Human Research Ethics Application Guide

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1. The Role of Ethical Review in Research

Ethics review is fundamental to the University's commitment to high-quality ethical human research. It offers a structured opportunity to test the soundness of a research proposal—its intent, methodology, risk and risk management, and its likely impacts. It is a core component of rigorous research design and responsible research conduct.

By engaging meaningfully with the ethical review process, researchers are better equipped to consider the implications of their work on participants, communities, and stakeholders. This guide provides clarity on the application process, documentation requirements, and expectations for ethical conduct in line with the *National Statement on Ethical Conduct in Human Research (2025) (National Statement).*

This guide provides advice on the ethical conduct of human research, is based on the *National Statement* and is designed to assist researchers at all stages of their research. Ideally, it should be read, and advice implemented in the planning stages of research, rather than at the time the application is being prepared.

2. What is Human Research?

Human research is broadly defined as research conducted with or about people, or their data or biological materials. It includes not only direct involvement with participants—such as through surveys, interviews, focus groups, or psychological and medical testing—but also research where individuals may not be directly involved, but their information or samples are used.

This encompasses observational studies, access to personal documents and materials, the collection and use of human biological specimens such as blood, saliva, urine, tissue, hair, or breath, as well as the use of data in identifiable, re-identifiable, or non-identifiable form drawn from existing or unpublished sources or databases.

3. The Human Research Ethics Committee (HREC)

The Human Research Ethics Committee (HREC) is an independent body established to ensure all research involving human participants upholds the highest ethical standards.

Constituted in accordance with national guidelines, the HREC is composed of a diverse group of experts, including researchers, community representatives, and legal or ethical specialists. This composition ensures that research proposals are reviewed from multiple perspectives, balancing scientific merit with respect for participant rights and welfare.

The HREC reviews all human ethics applications from students, staff, and adjuncts conducting research under the University's auspices in both Australia and Singapore.

The HREC operates impartially, making decisions based solely on the ethical integrity of each project as outlined under the *National Statement*, free from conflicts of interest. Its role is to protect the safety, dignity, and privacy of participants and their data and/or biological specimens, while supporting researchers in conducting responsible, high-quality research.

The JCU HREC operates under two main review pathways, the full HREC pathway and the Lower Risk review pathway. The full HREC includes all committee members and reviews higher risk research applications, as well as certain categories of lower risk research, including (i) research requesting a waiver of consent; (ii) overseas research; (iii) Aboriginal and Torres Strait Islander research; and (iv) research involving minors (<18 years of age). The Lower Risk Panels (Australia and Singapore) review lower risk research proposals through an expedited review pathway led by Deputy Chairs.

4. Scope and Applicability

The *National Statement on Ethical Conduct in Human Research (2025)* provides the foundational framework that governs all human research conducted under the auspices of James Cook University (JCU) as well as other Australian institutions. It sets out the ethical principles and guidelines designed to protect the rights, dignity, welfare, and safety of participants while promoting high-quality research.

A key feature of the *National Statement* is the establishment of a continuum of risk that guides the ethical review process. This continuum recognises that human research varies in the level of potential risk or harm to participants, ranging from negligible to high risk.

Accurate and transparent classification of research within this risk continuum is critical. It ensures that the University applies a proportionate and appropriate review pathway—one that safeguards participant welfare without imposing unnecessary administrative burdens on researchers or delaying valuable research.

Well-considered risk classification and comprehensive, thoughtfully prepared ethics applications contribute directly to:

- Robust research design that respects ethical principles
- Effective protection of participant rights and wellbeing
- Efficient and timely review processes
- The University's reputation for ethical rigour and research excellence

Researchers are strongly encouraged to engage with the JCU Ethics Office early in the planning stages of their research to familiarise themselves with JCU's ethics review processes, understand applicable requirements, and facilitate smooth progression through the ethics review pathway.

Lower Risk Research

Lower risk research involves research in which the only foreseeable risk is no greater than discomfort, and there is no risk of harm. Any potential burdens are minimal and unlikely to impact participants beyond everyday life. Examples include:

- Surveys or interviews on non-sensitive topics
- Research involving adults who are competent to consent and not from a population who may be at higher risk
- Behavioural observations in non-intrusive settings

Lower risk projects are eligible for expedited review through the University's Lower Risk Panels, with the exception of (i) research requesting a waiver of consent; (ii) overseas research; (iii) Aboriginal and Torres Strait Islander research; or (iv) research involving minors (<18 years of age). Preparing a clear, detailed application outlining risk mitigation including addressing any participant burden, is critical to successful expedited review.

Higher Risk Research

Higher risk research encompasses any project where the level of risk exceeds discomfort and could include potential harm, i.e., could affect participants physically, psychologically, socially, legally, or culturally. This includes research that:

- Engages populations or individuals with reduced decision-making capacity
- Uses sensitive or identifiable data that may lead to harm or distress

- Employs deception or incomplete disclosure requiring enhanced safeguards
- Involves physical or psychological interventions or invasive methods

Higher risk projects are reviewed by JCU full HREC at monthly meetings.

As previously stated, certain types of research must be reviewed by the full HREC, irrespective of the level of risk. This includes all projects involving Aboriginal and Torres Strait Islander Peoples, research with children, studies seeking a waiver of consent, and research conducted overseas.

Exemption from Ethics Review

Research classified as negligible risk, where there is no foreseeable risk of harm or discomfort, and any potential risk is no more than trivial inconvenience, may be eligible for exemption from formal ethics review under the *National Statement* Section 5.1.15–5.1.18.
Examples of research that may meet these criteria include:

- Use of previously collected non-identifiable data or information that is publicly available and protected by law
- Surveys or observations of public behaviour collected without personal identifiers
- Audit, evaluation, or quality assurance activities not designed to contribute to generalisable knowledge

Researchers must submit an **Ethics Review Exemption Request** in GECO with a clear justification addressing the negligible risk criteria. Each submission is **assessed by the HREC Chair** to ensure compliance with the *National Statement* while minimising unnecessary regulatory burden.

Externally Reviewed Projects (External Acknowledgement)

For multi-institutional or collaborative research projects already reviewed and approved by another NHMRC-registered HREC, JCU offers an external acknowledgement process. This pathway recognises the original ethical review, avoids duplication, and facilitates research efficiency (as per the *National Statement* Chapter 5.5) and can be accepted without any additional ethics review.

