Application Guide:
Human Research Ethics

JCU Human Research Ethics
Servicing JCU Researchers

1. Introduction

"All human interaction, including the interaction involved in human research, has ethical dimensions. However, "ethical conduct" is more than simply doing the right thing. It involves acting in the right spirit, out of an abiding respect and concern for one's fellow creatures." (The National Statement)

To ensure human research is conducted ethically, human research conducted by JCU's staff and students is reviewed by the JCU Human Research Ethics Committee conducts its human research in line with the *National Statement on Ethical Conduct in Human Research* and related legislation including the *Information Privacy Act* and the *Human Rights Act*.

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' and when is the ethical review of activities required?

All human research projects conducted at the University (both in JCU-Australia and JCU-Singapore), or by staff and students of the University, must undergo ethical review and the JCU HREC will accept applications from all JCU staff and students, and adjunct staff but only where the research is being conducted under JCU's auspices.

Human Research

The *National Statement on Ethical Conduct in Human Research* defines human research as '*research that is conducted with or about people, their data or tissue*', and may involve human participation in:

- Surveys, interviews or focus groups.
- Comparing or investigating psychological, physiological or medical research.
- Clinical trials.
- Observation by researchers.
- Researchers having access to oral histories, personal documents or other materials.
- The collection and use of body organs, tissues or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens, etc.) or their exhaled breath.
- Access to their information (identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

(See the National Statement 'Purpose, Scope and Limits of this Document)

Exempt Research

The National Statement allows certain human research to be exempted from ethical review if it*:*
- *"Is negligible risk research*
- *Involves only the use of existing collections of data or records that contain only non-identifiable data about human beings" (Read Sections 5.1.22-23 of the National Statement)*

If you plan to carry out human research using only existing data or records and non-identifiable data, please contact the ethics team for advice as to whether your research requires ethical review, and send an email with a short description of your planned research, including whether the data you want to access had any consent statements attached outlining the consent given to collect the original data.

Quality Assurance Activities

Quality assurance activities do not require ethical review, however they must be carried out according to ethical principles. For information on ethics in quality assurance activities read the NHMRC's Ethical considerations in quality assurance and evaluation activities, and researchers are encouraged to read Section 2(e) Triggers for consideration of ethical review when deciding whether they need to request ethical review.

Undergraduate Student Projects

Undergraduate students conducting small research projects involving human participants as part of their course assessment will need to ethical review for these projects. However, in some cases it may be possible for the lecturer in charge of the subject to submit a single ethics application for the course to cover these smaller projects. Please contact the ethics team to confirm requirements for your proposed projects and to find out more about whether a single ethics application is able to cover a subject or assignment.

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.

Accessing Student Data in University Databases

If you plan to access personal data from the university's databases in your research, you must first request approval to access the data from the JCU Privacy Officer as per JCU policy. If approval is given you can then submit your application to the HREC.

Social Media as a Source of Data

Social media is increasingly being used as a source of data and there are often conflicting opinions about whether ethical review of this data is necessary since the information is in the public realm, but its use raises several ethical concerns such as consent, anonymity and the risk of harm, especially reputational harm to participants.

The *National Statement* only exempts human research if it meets both the criteria outlined above, which says that research can be exempt only if it uses non-identifiable data. Since data in social media is unquestionably identifiable, research using data derived from social media does require ethical review. For more specific guidance on using social media in your research and what you need to consider when planning your project, contact the ethics team.

Online Interviews, Focus Groups and other Online Interactions with Participants

The HREC requires that any online interactions with participants such as interviews, focus groups or transcription are carried out on **Microsoft Teams**, rather than Zoom or other applications. The HREC has had advice that **Teams** offers the most secure environment for these interactions, and **Teams** stores its data in Australia, and so meets Australian standards and requirements for data storage.

Advice on Internet Research

The internet is increasingly being used in research in many ways and with many uses. Advice on ethical principles relating to research on or using the internet. Resources are available online, but the current version of the National Statement provides only general guidance on internet research.

