher’s responsibility to follow the NHMRC guidelines while conducting their research. ([www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018](http://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018))

Generally, a co-ordinating or principal investigator is nominated by the research group and this individual takes overall responsibility for the project including submission of the project for ethical review. They are responsible for ongoing communication with the HREC and disseminating any outcomes/feedback to the co-investigators. Ethical considerations for researchers include:

- no research is to commence before ethics approval and governance authorisation is granted and/or discussions have occurred to establish best time for submission based on local HREC requirements (QA projects)
- all relevant information has been provided to the HREC and the Research Governance Office
- all relevant guidelines and legal requirements are complied with
- monitoring, including annual project reports, are submitted to the ethics office
- proposed protocol modifications/amendments have been submitted and approved
- safety monitoring and reporting requirements for trials are adhered to in line with state/territory requirements.

## Types of ethical approval

Before commencing an ethics submission, you will need to determine what type of ethics submission pathway you need to follow. The pathways are categorised in regard to their level of risk. Generally, you will find your jurisdiction will have a high risk, low risk, negligible risk and quality assurance pathways, or a combination of these. High and low and negligible risk projects will be overseen at a health service level, whereas quality assurance projects are governed by the local jurisdiction.

High risk research includes interventional research involving drugs or devices. Potential harms could include physical (e.g. effect of increased radiation dose), psychosocial, devaluation of personal worth, social harms, economic or legal harms.

Low risk research is foreseen to cause discomfort of the mind or body. Examples include minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview. Retrospective studies may also be considered low risk research if the data is accessed by a third party locally or internationally (e.g. university, partner hospital).



Negligible risk is defined as 'when there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience'.<sup>1</sup> Examples include use of existing de-identified clinical data with no foreseeable risk to the participants, and projects using surveys or basic short interviews.

Quality assurance activities pose no risk to the individual and 'is to monitor or improve the quality of service delivered by an individual or an organisation'.<sup>3</sup> Examples include clinical audits, quality improvement activity, or health service delivery evaluation.

### Research governance

To ensure your department/hospital can logistically accommodate and support your project, an application needs to be submitted to research governance known as a 'site specific application' (SSA). This process is separate but runs parallel to the ethics application.

### What is involved in an ethics application?

Investing time in preparation of your ethics application will help in making the approval process as smooth as possible. The creation of a comprehensive study protocol (see the May 2020 Issue of *Spectrum*) will provide a strong foundation for your ethics application as many of the questions within the application can be answered by the protocol. It is important to use simple, plain language throughout the application as it is unlikely the reviewers will be experts in your field. All documents submitted should have a header or footer describing the document, the date, page number and version control.

The ethics application and associated documentation is submitted via an online platform to facilitate the creation, processing and storage of:

- ethics (Human Research Ethics Applications) and SSA applications
- study protocol
- investigator CVs
- patient information consent forms
- additional study documentation including questionnaires, radiation reports and data collection forms
- post-approval and authorisation forms
- progress reports
- safety notifications and amendments.

It has the ability to track progress of ethics and governance applications (e.g. approvals and authorisations) and enables research office staff to track applications through pre- and post-approval and develop comprehensive reports.

### HREC meetings

Each jurisdiction will have a meeting and application submission calendar so you can plan the preparation of your submission. Depending on jurisdiction, low risk and quality assurance projects may go to the HREC or a different review committee.

Ethics applications take a substantial amount of time and co-ordination to complete. Always allow sufficient time before any application deadline to collect investigator CVs and gather their signatures. Ethics review times vary between jurisdictions.

### What is the most efficient way to get ethics approval for multicentre projects?

If you are co-ordinating a project across multiple HRECs you can utilise the National Mutual Acceptance Scheme to streamline the process. This provides a single ethical review of multicentre research in two or more of the participating states for clinical trials.

### Summary

Ethics is an important part of research to protect the health and rights of participants. We hope this article has demystified the ethics process, showing it is achievable for researchers of any experience level to successfully navigate.

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### Online platforms for ethics applications

NSW and ACT: Research Ethics and Governance Information System – REGIS <https://regis.health.nsw.gov.au>

Qld and Vic: Ethical Review Manager  
<https://au.forms.ethicalreviewmanager.com/Account/Login>

SA: Online Forms  
<https://au.ethicsform.org/SignIn.aspx>

WA: Research Governance Service – RGS  
<https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx>

Tas: Ethics Review Manager  
<https://ethics.utas.edu.au/>

NT: Top End Human Research Ethics Committee and Central Australia Human Research Ethics Committee  
<https://health.nt.gov.au/professionals/nt-health-research/research-ethics>

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The next article in this series will shine a light on statistics in research.

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### References

1. National statement on ethical conduct in human research 2007 (updated 2018). Available at [www.nhmrc.gov.au/guidelines/publications/e72](http://www.nhmrc.gov.au/guidelines/publications/e72)
2. Declaration of Helsinki. Available at [www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/](http://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)
3. Ethical considerations in quality assurance and evaluation. Available at [www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities#block-views-block-file-attachments-content-block-1](http://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities#block-views-block-file-attachments-content-block-1)