Applicants must provide full documentation of the external ethics application and approval notice in GECO. Projects approved by overseas or non-NHMRC registered review bodies will be assessed on a case-by-case basis by the HREC Chair in order to decide whether the approval can be accepted or an application submitted through JCU. The external approval can be accepted if the external review meets the standards of the *National Statement*. The JCU HREC retains discretion to assess equivalence and endorse the external review.

JCU will not accept overseas exemptions to ethics review since other countries have different requirements for when human research ethics reviews are required.

For more details on the external ethics reviews see the External Human Ethics Approval Procedure.

5. Other Activities

Quality Assurance and Evaluation Activities

Not all quality assurance (QA) or evaluation activities fall under the definition of human research and therefore may not require ethics review. However, where such activities:

- Involve human participants beyond routine service delivery,
- Collect identifiable or sensitive data,
- Are intended for dissemination beyond internal use (e.g. publication or conference presentation), or
- Introduce procedures outside of standard practice,

they may meet the criteria for human research and require ethical review under the *National Statement*.

Researchers must assess their project's purpose and design early. Ethics review cannot be granted retrospectively, and no data collection involving human participants or their information may commence until written approval is obtained. Researchers are expected to approach the HREC proactively if there is any doubt about the classification or review requirements, and our advice to educators and course coordinators is to apply for ethics approval if they think there's a chance they may want to use the results in publications or presentations.

Further guidance:

- NHMRC Ethical Considerations in Quality Assurance and Evaluation Activities
- National Statement (2025)

Teaching Activities Involving Human Participants

Ethics approval is not required for classroom-based exercises conducted solely for teaching and learning purposes, where:

- There is no intention to produce generalisable knowledge,
- Activities are confined to simulations or peer-based participation, and
- No data is collected for publication, presentation, or research purposes.

However, where classroom-based activities involve external participants, data intended for public sharing, or any level of risk, they fall within the definition of human research.

In such cases, formal ethics approval **must be obtained before the activity begins**. Retrospective review is not permitted under the *National Statement*, and applications submitted after data collection has commenced will not be considered.

Educators and course coordinators must ensure teaching activities that resemble research are reviewed early and assessed against ethical principles. Where uncertainty exists, staff should consult the Ethics Office well in advance and if there is a chance that the results will be disseminated and/or published, we strongly recommend that an ethics application be submitted.

Undergraduate Research Projects

Undergraduate student research involving human participants, their data, or biological samples is subject to the same ethical obligations as any other human research conducted under JCU's auspices. This includes coursework-related, honours, and independent study projects. Formal ethics approval is required prior to commencement where a student project:

- Involves human participants or data,
- Includes any level of risk (including discomfort or inconvenience), or
- Is intended for assessment, presentation, publication, or future research use

Some undergraduate projects may be provided with an exemption to ethics review if they meet the requirements outlined in Sections 5.1.17 of the *National Statement*.

Ethics approval or exemption cannot be granted retrospectively, and research conducted without prior approval is considered non-compliant and publication of research without formal ethics approval will not be authorised. Supervisors and students must plan early to ensure adequate time for ethical review.

Where courses involve repeated, similar student projects with minimal risk, course-level ethics approval may be possible. Coordinators interested in this option should contact the Ethics Office in advance to determine suitability.

Biomedical Research Conducted in Singapore

In Singapore, the Human Biomedical Research Act requires Institutional Review Board (HRECs) to be located in Singapore and registered with the Ministry of Health. For this reason, the JCU HREC is unable to review biomedical research (as defined in the above Act) in Singapore.

6. Accessing Data in Human Research

All human research involves the collection, use, or analysis of data relating to individuals. The type of data, how it is accessed, and the context in which it is used each carry distinct ethical considerations—particularly regarding privacy, confidentiality, consent, and potential harm. Whether researchers are collecting new data, reusing existing datasets, analysing publicly available sources, or interacting with participants online, these activities must be planned and justified within the ethics application. Researchers must ensure their methods of access comply with privacy legislation, institutional policy, and the principles of the *National Statement*.

Accessing Student Data via the University Database

Access to identifiable or potentially identifiable student data held in university systems—such as enrolment records, grades, academic performance, or demographic information—requires formal permission from the University's Privacy Officer.

Ethics approval alone does not grant permission to access institutional student data.
Researchers must provide:

- A detailed rationale for why access is required,
- The type and extent of data requested,
- A letter of support or authorisation from the Registrar, and
- Clear plans for de-identification, data security, and compliance with relevant privacy legislation.

This requirement applies even if researchers are internal staff members or educators.

Social Media as a Source of Data

The use of social media content (e.g. Facebook, Twitter/X, Reddit, TikTok, LinkedIn) for research purposes raises complex ethical considerations. While platforms may be publicly accessible, users often have varying expectations of privacy, and identifiable content is common.
Researchers must carefully consider:

- Whether the data is truly public, or requires login/membership
- Whether the individuals involved would expect their content to be used in research
- How consent will be managed if identifiable posts, images, or comments are captured
- Whether direct or indirect interaction with users will occur
- How anonymity and confidentiality will be preserved in reporting

Use of private groups, forums, or platforms requiring account creation or login is **not** considered public domain. Ethics applications must include the exact data source, screenshots where applicable, the site's terms and conditions and privacy policy, and a justification for data use without consent, if applicable.

Online Interviews, Focus Groups, and Interactions

Online interactions with participants—such as interviews, focus groups, or workshops conducted via platforms like Microsoft Teams—are considered direct participant engagement and must be reviewed through the same ethical lens as in-person methods. Researchers must ensure:

- Participants are fully informed about how the platform operates, including any limitations around privacy or data security
- Audio or video recordings are clearly disclosed and consented to
- Storage and transfer of recordings are secure, encrypted, and consistent with data management plans
- Attempts are made to preserve confidentiality in group settings (especially in online focus groups)

Participants should be advised to access online sessions from a private location where possible, requested not to share discussions outside the session, and be informed of any potential risks associated with digital communication platforms prior to commencement.

For data security reasons, the HREC recommends researchers use Microsoft Teams (JCU licenced) as the interview and transcription platform since the data is stored in Australia and is therefore subject to Australian privacy laws.