The Association of Internet Research provides guidance on research ethics related to the internet. Resources are available on the **AoIR website**.

Clinical Trials

The JCU HREC does not review clinical trial research. The Townsville Hospital and Health Service (THHS) HREC reviews JCU's clinical trials for us. For information on how to apply to the THHS HREC please see their website and download their submission checklist.

3. Human Research Ethics Training

Training in human research ethics is provided with resources available in LearnJCU organisation "Human Research Ethics". Face-to-face training or workshops can be requested on topics of interest to Ethics Advisors

Open access online training modules developed by the University of Southern Queensland can be accessed by JCU staff. You will need to register as a guest user to get a guest login before enrolling in the module. This module is free.

All researchers and students conducting Aboriginal and Torres Strait Islander research should complete Aboriginal and Torres Strait Islander cultural competency. JCU staff and students can access training through the Centre for Cultural Competence by enrolling through the JCU Staff Learning Hub training portal. Please provide a copy of your course completion certificate with your application.

4. The Research and Innovation Services Human Ethics Team

The human ethics team consists of the Human Ethics Officer (HEO) and the Manager, Animal Welfare and Research Ethics. We aim to facilitate the ethical review process in an efficient and supportive manner.

The team is available to provide advice and assistance to investigators in their dealings with the HREC, including:

- Advice on planning and conducting ethical and compliant human research
- Advice on the *National Statement* and legislation
- Processing of applications and other submissions to the HREC
- Provision of training, drop-in Q&A sessions or small workshops in the ethical animal research and teaching and human research practices, the *National Statement* and legislation

5. Application Procedures

The HREC meets monthly, except for January, usually on the last Tuesday of the month. Submissions to a HREC meeting must be received at least 3 weeks before the scheduled meeting date. On rare occasions, and only if there is a good reason, late applications maybe accepted or urgent review may be arranged.

Human Research Ethics Advisor Review

The process for Ethics Advisor review varies depending on the college or discipline. The review report template breaks down the review into the sections of the application and elements of research outlined in Section 3.1 of the *National Statement.* This guide can be used alongside the application and the National Statement.

Documentation for Submission

The following documents must be submitted in order for an application covering human research:

- A fully completed Risk Assessment Checklist

- A fully completed Human Research Ethics Application Form

- A Human Ethics Advisor report

- Any of the Additional Documentation as applicable to your research project (see below)

Participant Information Sheet/Plain Language Statement

All applications must have a form of Information Sheet or Plain Language Statement outlining the project in lay language suitable to the participant group(s), whether that is a written document, statement in a survey or script for informing participants orally.

Researchers can use the JCU HREC's Information Sheet template, or one of equivalent content meeting the requirements of the National Statement.

Consent Form

All applications must include either an outline of how the participants will provide informed consent or a justification for a waiver of consent. (*See the National Statement Sections 2.3.9-12*)

When consent will be obtained in writing, researchers can use the JCU HREC's Informed Consent Form Template, or one of equivalent content meeting the requirements of the National Statement.

If consent is to be verbal, an outline of what will be said to participants when obtaining consent will need to be provided.

Survey, Questionnaire, Forum/Focus Group Questions or Script

If the research involves a survey, questionnaire, forum or focus group, a copy of the questions (either draft or final) must be submitted with the application. If the survey will be oral in person, over telephone or via videoconference, a copy of the script will need to be submitted.

Advertisements

If the recruitment method involves the use of advertisements or social media posts, a copy of the

advertisements or post must be provided with the application, as well as details of which social media sites, the advertising media need to be provided. If social media is to be used, then the account should not be a private account.

Letters of Support.

When other organisations are to be involved in the research, such as in assisting in recruitment, Letters of Support will need to be provided. These should be on official letterhead of the organisation.

