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Research ethics and governance in
Australia and New Zealand:
Guidance for anaesthesia research
departments

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Purpose of document:

Research ethics and governance are essential to conduct responsible and ethical research. This guidance document provides an overview of essential concepts, practical steps, and useful resources to assist researchers throughout the governance and ethics approval process, with a particular focus on high-risk ethics and governance applications for a multi-centre clinical trial run in collaboration with the ANZCA Clinical Trials Network (CTN). It includes concepts discussed by Dr Kate Drummond at the CTN workshop at the 2025 ANZCA Annual Scientific Meeting.

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Table of contents

Introduction	4
Preparing your research protocol	4
The ethics approval process	4
Types of ethical reviews	4
Key ethical considerations	4
Australia specific information	5
Example documents required for an ethics application review	5
New Zealand specific information	6
Systems used for ethics and governance applications in Australia	6
Key elements of research governance	6
Example documents required for governance approval	7
Research conduct and management	7
Ongoing responsibilities	7
Final reporting and dissemination	7
Key steps	7
Conclusion	8

Research ethics and governance in Australia and New Zealand: Guidance for anaesthesia research departments

Introduction

Research ethics and governance are essential to conduct responsible and ethical research. This guidance document provides an overview of essential concepts, practical steps, and useful resources to assist researchers throughout the governance and ethics approval process, with a particular focus on high-risk ethics and governance applications for a multi-centre clinical trial run in partnership with the ANZCA Clinical Trials Network (CTN). It includes concepts discussed by Dr Kate Drummond at the CTN workshop at the 2025 ANZCA Annual Scientific Meeting.

Preparing your research protocol

Creating a robust research proposal is required to receive ethics approval and institutional support. The proposal should clearly outline the research question, methodology, expected outcomes, and ethical concerns.

Standard proposal components:

1. Title and abstract: describe the research aim and significance concisely.
2. Background and rationale: provide context and justify the research.
3. Methodology: detail data collection, analysis, and risk mitigation strategies.
4. Ethical framework: outline how you will address consent, confidentiality, and data protection.
5. Feasibility and funding: demonstrate that resources are available and the trial is sustainable.

The ethics approval process:

Ethics approval is essential for any research involving human participants. It ensures the rights, dignity, and well-being of participants are respected. The process varies based on the nature of the research and the policies of individual institutes.

Types of ethical reviews:

- Full ethics review: required for high-risk interventions or clinical trials. Reviewed by a full panel of ethics experts.
- Low and Negligible Risk (LNR) review: suitable for studies involving minimal discomfort, such as surveys or data analysis from existing records.
- Exempt from review: quality improvement projects that do not aim to generate generalisable knowledge but may still require institutional review. If a study is exempted from review, it may preclude the findings being published.

Key ethical considerations:

1. Respect for persons: informed consent, confidentiality, and participant autonomy are critical.
2. Beneficence: the potential benefits of the research must outweigh the risks.

3. Justice: participants should be selected fairly, and vulnerable groups should not be exploited.
4. Integrity: honesty, transparency, and data accuracy must be maintained throughout the research process.

ANZCA CTN trials usually have a lead site or a trial management/coordinating team who apply for ethics approval for the overall trial. If the lead site is also a participating site in the trial, they can also apply for governance locally at the same time as applying for ethics. For trials with an Australian lead site but recruiting in New Zealand, there will need to be a New Zealand lead site also. Much of the New Zealand ethics and governance will be delegated to this lead site.

Australia specific information

[National Mutual Acceptance \(NMA\)](#) is a national system whereby the ethical review of single, accredited Human Ethics Research Committee (HREC) is then accepted by multiple publicly-funded health services across jurisdictions. A single ethical review can then be provided to several sites across states and territories in Australia instead of applying at each site individually.

Note: This information is relevant to public hospitals/institutes in Australia. Private hospitals will have separate ethics and governance processes (although some will accept an NMA approval).

General information on preparing an application for ethics review:

1. If you are unsure which category the research falls under, phone your local Research Office for advice.
2. A clinical trial will require a full ethics review by a HREC. Most HRECs will have submission deadlines.
Tip: Find out the dates for when an application needs to be submitted by, and work towards this timeline.
3. A pre-submission registration with the HREC may be required to notify the HREC that you intend to submit a full application. Some HRECs may offer a pre-submission interview to ensure you have chosen the correct approval pathway and have all the documents required to submit.
4. Ethics offices will have checklists and templates for what is required to submit (See Alfred Health example).
5. Consider if your study requires Māori (New Zealand) or other First Nations consumer consultation and engagement before it is submitted for ethics.

Example documents required for an ethics application review

- [Human Research Ethics Application \(HREA\) \(Australia\)](#), Health and Disability Ethics Committee (HDEC) Application (New Zealand).
- Trial protocol.
- Participant questionnaires or surveys.
- Site Principal Investigator (PI) CV for each site.
- Master Patient and Information Statement and Consent Form (PISCF) (or Waiver of Consent etc).
- [Clinical Trials Notification \(CTN\)](#) (registering the trial with the Therapeutic Goods Administration (TGA) with list of sites involved in the trial) (Australia).
- [Medsafe Notification](#) (New Zealand).
- Clinical trials insurance certificate.
- Specific forms required in some states in Australia:
 - Victoria: Victorian Specific Module (VSM).
 - Western Australia: Western Australia Specific Module (WASM).
- Telephone script if participants to be contacted by telephone first.
- Investigator brochure or product information (If a clinical drug trial).
- Material for participants (i.e., advertisements, flyers, letters, emails, diaries).
- Webpage material if information about the trial is on a website.
- Trial budget.