Internet-Based Research and Passive Data Collection

Research involving online environments—such as forums, comment sections, streaming platforms, or web scraping—requires a clear justification of how and why data is being accessed. Key considerations include:

- Whether participants can be identified directly or indirectly
- Whether the data is intended for private or public consumption
- The nature of the platform (open web vs. membership-based or gated communities)
- Any risks associated with re-identification, especially when combining datasets

Ethics applications must clearly define the boundaries of online engagement and describe how data will be captured, de-identified, and stored. Researchers must also explain how the context of user activity aligns with ethical principles such as respect and consent.

Retrospective and Secondary Data Use

Use of existing datasets—whether created for prior research, administrative, or service delivery purposes—requires careful ethical consideration. Retrospective data use still constitutes human research if the data pertains to individuals.

Applications must:

- Clearly describe the source, content, and scope of the dataset
- Identify whether consent was originally obtained and whether re-consent is feasible
- Justify any request for a waiver of consent under the *National Statement* Section 2.3.10
- Provide documentation of permission from the data custodian
- Provide a copy of the original Participant Information Sheet and Consent Form to demonstrate consent for secondary use (if applicable)
- Address data security, privacy controls, and plans for de-identification

Even where the researcher was the original data collector, a new ethics application is required if the data is to be used for a different purpose than originally approved.

Publicly Available Datasets

The availability of data in the public domain does not remove ethical responsibilities. Public datasets—such as those hosted by government bodies, academic repositories, or open access platforms—may still contain sensitive, identifiable or potentially re-identifiable information.

Before using publicly available datasets, researchers must:

- Determine whether ethical oversight was part of the original data collection
- Confirm whether any usage restrictions apply (e.g. licensing, attribution, restricted access conditions)
- Avoid any attempt to re-identify individuals or link data in a way that introduces risk
- Justify any potential risks associated with reuse, and put in place risk management plans

Where necessary, approval from the original data custodian must be obtained. JCU's Ethics Office may also request evidence of the dataset's public status and documentation of its original ethical and legal oversight.

Accessing Health or Clinical Datasets

Research involving patient data collected through clinical or health service settings—such as hospitals, community health centres, or public health databases—requires strict ethical oversight due to the sensitivity of the information and the obligations attached to clinical care records.

Where the dataset is held by a public health body—including Queensland Health, Hospital and Health Services, or other national or state health departments—ethics approval must be sought from a certified Hospital and Health Service (HHS) Human Research Ethics Committee. JCU's HREC cannot approve access to these datasets and will not review such applications.

Researchers must:

- Identify the data custodian and seek formal permission for access
- Apply to the relevant HHS HREC for ethical approval prior to any data access
- Where JCU involvement remains (e.g. JCU researchers on the team), submit an external ethics acknowledgement request to the JCU Ethics Office once HHS approval is granted
- Confirm compliance with applicable legislation, such as the Hospital and Health Boards Act 2011 (Qld) and relevant privacy laws

Where health datasets are privately held (e.g. by non-government organisations, clinics, or research partnerships), JCU may review the application, provided all ethical, legal, and custodial requirements are met but retains the rights to refer review to an appropriate HREC when required. For applications involving data from Mater Health Group, ethics approval must be sought from Mater Misericordiae Limited HREC.

Clinical Trials

JCU does not conduct ethics review of higher risk clinical trials. All clinical trials involving therapeutic goods, medical interventions, or invasive procedures must be reviewed by a certified Hospital and Health Service (HHS) Human Research Ethics Committee, consistent with national regulatory frameworks.

This includes—but is not limited to—trials involving:

- Therapeutic goods (as defined under the Therapeutic Goods Act 1989)
- Investigational medicinal products
- Medical devices
- Surgical or diagnostic interventions
- Interventional comparative studies with clinical outcomes

Researchers affiliated with JCU who are involved in clinical trials must seek ethics approval through the relevant HHS HREC. Once approval is granted, researchers must submit an external ethics acknowledgement request to the JCU Ethics Office, confirming JCU's institutional involvement and enabling proper research governance.

All clinical trials must also meet the requirements of the National Clinical Trials Governance Framework, including registration in a recognised public registry such as ANZCTR.

For questions regarding JCU's role in clinical trials, external acknowledgement processes, or governance documentation, contact the Ethics Office before commencing your project.

7. The Ethics and Research Integrity Team

The Ethics and Research Integrity team provides expert guidance, training, and administrative support across all aspects of human research ethics at JCU. The team facilitates the ethical review process, advises researchers on preparing high-quality applications, and ensures alignment with the *National Statement* and institutional policy. Key responsibilities include:

- Coordinating submission, review, and correspondence for all human ethics applications
- Providing pre-submission and post-approval advice to researchers and supervisors
- Supporting the operations of the Human Research Ethics Committee (HREC) and Lower Risk Panels
- Managing external ethics acknowledgements and exemption processes
- Maintaining records and reporting in accordance with compliance and audit requirements
- Promoting awareness of responsible research conduct through training and resources

Researchers are strongly encouraged to contact the team early in the research planning process to ensure their project is designed with appropriate ethical considerations in place. The team's role is advisory and administrative; it operates independently of decision-making processes to preserve the integrity and impartiality of HREC review.

8. Submission Process and Review

All human research conducted under the auspices of JCU requires formal ethical review and approval prior to commencement. Researchers must ensure that their application is complete, well-considered, and aligned with the *National Statement* to avoid delays in processing. Ethical approval, including for exemptions and external acknowledgements, must be formally obtained **prior to** commencing any research activities. Retrospective ethics approval is not permitted under any circumstances and publication of research without formal ethics approval will not be authorised.

Submission via GECO and indicative timeframes

All ethics applications, exemption requests, amendments and reports must be submitted electronically through **GECO**. This platform facilitates the preparation, submission, and tracking of human ethics applications. Users must:

- Log in using their institutional credentials
- Select the appropriate application form (new, amendment, annual report)
- Complete all required fields with accurate and complete project information
- Upload required documents and supporting materials (see below)
- Ensure that all institutional approvals are secured before final submission

Access GECO: https://geco.jcu.edu.au

To ensure your application is reviewed at the next scheduled Ethics Committee meeting, it must be submitted in GECO **well in advance** of the published deadline. Once submitted, your application must progress through multiple levels of approval (e.g., Academic Supervisors, Ethics Advisors, Facility Managers, Deans, etc.). This process can take time, particularly if revisions are requested or if there are unforeseen delays. Applications submitted on the **day of the deadline** will likely not be reviewed until the following month's meeting.