Return of Review

Once you have your review from the Human Research Ethics Advisor, please make the requested amendments (if applicable) and combine all documents into one pdf so that it can be sent to the Dean/Delegate for their signature and subsequent submission to ethics@jcu.edu.au.

6. Review Pathways

The level and pathway of ethical review of human research will depend on the potential risks the research may present to the participants, as described in the National Statement *(Read Sections 5.1.6 – 8)*

Low and Negligible Risk (LNR) Research Review

Research that involves meets the criteria of low or negligible risk, may be reviewed by the HREC's Executive, which consists of the Chair and one other member of the HREC.

For negligible and low risk executive review, we aim to have your application reviewed within 5-7 working days.

To help guide you determining the risk of your research please refer to the Human Research Ethics Risk Assessment.

HREC Review for Research Involving More than Low Risk

Full HREC review is required for all human research that involves more than low risk to the participants, or research that raises certain other ethical issues, such as:

- Participant groups that require special consideration.
- Clinical trials.
- The use of human biospecimens.
- Genomic research.
- Animal-to-human xenotransplantation.
- People highly dependent on medical care who may not be able to give consent
- Pregnant women or the human foetus.
- People who may be involved in illegal activity.
- Aboriginal and Torres Strait Islander people.

For the review of research where the risk may be more than discomfort, we aim to have a response from the Committee within 10 working days after a meeting.

External HREC Approvals

In accordance with the *National Statement*, if you are a JCU staff member or students and have research approved by an external/non-JCU HREC, we can acknowledge the approval so that you don't need to submit another application to the JCU HREC. JCU will not conduct another review of the research, we will only acknowledge that you have approval already.

To have an external approval acknowledged, the external HREC must be registered with the NHMRC if it is an Australian HREC or if overseas it should be a recognised ethics committee within that country; and the person submitting the request will need to be listed as an investigator on the approval.

Complete the Cover Sheet External HREC Approvals as well as your external HREC Application and supporting documents according to the HREC's submission guidelines to ethics@jcu.edu.au

If your application has been reviewed and approved by an oversees review body, we may or may not be able to acknowledge that approval depending on where the approval was granted. Contact the ethics

team to seek advice.

Exempt Research Review

If you feel your research meets the criteria and may be exempt from ethical review, contact the ethics team to confirm its exemption or submit a negligible risk application form for review.

7. Guide to the JCU HREC Application Form

The JCU HREC will accept either the JCU HREC Application Form or the National Human Research Ethics Application online application form.

Before completing the application form, researchers should:

- Read the *National Statement*

- Read all appropriate guidance documents related to their discipline of research and research project

- Complete a human research ethics online training module

The ethical review of your research will be guided by the *National Statement,* and decisions made will be based on this document, related guides and legislation.

References to the applicable sections of the *National Statement* are provided below and in both the JCU HREC application form and the HREA online form. To give your application the best chance of approval it is recommended that researchers (especially students, early career researchers and those submitting their first application) read the *National Statement* and use these references to inform their research planning and completing your application.

Each application should contain information related to the one project and research aims. Applications containing multiple research projects should be submitted in separate applications. This will improve the chances of approval.

Human Research Ethics Risk Assessment

The Risk Assessment is designed to prompt researchers to consider what risks may be present in their research plans so that they can be considered, gauged and either removed, minimised or managed *(Read the National Statement Chapter 2.1* for more information). The checklist contains common risks that arise in human research. It will also inform ethics advisors about whether their research is of a negligible, low or more than low risk and so the review pathway their application will be sent through and which of the 6 risk levels below, it belongs in. If the checklist contains a "yes" it's likely that the research will involve more than low risk and so will need full HREC review. Advisors may ask researchers to reconsider the risk category of the research they have chosen using this checklist as a guide. (Table 1.)