- Financial agreements with pharmacy and pathology services if applicable.
- Ethics and governance fee payment form.

New Zealand specific information

- [Health and Disability Ethics Committees \(HDEC\)](#): Is the national body in New Zealand that ethics applications are submitted to.
- There is a list of [meeting dates and times](#) available to guide when research can be submitted.
- [Ethics Review Manager \(Ethics RM\)](#) is the system that is used to submit an ethics application.
- An example of HDEC templates and guides can be found on the [HDEC website](#).
- The [Health Research Council of New Zealand Resource Library](#) has useful resources including ethics and regulatory guidance and Māori and Pacific Health Research.
- Consider consulting Māori as early as possible on the design and conduct of research that is of relevance to them (see '[Guidelines for Researchers on Health Research Involving Māori](#)'). If formal consultation with Māori is not considered/required for your study, you will be asked to justify why in the New Zealand HDEC application. Whether/how your study may benefit Māori and/or reduce health inequalities, along with identification of any cultural issues that may arise for Māori participants and how these will be addressed are also required by HDEC.

Systems used for ethics and governance applications in Australia

There are various systems used across Australia to apply for ethics approval depending on what state the site taking part in the clinical trial is in. The Site Principal Investigator must have an account in the system used in the state to apply ethics and governance. The application can then be delegated to other team members to be completed. Note: Some sites may use their own system to manage ethical and governance review (i.e., Alfred HREC).

- Queensland and Victoria: [Ethical Review Manager \(ERM\)](#)
- Northern Territory: [Northern Territory Health](#)
- South Australia: [Research Gems](#)
- Tasmania, New South Wales and Australian Capital Territory: [Research Ethics Governance Information System \(REGIS\)](#)
- Western Australia: [Research Governance Service \(RGS\)](#)

Understanding research governance (Australia) or localities authorisation (New Zealand)

Research governance/localities refers to the framework through which an institute ensures that research is conducted responsibly, ethically, and is compliant with legal and professional standards. This aims to safeguard participants, ensure data integrity, and maintain public trust in research practices.

Key elements of research governance:

1. Ethics and regulatory compliance: ensures that research adheres to relevant ethical guidelines and legal requirements.
2. Institutional accountability: institutes are responsible for approving research, overseeing conduct, and managing data.
3. Financial management: verifies that funding is used appropriately and that there are adequate resources for project completion.
4. Risk and safety management: identifies potential risks and outlines measures to mitigate them.
5. Public and stakeholder engagement: encourages active involvement and transparency with communities affected by research.

Sites that will mostly apply for research governance locally using a Site-Specific Assessment (SSA) in Australia. This is a 'locality authorisation' in New Zealand.

Example documents required for governance approval

- Site Specific Assessment (SSA) (Australia).
- Copy of ethics approval certificate(s).
- All documents listed in ethics approval certificates, e.g.:
 - Copy of the HREA .
 - Copy of the state specific modules (e.g. VSM) if applicable.
 - Master PISCF.
 - Participant facing material.
 - CTN.
 - Clinical trial insurance.
- Site Specific PISCF.
- Clinical Trial Research Agreement (CTRA) between the sponsor and site.
- Head of department sign off.
- Head of supporting department sign off e.g. surgical team, pathology, medical records.
- Site investigator(s) CV.
- Site investigator medical registration.
- Site investigator Good Clinical Practice (GCP) certificate.
- Site budget.
- Ethics and governance payment form.

Research conduct and management

After obtaining ethics and governance/localities approval, researchers must adhere to approved protocols and monitor the study's ethical compliance continuously.

Ongoing responsibilities:

- Amendments: seek approval for any significant changes to study methods or objectives (i.e., updates to the study protocol or PISCF). There may be a financial cost for this review.
- Reporting adverse events: report any harm or unexpected outcomes to ethics committees and trial management team promptly. See Trial guidelines and [NHMRC document on reporting adverse events](#) (in Australia).
- Data management: Secure storage and controlled access to sensitive data.
- Progress reports: Submit regular annual progress and safety reports to ethics and governance committees as specified. These will normally be submitted to the lead ethics committee for approval and then sent to sites to submit for governance approvals.

Final reporting and dissemination

Upon project completion, researchers must compile a comprehensive report for stakeholders and ethics committees.

Key Steps:

1. A final report should be submitted to ethics to close the study out. Each participating site will also need to submit a final report to governance locally to close out the trial at the site.
2. Data analysis: the research data will need to be analysed and interpreted clearly and accurately.
3. Publication, authorship and acknowledgement ethics: acknowledge contributions appropriately and adhere to data sharing policies.
4. Archiving and record keeping: maintain accessible and secure records for a specified period as required by institutional policy.
5. Letters with study results can be sent to participants at sites.
6. A webinar/seminar may be organised for trial results.
7. Results can be disseminated locally to supporting departments/teams to keep them engaged.

Conclusion

Navigating research governance and ethics is integral to maintain public trust and scientific integrity. By adhering to best practices and maintaining transparency, researchers ensure their work contributes positively to the academic community and broader society.

For further guidance, contact your local Research Office or consult ANZCA CTN resources for mentorship and support. For trials recruiting in New Zealand, additional advice and support can be sought via the New Zealand lead site.