As each application varies, it is difficult to provide a definitive timeframe for submission. The duration depends on factors such as the complexity of the project, the number of required approvers, whether changes are requested, and potential delays. In most cases, 1–2 weeks may be sufficient, but the process can take significantly longer.

Until the application status in GECO is listed as **"With Ethics Office,"** the responsibility for its progress lies with the **research team**. We strongly recommend that you **proactively contact all relevant approvers** to notify them that your application is awaiting their review. This will help support a smooth and timely approval process.
Please note, the JCU Ethics Office will **not be aware of your application** until it reaches the status **"With Ethics Office"** in GECO. If you notice your application is **'stuck'** with an approver for a long time or if the reviewer is unavailable, email the Ethics Office who can push it past them.

Review Turnaround Times:

- **Lower Risk applications** are generally reviewed within 10 to 14 working days.
- **Amendments, Exemption and External Acknowledgement requests** are typically processed within 7 to 10 working days.
- **Higher Risk applications** are reviewed at scheduled HREC meetings, with a response provided within three working days following the meeting.

Review Outcomes:

Applicants will receive formal feedback from the reviewing committee, which may include:

- **Approval:** A formal letter of approval, exemption, or acknowledgement will be issued, confirming ethical clearance.
- **Clarifications Required:** The committee may request further information or amendments. Researchers must respond appropriately by resubmitting updated documents through GECO within 7 to 10 working days for each clarification request. Applications remain unapproved until all issues are satisfactorily addressed and endorsed by the HREC.
- **Revise and Resubmit:** The application does not meet the required standard and must be comprehensively revised and resubmitted for full review.
- **Not Approved:** The reviewing committee has determined that the submitted application does not meet ethical requirements under the *National Statement* and cannot be approved in its current form.

Human Ethics Advisor Review

Review by a **Human Ethics Advisor (EA)** is **mandatory** for all JCU applications prior to formal submission. Lower risk applications being submitted **from JCU Singapore only**, amendments, exemption requests and external acknowledgements do not require EA review. EAs are discipline-specific academic experts who provide essential guidance on the ethical and methodological soundness of research proposals.
This mandatory pre-review offers the research team an invaluable opportunity to:

- Identify and address potential ethical or design issues early
- Enhance the quality and completeness of the application
- Ensure alignment with JCU ethics policies and the *National Statement*
- Facilitate a smoother review process with the Lower Risk Panel or HREC

Engaging with an EA strengthens research integrity and expedites ethics approval by reducing the need for extensive revisions later. Researchers must obtain documented EA endorsement in GECO before progressing. Researchers are required to contact an EA **prior** to submitting the application to them to confirm their availability for the review.
A list of Human Ethics Advisors is available on the JCU Ethics website.

Supervisor and College Delegate Approval

Endorsement from the Primary Supervisor (for student-led research) and the College Dean or Delegate is also mandatory before an application proceeds to HREC review.

These approvals serve as crucial academic and organisational quality checkpoints by:

- Confirming appropriate academic oversight and support
- Ensuring the project is feasible and resourced within the College framework
- Verifying compliance with institutional policies and strategic priorities

Required Documentation

Ethics applications must include clear, complete, and final versions of all relevant documents. These materials enable the Human Research Ethics Committee to assess the ethical and practical aspects of the proposed research. Accurate documentation of participant information, consent processes, data collection methods, recruitment strategies, and data management is essential for an efficient review and approval process.
Incomplete or unclear documents commonly cause delays and may require resubmission. Researchers are expected to ensure all documents meet institutional standards prior to submission.
The primary categories of documentation include:

- **Participant Information Sheet and Consent Form (PISCF):** These documents inform prospective participants about the research and obtain their voluntary consent. They are foundational to respecting autonomy and ensuring informed participation.
- **Data Collection Instruments:** Tools such as surveys, interview guides, and focus group protocols that detail how data will be gathered. These demonstrate the appropriateness and sensitivity of your methods.
- **Recruitment Materials:** Communications used to invite and enrol participants. These reflect the transparency, voluntariness, and fairness of your recruitment strategy.
- **Research Data Management Plan (RDMP):** A detailed outline of how data will be collected, stored, secured, accessed, shared, and ultimately disposed of, ensuring compliance with legal, ethical, and institutional requirements.
- **Supporting Documents:** Additional materials such as letters of support, data access permissions, evidence of ethics training completion, and safety protocols that provide context, authority, and assurances about your project's ethical compliance and conduct.

Careful preparation and submission of these documents, in their final form, is critical to achieving a smooth and timely ethics review.

Participant Information Sheet and Consent Form (PISCF)

- Must clearly explain the purpose, procedures, risks, benefits, and participant rights in plain, accessible language.
- Include information about confidentiality, data handling, and withdrawal without penalty.
- Reflect the exact processes participants will encounter, including any audio/video recording or use of data in publications.
- Consent forms should align precisely with information sheets and specify whether Specific, Extended or Unspecified consent is being requested.
- Translated versions must be provided if participants are non-English speaking, with evidence of accurate validated translation.
- Researchers should download and use the JCU HREC and *National Statement*-compliant PISCF templates for different study methodologies available from the JCU Human Ethics webpage.

Data Collection Instruments

- Final or near-final versions of all surveys, questionnaires, interview guides, focus group protocols, or experimental scripts must be included.

- Instruments should be logically organised, labelled, and consistent with the study aims, GECO application, and ethical considerations.
- Sensitive or potentially distressing questions require clear justification and mitigation strategies.
- Where piloting is planned, provide a description and timing relative to ethics approval.

Recruitment Materials

- All materials used to recruit participants must be included, such as email invitations, flyers, posters, social media posts, or scripts for verbal recruitment. If a QR or weblink will be used, these must be provided for HREC review and checking.
- Recruitment documents must clearly state voluntary participation, the purpose of the research, eligibility criteria, participant tasks and estimated time commitment, HREC Reference Number, JCU logo, and researcher contact details for queries or withdrawal.
- Use plain language appropriate to the target population and avoid coercive or misleading statements.

Research Data Management Plan (RDMP)

- Must be developed in Research Data JCU and a completed copy provided for HREC review.
- Must clearly outline the processes for data collection, storage, security, access, sharing, retention, and disposal.
- Demonstrate compliance with relevant legislation, including the Privacy Act and JCU data policies.
- Comply with Indigenous Data Sovereignty Principles if Aboriginal and Torres Strait Islander research or research involving other Indigenous populations.
- Include details on who will have access to data and under what conditions.
- Address plans for de-identification or anonymisation where appropriate.
- Outline strategies for secure data transfer if involving external collaborators.