Table 1. Human Research Ethics Risk Assessment

Category	Procedure	Examples
1	Negligible Risk: Research or teaching projects with no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience. No deception involved and no invasion of privacy.	*Non-intrusive anonymous questionnaires, non-aversive stimulus manipulation and/or response measures; development, learning, teaching processes; dietary controls.*
2	Low Risk: Research or teaching projects where the only foreseeable risk is one of discomfort. Could include some form of personality or clinical assessment. (Cite tests or enclose copies if unpublished instruments are to be used.)	*Clinical examinations, Manifest Anxiety Scale, surveys with questions or subjects that may make some people uncomfortable.*
3	Information requested or provided that might result in some mild psychological distress, or clinical procedures resulting in mild physical stress. (If there is a possibility of minor deviation from the complete and frank disclosure as to the true nature of a project, classify as Category 3.)	*Insignificant deprivations, manipulations or stimuli, clinical treatments, blood sampling.*
4	Projects similar to Category 3 that could result in genuine but not severe psychological distress or physical pain with no long-term effects. (Where some deception may be involved in the explanation given to participants, classify as Category 4.)	*Exposure to toy spiders in phobia treatment, hypnosis, sports and exercise science tasks, running, weightlifting/bearing, elevated heart rate, etc*
5	As for Categories 3 and 4 but with a potential for a greater degree of psychological distress or physical pain. (If there is any possibility of long-term effects or if substantial deception will be involved, classify as Category 5.)	*Aversive behavioural conditioning; exposure to real snakes or spiders in phobia treatment, surgery.*
6	Projects which, in addition to Categories 2 to 5, may raise some serious ethical problems.	*Projects with populations that require special ethical consideration such as vulnerable people, prisoners, or the terminally ill.*

Project Duration

How long do you need ethics approval for? Please provide a date range noting you cannot start your project until ethics approval has been provided to you via an ethics approval notice. The HREC generally approves research for up to three years, contingent on the submission of satisfactory annual progress reports. If you feel you need more, and have the resources to support the research over that amount of time, you can request longer approval if you provide justification for the extended approval.

Role and Experience

The *National Statement* outlines a set of principles for ethical human research. The first '*Research merit and integrity'* says that for research to have merit it must be '*conducted or supervised persons or teams with experience, qualifications and competence that are appropriate for the research' (Read Section 1.1(e)).* In this section each investigator should describe their role in the research and outline their experience and qualifications in that role in relation to the research being conducted. If a researcher is a student or doesn't yet have experience in that role, they need to describe how they will be trained and supervised until they are competent.

Funding and Financial Benefits

To meet the principle '*Research merit and integrity',* the research must be *'conducted using facilities and resources appropriate for the research' (1.1(f))* that *'are sufficient to conduct and complete the research as designed' (3.1.9(a)).* In this question outline the financial support for the project. If the research doesn't have any funding support, it may have in-kind support through the use of computer equipment, space or use of other equipment that will allow the research to be conducted appropriately.

Some researchers will use the term self-funded, which may be problematic and the HREC will need to know more information about what exactly will be paid for by the researcher. Some researchers use the term when they really mean in-kind funding such as the use of their employers IT equipment, facilities or the researcher's time. In-kind funding will also need to be elaborated on.

If there is financial support provided for the research, the participants need to be informed before consenting, usually by including it in the information sheet. This is so they can take that into account when consenting to participate.

(Read the National Statement 1.1(f), 2.2.6(h), 3.1.9(a), 5.2.8))

Aims and Background

To meet the principle '*Research merit and integrity'* the research must be *'based on a thorough study of the current literature' (1.1(c))* and be *'searching for knowledge and understanding'(1.3)*. To demonstrate how the proposed research meets this principle, the background of the research should be explained and justified based on the literature and current knowledge and the aims clearly outlined. References should also be provided for this section.

(Read the National Statement 1.1(c), 1.3, 3.1.1-11)

Participants Details

To meet the principle of *Justice, 'the process of recruiting participants is fair'* describe the participant groups that will be targeted in the recruitment and any inclusion/exclusion criteria, including anything that's relevant to the research, such as:

- Age groups
- Culture/Ethnicity
- Sex
- Location
- Profession

Explain what measures will be put in place to ensure there is no sampling bias in the data collected eg imbalances in sex or age.