Other Supporting Documents

- Letters of support or approval from external organisations or institutions involved in or facilitating the research.
- Documentation of data access permissions (e.g., from University Secretary, JCU Privacy Officer, custodians of secondary datasets).
- Evidence of completion of mandatory ethics training for all research team members.
- Safety protocols or risk management plans, particularly for studies involving populations who may be at greater risk or sensitive topics.

Document Formatting and Quality Standards

- Use clear, professional formatting: legible fonts, logical headings, and consistent terminology.
- Avoid jargon, abbreviations, or technical terms without explanation.
- Proofread all materials carefully to avoid errors or ambiguities.
- Ensure all documents are the versions intended for participant use—drafts or incomplete documents will result in application delays.

9. Research Proposal Considerations Reviewed by the HREC

The HREC undertakes a rigorous review of research proposals to ensure that projects are ethically sound, methodologically robust, and compliant with the principles outlined in the *National Statement*. The Committee's assessment extends beyond procedural compliance to critically evaluate the research merit and integrity and potential impact of the proposed research, as well as the experience and competence of the research team to conduct the proposed research ethically and in accordance with the principles of the *National Statement*.

Key considerations include:

Research Design and Methodology

- The clarity and appropriateness of the research question, aims, and objectives.
- Suitability of the chosen methodology and methods in addressing the research aims.
- Justification for participant selection, including inclusions and exclusions.
- Adequacy of sample size and recruitment strategies to ensure representativeness and validity.
- Consideration of alternative methods that may reduce participant risk or burden.

Risk Identification and Mitigation

- Comprehensive identification of potential risks—physical, psychological, social, legal, or economic—to participants.
- Strategies to minimise, manage, and monitor identified risks throughout the research lifecycle.
- Plans for responding to adverse events or unanticipated outcomes.
- Assessment of whether the risks are proportionate to the potential benefits and knowledge gained.

Informed Consent Processes

- Clarity, completeness, and accessibility of Participant Information Sheets and Consent Forms.
- Appropriateness of consent procedures, including provisions for populations who may be at greater risk, or requests for a waiver of consent where applicable.
- Mechanisms to ensure consent is voluntary, informed, and ongoing.
- Considerations for cultural sensitivity and language barriers, including translated materials.

Confidentiality and Data Management

- Safeguards to protect participant privacy and confidentiality.
- Secure data storage, access controls, and data retention/destruction policies.
- Plans for data de-identification or anonymisation where possible.
- Compliance with relevant privacy legislation and institutional policies.
- A full, completed Research Data Management Plan is required to accompany the ethics application.

Recruitment and Participant Engagement

- Fair and ethical recruitment methods consistent with respect for autonomy and avoidance of coercion.
- Transparency and fairness in participant eligibility criteria and recruitment materials.
- Consideration of participant burden, incentives, and the right to withdraw without penalty.

Special Considerations

- Ethical implications involving populations who may be at greater risk, including children, Aboriginal and Torres Strait Islander Peoples, or others requiring additional protections.
- Research involving sensitive topics, including trauma, mental health, or illegal behaviours.
- Use of novel or emerging methodologies, including AI, digital and online data collection.

10. Application Particulars, Researcher Considerations, HREC Review

Submission Platform

All human research ethics applications at JCU must be submitted exclusively through GECO, the University's online ethics management system. Paper forms are no longer accepted. This centralised system ensures consistency, transparency, and traceability of all ethics applications and correspondence. Researchers are responsible for uploading all required documentation and ensuring their application is complete before submission. Early preparation and thorough review within GECO improves the efficiency and speed of the ethics review process.

Preparation Before Application

Why this matters:

The *National Statement on Ethical Conduct in Human Research* (2025) is the cornerstone for ethical research in Australia and provides a framework for protecting participants and ensuring research integrity. Reading the *National Statement* and related guidance helps researchers align their project design with ethical principles from the outset, reducing avoidable delays and deficiencies in applications. Completion of the mandatory online training by all research team members demonstrates baseline competence in human research ethics and equips researchers to identify and address ethical considerations and challenges specific to their project.

How to apply this:

Before beginning the application, researchers should actively:

- Engage with the latest version of the *National Statement*, paying particular attention to sections relevant to their research methodology and participant population.
- Review discipline-specific and institutional guidance documents to understand expectations and best practices.
- Complete the human research ethics training module, which introduces key ethical concepts, researcher responsibilities, and the approval process.

These preparatory steps ensure researchers submit well-informed, high-quality applications and contribute to ethical research culture.

Human Research Ethics Risk Assessment

Why this matters:

Risk assessment is fundamental to protecting participants and researchers from harm and discomfort. The *National Statement* (Chapter 2.1) requires researchers to identify risks, estimate their likelihood and severity, and implement mitigation strategies. Categorising risk informs whether the application is eligible for expedited review or requires full committee consideration, ensuring that oversight is proportional to risk.

What the HREC reviews:

The Risk checklist in the GECO application guides reviewers to determine the ethical risk category of the project. Research in which the risk for participants or others has the potential to exceed discomfort and cause harm will be classified as higher risk research and undergo more rigorous review, as these projects warrant enhanced scrutiny to ensure participant safety and ethical conduct.

Application tips:

Researchers should:

- Conduct a thorough and honest risk assessment, considering physical, psychological, social, legal, and economic risks, noting that risk does not just apply to individual participants, but can also apply to groups or communities as well as to non-participants such as family members.
- Describe risks clearly and explain plans for managing or minimising these risks.
- Avoid underestimating risk to prevent unexpected ethical issues during research.
- Use the risk checklist as a guide to anticipate the level of scrutiny and prepare accordingly.

A transparent and detailed risk assessment demonstrates responsibility and ethical foresight. Researchers should be aware that the risk classification of their project may be elevated from lower risk to higher risk during the review process.

Project Duration

Why this matters:

The duration of ethics approval impacts project feasibility and oversight. The *National Statement* emphasises that research should be adequately resourced and monitored over time (Section 3.1.9, Chapter 5.8). The HREC must ensure projects have realistic timelines and resources to protect participants and data integrity throughout the study lifecycle.

What the HREC reviews:

The committee evaluates whether the requested duration aligns with the project's scope and complexity.

Application tips:

Researchers should:

- Justify any request exceeding three years with evidence of funding, staffing, and resources.
- Understand that research must not commence without formal ethics approval issued via GECO.

Setting realistic project timelines supports responsible research management.

Role, Experience, and Research Team Composition

Why this is important:

The *National Statement on Ethical Conduct in Human Research* (Section 1.1(e)) highlights that research must be conducted or supervised by individuals with appropriate qualifications, skills, and competence. This is fundamental because competent researchers ensure the study is scientifically sound, that ethical safeguards are implemented properly, and that participants are treated respectfully and safely.

What the HREC is looking for:

The HREC needs assurance that every team member has the expertise to carry out their assigned role or will be adequately supervised or trained. Inexperienced researchers (especially students or early career researchers) must demonstrate how they will receive support to build competence and protect participant wellbeing and data integrity.

How to prepare your response:

- Clearly define each team member's role and responsibilities during each phase of the research lifecycle (e.g., data collection, recruitment, data analysis, participant interaction, dissemination).
- For each person, describe in sufficient detail their **relevant** qualifications, training, and prior experience related to these tasks.
- If a team member lacks direct experience:
    - What specific training will they receive before and during the project?
    - Who will supervise or mentor them, and how?
    - How will competency be ensured before data collection, participant interaction, and/or analysis?
- If the research involves culturally sensitive populations or special methodologies, provide evidence that the research team have appropriate cultural competence or specialized skills.
- Ensure roles are realistic and aligned with team members' expertise to maintain participant safety and data integrity.
- Ensure any conflicts of interest (actual or potential) for the research team, including financial interest, other relationship or affiliation, is clearly disclosed and the associated risk minimized.

Ask yourself:

- Have I mapped out every team member's specific role in this project?
- What formal qualifications or practical experience supports their ability to perform their role?

- How will inexperienced members be prepared and monitored?
- Do we have enough expertise and oversight for ethical compliance?

Funding and Resources

Why this is important:

The *National Statement* (1.1(f), 3.1.9) requires that research is "conducted using facilities and resources appropriate for the research" and that these are sufficient to complete the research as designed. Insufficient resources threaten participant safety, data quality, and project completion.

What the HREC reviews:

The committee needs clear details about all financial and in-kind support. Lack of clarity or inadequate funding may suggest that the project is under-resourced, risking project incompletion and reputational damage.

How to prepare your response:

- List all funding sources, whether cash, grants, scholarships, or in-kind contributions such as equipment, space, software, or researcher time.
- For each source, specify what it covers (e.g., participant reimbursements, translation costs, equipment, data storage).
- Describe how funding arrangements will be disclosed to participants, especially regarding any required disclosures to the funding body, and where there is an actual or perceived conflict of interest related to the funding body.

Ask yourself

- Have I clearly identified and described all funding and resource support, including in-kind support?
- Can I justify that the resources are sufficient for safe and effective project delivery, including access to required facilities, equipment, and software?
- Are participant incentives and reimbursements covered by the available funding?

Research Aims, Background, and Scientific Merit

Why this is important:

Ethical research must have merit; it must be valuable, justified, and based on existing knowledge (*National Statement* 1.1(c), 1.3). A clear rationale protects participants from being involved in unnecessary or poorly designed research.

What the HREC reviews:

The committee evaluates whether the research is built on a thorough literature review, has clear achievable aims and research questions, and pursues genuine knowledge gain. Vague or weakly justified projects may be rejected.

How to prepare your response:

- Provide a **concise summary of the relevant existing literature** that identifies gaps or unresolved questions your research will address.
- Clearly state your **research questions, objectives, and/or hypotheses.**
- Explain the **significance and potential impact** of the study.
- Include **references** to key studies or sources to demonstrate your scholarly foundation. A reference list can be added in the Aims and Background GECO section or provided as a separate attachment.

Ask yourself:

- Have I clearly and succinctly demonstrated why this research is necessary and what new knowledge it aims to generate?
- Is the literature review current and relevant?
- Are the aims clear, measurable, and achievable?
- Have I demonstrated how the research will build upon or differ from prior work?

Research Methods

Why this is important:

Ethical research must be methodologically sound and appropriate to the aims (*National Statement* 1.1(b), 1.3). Methods impact participant risk and data validity.

What the HREC reviews:

The committee evaluates whether your chosen design, data collection, and analysis methods are justified, suitable, and ethically considerate.

How to prepare your response:

- Outline your research design (qualitative, quantitative, mixed methods).
- Describe how data will be collected (surveys, interviews, observations).
- Detail all participant tasks and expected time commitment.
- Explain your sampling strategy and rationale.
- Provide an overview of your data analysis plan related to your aims.
- Consider participant burden and ensure your methods minimise risk including inconvenience and discomfort.

Ask yourself:

- Are my methods including data analysis strategy appropriate to answer my research questions?
- Have I detailed all participant tasks and their expected duration?
- How will I ensure data quality and participant wellbeing?
- Have I considered alternatives that might reduce risk or burden?

Dissemination of Results

Why this is important:

Sharing findings transparently promotes scientific integrity and respects participant contributions (*National Statement* 1.3, 1.5).

What the HREC reviews:

The committee assesses plans for disseminating results responsibly and whether participants will be offered accessible summaries.

How to prepare your response:

- Identify when and how results will be shared (publications, presentations, reports).
- Specify to whom results will be disseminated, including participants if applicable.
- Address any limitations on dissemination (confidentiality, cultural sensitivities).
- Describe how results will be communicated in plain language for participants and other relevant populations.

Ask yourself:

- How will I ensure transparency and accessibility of my findings?
- Will participants have the option to receive results?
- How will I protect confidentiality when reporting?
- Are dissemination plans culturally appropriate and ethically sound?

Participants and Recruitment

Why this is important:

Fair and respectful participant recruitment is central to the principle of Justice (*National Statement* 1.4). Recruitment strategies must be equitable, avoid coercion, and consider participant diversity.

What the HREC reviews:

The committee examines participant characteristics, inclusion/exclusion criteria, recruitment methods, protections for populations that may be at greater risk, and how informed decision-making is supported.