If the participants could be under the age of 18, a working with children approval will need to be in place. JCU-A researchers will need to get a Blue Card and JCU-S will need a Singapore Police Certificate of Clearance. A copy of these documents will need to be provided to the HREC with the HREC application.

If the participant groups have a dependent or unequal relationship with the researcher there may be a risk of coercion. Research will need to be designed to ensure that the risk of coercion is managed. Advice on how this may be done is provided in the *National Statement Chapter 4.3*. For more information on managing these relationships in research contact the Human Ethics Officer who can direct you to additional resources.

(Read the NS Section 4 and 1.4(a), 3.1.14-15, Section 4 – as relevant to the participants)

Aboriginal and Torres Strait Islander Research

If you are thinking about conducting a research project with Aboriginal and Torres Strait Islander peoples or communities, the design of your project must respect and take into account the values, and cultural protocols of Aboriginal and Torres Strait Islander peoples. As such there are additional considerations for research projects that:

- Will involve or be conducted in or with Aboriginal and Torres Strait Islander communities

- Uses data/information related to Aboriginal and Torres Strait Islander peoples that is not otherwise publicly available

- Targets participants who are Aboriginal and Torres Strait Islander people/s

- The recruitment population is likely to include a significant number of Aboriginal and Torres Strait Islander peoples, i.e. health population studies, certain school populations

For guidance on the planning, design and conduct of ethical Aboriginal and Torres Strait Islander peoples research, please read the following documents and refer to the JCU Application and Submission Guidelines for Aboriginal and Torres Strait Islander research.

- National Statement on Ethical Conduct in Human Research (2007) - Updated 2018

- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018

- Keeping research on track II 2018

If you are carrying out Aboriginal and Torres Strait Islander research, please also complete the Aboriginal and Torres Strait Islander application supplement and address the six core values.

Methods

To meet the principle '*Research merit and integrity',* the research must be '*designed or developed using methods appropriate for achieving the aims of the proposal' (1.1(b))* and follow *'recognised principles of research conduct' (1.3(b)).* Demonstrate how your research will meet these principles by providing an overview of the methods you plan to use to meet the aims described previously (max. 250 words). Later questions will look more closely at the elements of research outlined in Chapter 3 of the National Statement, so provide an overview of the following:

- research design

- details of data collection techniques eg survey, focus group, observation

- sampling strategy

- tasks participants will be asked to complete

- the estimated time commitment involved

- how data will be analysed to achieve the aims of the study

Ethics advisors are in a good position to assess the merit of the scientific methods being used and can provide feedback and suggestions based on their own experience.

(Read the National Statement 1.1(b), 1.3, 3.1.1-11)

Videos and Photographs

If you are taking videos or photographs of the participants, explain why this is necessary to meet the aims of the project, especially if they clearly identify the people involved. Participants will also need to be informed and consent to this happening and be told how and where these images will be used.

Where there will be photos identifying people participants will need to complete the JCU Talent Release Form, so submit a copy of this form with your application.

Research Sites and Locations

To meet the principle '*Research merit and integrity',* the research must be *'conducted using facilities and resources appropriate for the research' (1.1(f))* and '*are appropriately allocated and sufficient for the research to be completed safely' (3.1.9(b)).* Describe the proposed facilities/settings where the research will be conducted and how they are appropriate for the research and meet any emotional or physical needs and the safety of the participants. This is particularly important if the participants are from certain groups with special needs or if the research is such that certain conditions or equipment is required for the research to be safe.

If the research is done online, describe the systems to be used and how the emotional wellbeing of participants will be protected if the research topics are such that they may cause distress.