How to prepare your response:

- Describe who your participants are – age range, sex/gender, location, any specific characteristics relevant to your aims.
- Explain why these groups are targeted and how inclusion/exclusion criteria were set to ensure fairness and target population representativeness.
- Address sampling strategies to avoid bias (e.g., balanced age and gender representation or justification for any imbalance).
- If recruiting minors or populations that may be at greater risk, provide evidence of required approvals (Blue Card, Police Clearance).
- Describe your recruitment process in detail - How will participants be aware of the study? How will you contact participants? What screening is involved?
- Address any potential coercion, especially if participants have dependent or unequal relationships with researchers and/or organizations or others facilitating recruitment. Explain how you will mitigate this risk.
- If using social media or digital platforms, specify which ones, and consider how this affects accessibility and diversity.
- Provide all recruitment materials for HREC review.

Ask yourself:

- Who exactly will be invited to participate, and why?
- How will I reach these participants fairly and ethically?
- How will I ensure participants understand the research and be made aware of that participation is voluntary?
- What steps will I take to protect individuals who may be at greater risk?
- Are my recruitment materials clear, accurate, and culturally appropriate?

Aboriginal and Torres Strait Islander Research

Conducting research involving Aboriginal and Torres Strait Islander peoples, lands, or knowledge demands rigorous ethical clarity, cultural understanding, and meaningful engagement. Before starting, researchers should ask themselves the following reflective questions—which help align your approach with the six core values from the NHMRC Guidelines (Spirit and Integrity, Cultural Continuity, Equity, Reciprocity, Respect, Responsibility), as well as the AIATSIS principles of Indigenous self-determination and leadership.

Foundational Questions

- Could my research involve traditional knowledge, stories, or practices that require respect for Indigenous ownership and protocols (e.g., cultural copyright, custodianship)?
- Will my research be conducted on land or regions where Traditional Owners should be consulted or granted permission?
- Does the research require prior approval from local Indigenous governance structures or Elders to ensure community consent?
- How can I design my research to meet the six core values of Indigenous research-Spirit and Integrity, Cultural Continuity, Equity, Reciprocity, Respect, and Responsibility?

Cultural Competence and Capacity-Building

- Does the research team have adequate cultural competence to conduct this research respectfully, including cultural advisors, mentors, and/or Indigenous co-researchers?
- Have I built relationships and trust with Indigenous communities that reflect ongoing engagement rather than instrumental consultation?
- Is there opportunity to support capacity building within Indigenous communities by involving local partners or providing skills or knowledge exchange?

Benefits and Reciprocity

- How will the outcomes of this research meaningfully benefit Aboriginal and Torres Strait Islander communities?
- Are there mechanisms to ensure knowledge, findings, or products generated are returned to and co-owned by the communities?
- Have I considered models of shared ownership and the ethical use or storage of cultural or biological data?

Research Design and Epistemological Alignment

- Does the research methodology align with Indigenous ways of knowing and being (e.g., storytelling, yarning, seasonal calendars) rather than imposing solely Western research paradigms?
- Have I adopted participatory or co-design approaches that centre Indigenous epistemologies and leadership?

Ethical Responsibility and Long-term Governance

- Have I sought or will I seek consent from relevant Indigenous bodies before data collection begins, and ensured consent remains ongoing and informed?
- Do I have a clear plan for governance and control of data, including how materials or findings can be withdrawn on request or secured if culturally-sensitive?
- Have I accounted for implementing the six NHMRC core values and the AIATSIS principles throughout the project lifecycle?

Reflecting on these questions not only strengthens your ethics application by anticipating HREC expectations but also elevates the design of your research to be respectful, culturally safe, and beneficial to Indigenous communities. For more guidance, refer to NHMRC's Indigenous research guidelines and the AIATSIS Code of Ethics.

Consent Process

Why this is important:

Informed consent respects autonomy and ensures participation is voluntary and informed (*National Statement* 1.12,.2). Poor consent processes undermine trust and validity.

What the HREC reviews:
The committee looks for clear, tailored consent strategies that suit participant demographics, research context, and risks.

How to prepare your response:

- Describe how participants will receive information about the study (e.g., Information Sheets).
- Detail the timing and manner of consent (written, verbal, specific, extended, unspecified).
- Explain provisions for participants with limited capacity or language differences.
- Describe how participants can withdraw consent and what happens to their data.
- Provide Consent Forms in GECO.

Ask yourself:

- Is my consent process clear and accessible to my participants?
- Have I accounted for different needs or vulnerabilities?
- Does the information provide all necessary details for an informed decision?
- Can participants easily withdraw if they choose?

Risk Management and Benefits

Why this is important:
Balancing risks and benefits ensures participant protection and ethical acceptability (*National Statement* 1.6, 1.7(a)).

What the HREC reviews:
The committee requires a thorough risk identification, assessment, and management plan alongside a clear statement of potential benefits.

How to prepare your response:

- Identify all possible risks (physical, psychological, social, legal).
- Assess their likelihood and severity honestly.
- Describe specific strategies to minimise and manage risks throughout the project.
- Explain how the potential benefits outweigh the risks.
- Plan for monitoring and reporting adverse events.

Ask yourself:

- Have I identified all realistic risks?
- What steps will I take to reduce or eliminate these risks?
- How will I respond and provide support if a participant experiences harm?
- What benefits does my research provide, directly or indirectly?

Data and Information Management & Privacy

Why this is important:
Secure and ethical handling of data respects privacy and ensures research integrity (*National Statement* 3.1 Element 4, Privacy Acts).

What the HREC reviews:
The committee looks for robust plans on data collection, storage, access, sharing, retention, and disposal that comply with laws and policies.

How to prepare your response:

- Detail how you will collect and store data securely (e.g., encryption, password-protection).
- Explain who will have access and how this is controlled.
- Specify whether anonymous/de-identified data (including raw datasets, interview/focus group transcripts) may be shared publicly and/or used by other researchers in future research projects.
- Describe how you will de-identify data to protect privacy.
- Provide data retention timelines and destruction plans.
- Outline compliance with privacy legislation (e.g., Australian Privacy Act).
- Ensure details are consistent with the Research Data Management Plan (RDMP) developed in Research Data JCU.

Ask yourself:

- Are my data security measures appropriate to the sensitivity of the data?
- How will I protect participant confidentiality?
- What are my data sharing and reuse policies?
- Am I fully compliant with applicable privacy laws?

Outward-Facing Materials (Participant Information Sheets, Consent Forms, Flyers, Recruitment Scripts)

Why this is important:

Outward-facing materials are the primary way participants learn about your research. They are critical tools for respecting participant autonomy and promoting informed consent, fulfilling the *National Statement* principle of Respect (Section 1.10-1.13). Well-designed materials build trust, support participant understanding, reduce confusion or anxiety, and ensure recruitment is ethical and transparent. Poorly written or unclear materials can lead to misinformation, undermine voluntary participation, and delay ethics approval.

What the HREC reviews:

The Human Research Ethics Committee closely examines these materials to ensure they:

- Provide clear, accurate, and comprehensive information about the study purpose, procedures, risks, benefits, and participant rights
- Use language and formatting appropriate to the target population's literacy, culture, and language proficiency
- Include all mandatory elements required by the *National Statement* and JCU policies
- Explain privacy, data use, and withdrawal rights clearly
- Avoid coercive or misleading language, particularly around incentives or benefits
- Align with the recruitment strategy and study design
- Respect cultural sensitivities and include translated versions or interpreters when needed

How to prepare your materials:

Participant Information Sheet (PIS):

- Download and adapt the appropriate PISCF template that aligns with the study methodology from the JCU Human Ethics webpage.
- Use plain, non-technical language tailored to your audience's reading level. Avoid jargon or acronyms.
- Clearly state the research's purpose, what participation involves, duration, and what participants can expect.
- Describe any risks and benefits, including whether participation might affect them negatively or positively.
- Outline participant rights, especially the right to decline or withdraw without penalty, and what happens to their data if they withdraw.
- Explain confidentiality protections, data handling, and who to contact for questions or complaints.

- Provide contact details for the research team and the Ethics Office.
- Use headings, bullet points, and spacing to improve readability.

Consent Form:

- Download and adapt the appropriate PISCF template that aligns with the study methodology from the JCU Human Ethics webpage.
- Reflect the Participant Information Sheet content accurately and succinctly.
- Include a clear statement that participation is voluntary.
- Provide space for signatures, dates, and if applicable, witness or translator information.
- Ensure the form aligns with consent methods (written, verbal, specific, extended, unspecified) and is suitable for the participant population (e.g., parental consent for minors).

Flyers, Posters, Recruitment Scripts:

- Keep messages clear, accurate, and concise.
- Avoid overstating benefits or using language that could be interpreted as pressure.
- Include necessary ethical disclaimers (e.g., "Participation is voluntary," "Approved by JCU HREC #xxxx").
- If using images, ensure they are appropriate and culturally sensitive.
- Provide contact details for interested participants.

Language and Accessibility:

- Consider translations or versions adapted for different literacy levels.
- Include information about interpreters if your study involves non-English speakers.
- Use accessible formats for participants with disabilities when required.

Review and Feedback:

- Have your materials reviewed by colleagues, supervisors, or representatives of the target population to ensure clarity and appropriateness?
- Be prepared to revise based on HREC feedback to meet ethical and communication standards.

Leading questions for your application and preparation:

- Are my participant materials clear, complete, and tailored to my participant group?
- Do they fully explain the research purpose, procedures, risks, benefits, and participant rights?
- Is the language accessible and free from jargon?
- Have I included all required contact and ethics approval information?
- Have I avoided coercive or misleading statements, especially around incentives?
- Are my recruitment materials consistent with the information provided in consent documents?
- Have I accounted for cultural and linguistic diversity in my materials?
- Have I obtained feedback on these materials from others before submission?

11. Post-Approval Project Management

Maintaining ongoing compliance with ethical standards and institutional requirements is essential throughout the lifespan of a research project. The JCU HREC requires active oversight to ensure participant welfare, data integrity, and adherence to approved protocols. Researchers bear the responsibility to manage their project in line with ethical principles and promptly communicate with the HREC as needed.

Amendments

Any proposed change to the approved research project must be submitted as a formal amendment application through GECO **prior to implementing the change.** This includes modifications to the research design, participant recruitment, consent process, data collection methods, research personnel, or any outward-facing participant documents such as Information Sheets, Consent Forms, or recruitment materials.

It is critical to understand that **retrospective approval of amendments is not permitted under any circumstances.** Conducting activities outside the scope of approved protocols without prior HREC consent compromises ethical compliance and may result in suspension or termination of ethics approval.

The GECO amendment application requires researchers to provide a detailed justification aligned with the *National Statement*. This justification must explicitly demonstrate that the amendment continues to protect participant rights and safety, preserves scientific integrity, and complies with relevant policies and legislation. All revised participant-facing materials must be included in the submission and approved before use.

Researchers should allow sufficient time for the review process by submitting amendments well before any planned changes are enacted.

Annual and Final Reporting

Ethics approval is generally granted for a defined period, often up to three years, subject to satisfactory ongoing review. Researchers must submit **annual progress reports** through GECO to the HREC to confirm that the project is proceeding in accordance with the approved protocol and ethical standards. These reports provide an opportunity to update the committee on recruitment status, any issues encountered and confirm continued compliance.

At project completion, a final report must be submitted to formally close the ethics approval. The final report should summarize the conduct and outcomes of the research, any deviations from the protocol, and confirmation that data and materials have been managed in line with ethical and institutional requirements.

Timely and accurate reporting is essential for maintaining the integrity of the research oversight process and ensuring continued institutional support.

Adverse Events and Unanticipated Issues

Researchers are obligated to report promptly through GECO any adverse events, unanticipated problems, or complaints related to the research that could impact participant safety or wellbeing. This includes any incidents that may cause physical, psychological, social, or legal harm.

Clear, timely reporting enables the HREC to assess the situation and determine appropriate actions, which may include modifying or suspending the research to mitigate risks. Failure to report adverse events promptly jeopardizes participant safety and may result in withdrawal of ethics approval.

Researchers should familiarize themselves with the definitions and reporting requirements outlined in the *National Statement*, and proactively engage with the Human Ethics Officer or HREC Chair for guidance when unexpected issues arise.

Appeals

If a researcher disagrees with an HREC decision, including applications that are not approved or require substantial revision, there is a formal appeal process. Appeals must be lodged in writing, addressing the reasons for disagreement and providing any additional information or clarifications.

The appeal is reviewed by an independent panel or committee, separate from the original reviewing body, to ensure impartial consideration. Researchers are encouraged to engage early with the Human Ethics Officer for advice on preparing appeals and understanding the grounds for review.

Appeals should be made promptly to avoid unnecessary delays in commencing or continuing research.

See also the HREC's Complaints and Non-Compliance Procedures