(Read the National Statement 1.1(f), (3.1.9(b))

Queensland Health Service Districts or Patients

Any research being conducted involving Queensland Health staff, patients, sites and/or data must be approved by the appropriate Queensland Health HREC according to the Queensland HREC procedures. Please submit your documents as outlined under External HREC Approvals above for acknowledgement.

Research carried out in other health facilities including interstate should check with the administering organisation to determine what their application requirements are before submitting to the JCU HREC.

Research Taking Place in Queensland Department of Education Facilities

Research taking place in Queensland Department of Education (QDofE) facilities (schools) must first obtain JCU HREC approval, and then be submitted to the QDofE Research Services as outlined on their website.

QDofE Research Services will then process the application and guide it to the appropriate review processes as a part of their internal governance.

Research Taking Place in Queensland Catholic Education Facilities

Research taking place in catholic education facilities should consult their website for information on research involving their staff and students.

Research Taking place in other Education Facilities

Research being conducted in education facilities not administered by the Queensland Department of Education Approach the educational institution directly to find out their requirements for their participation in research.

Overseas Research

If research is to be conducted in a country, JCU researchers must still comply with the *National Statement* and the same values and principles will apply. Researchers may also have to comply with local laws or requirements for human research, and it is up to the researcher to inform themselves of these before they seek HREC approval. Chapter 4.8 outlines requirements that relate to research in other countries (other than Australia – JCU-A and Singapore – JCU-S).

Researchers conducting research overseas need to provide the HREC with documentation that shows approval or support for their research from the governments of these countries and evidence that no other human research ethics approvals are required e.g. links to websites or guidance documents from those countries, correspondence from government officials etc.

(Read the National Statement Ch. 4.8)

Recruitment

Describe the recruitment process including:

- The recruitment strategy
- How contact details will be accessed
- Screening process for inclusion/exclusion of certain participants
- How will the recruitment strategy facilitate obtaining consent?
- How will the recruitment strategy ensure that participants can make an informed decision about participation?
- Are there any risks associated with the recruitment strategy for the potential participants or viability of the project?
- What is the impact of any relationship between researchers and potential participants on recruitment?
- If social media is to be used, what platforms, groups, pages. Will the use of chosen platforms lead to the exclusion of certain groups/demographics of people and if so, how will any bias be addressed? *(See below)*

Copies of advertisements, scripts used for oral recruitment, social media wording and photos or any other tools used in the recruitment strategy need to be submitted with your application. Resources and advice on using social media as a recruitment strategy can be provided by the Human Ethics Officer.

Letters of support from any organisation involved in the recruitment or research: including access to data, premises, staff, schools need to be provided before approval can be released.

Considerations when using Social Media as a Recruitment Tool

The National Statement does not specifically provide advice on the use of social media in recruitment of participants; however, several publications offer considerations for researchers. A summary of issues related to social media in recruitment can be found on the [AHRECS website.](#)

(Read the National Statement 1.4(b), Ch 3.1 Element 2, Section 4 – as relevant to the participants)

Consent

To meet the principle of *Respect*, researchers need to give '*due scope, throughout the research process, to the capacity of human beings to make their own decisions' (1.12)* and informed consent is an essential part of ethical human research. Researchers need to describe to the HREC how they plan to get informed consent from potential participants.

The *National Statement* says that *'a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation'* in it and a *'well-designed consent strategies are appropriately tailored to the potential participants, the research design, the topic and the context'.* Researchers need to describe to the HREC how they plan to get informed consent from potential participants.

Information can be provided in a number of ways, with the most common being through an Information Sheet. The JCU HREC has a template that covers all the information that needs to be provided to potential participants so they can make an informed decision about their participation. Please use this template when preparing your applications

There are several ways a potential participant can provide consent including:

- Signing a consent form
- Verbal consent
- Implied consent, such as starting or returning a survey

For more information on consent including renegotiating or withdrawing consent, dependent and unequal relationships and consent for the future use of data or tissues, opt-out consent and waivers of consent read the *National Statement Ch. 2.2, 2.3.*

For further guidance on consent and information sheets, see Appendix XX or you can use the JCU HREC's Consent Form and Information Sheet proformas.

(Read the National Statement 1.12, Ch. 2.2, 2.3, 3.1 Element 3)

Reimbursements and Incentives

While it's acceptable to offer reimbursement to participants to cover any time or other costs incurred as a result of their participation, these should not be excessive or disproportionate such that it may induce people to take risks they would not normally be prepared to take. Examples of appropriate reimbursements or incentives include:

- Reimbursement of travel, parking costs
- Small sums of money (gifts or vouchers are generally preferred)
- Credit point recognition eg SONA credit points
- Gifts or vouchers worth only small amounts of money

(Read the National Statement 2.2.10-11)

Risk Management and Benefits

To meet the principle of *Beneficence, 'the likely benefit of the research must justify any risks of harm or discomfort to participants' (1.6)* and is should be designed to *'minimise the risks of harm or discomfort to participants' (1.7(a))*. In the research design stage, researchers are required to:

- Identify any risks
- Gauge their probability and severity
- Assess the extent they can be minimised
- Determine whether they are justified by the potential benefits
- Determine how they can be managed during the research

More information on risks and benefits can be found in the *National Statement Chapter 2.1,* researchers should refer to this chapter, and work through the process of risk identification, minimisation and management in their applications.

Researchers also need to provide a statement that demonstrates that the research is ethically acceptable because the '*potential benefits justify any risks involved in the research'*.

(Read the National Statement 1.6, 1.7(a), Chapter 2.1)

Data and Information Management

Human research data must be managed using the Research Data JCU platform and according to JCU's Research Data Management policies and procedures.

Read the *National Statement Section 3 Element 4*, refer to the Research Data Management Toolkit and please ensure that you have read the *Code for the Responsible Conduct of Research* and *Management of Data and Information in Research.*

When completing the application, consider the following aspects of data and information management, including data:

- Generation and collection
- Identifiability
- Use and analysis
- Storage
- Access, sharing and re-use
- Retention and disposal

If the data will be non-identifiable, provide details.

(Read the National Statement Section 3 Element 4)

Privacy

Please give attention to privacy implications and compliance with legislative requirements including the Privacy Act (Australia), Information Privacy Act (Queensland) or the Personal Data Protection Act (Singapore). Please see the *Guidelines Approved under Section 95A of the Privacy Act 1988* produced by NHMRC. See Queensland Health for information on applying for access to information held by Queensland Health and submitting a PHA application.

Dissemination of Results

To meet the principle of *Integrity*, *'disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public scrutiny and contribute to public knowledge and understanding' (1.1)* and '*Research outcomes should be made accessible to research participants in a way that is timely and clear*.'(*1.13(d)*)

Researchers need to consider how they plan to disseminate results of their research, and can include publications, presentations, and through other media, and also whether and how participants will be provided with the results. Researchers should read *Chapter 3 Elements 6 and 7* of the *National Statement* and consider the points and questions in these sections when completing your application.

(Read the National Statement 1.1, 1.13(d), Ch. 3, Elements 6 and 7)

8. Managing Your Research Project

Approval Notification

Once your research has been reviewed, you will receive formal notification outlining the decision. The HREC may:

- Approve the application – your research was reviewed without reservation and you may now commence your research.

- Approve with conditions – the HREC may have additional questions or require minor amendments to the research but cannot be approved until these have been received.

- Defer the application – if the research raises ethical issues that have not been adequately addressed in the application, if major amendments are required or if there is insufficient information in the application for the HREC to make a decision, the application will need to be redrafted and resubmitted for reviewed.

- Reject – the HREC may reject the application if there are major ethical issues in the research or it doesn't meet the principles of the *National Statement*.

The HREC will notify the Principal Investigator when approval has been granted, meaning you may commence your research once you receive the ethics notice. You cannot start your research until you have received this written notification, and that includes any advertising or recruitment of participants.

Where there are outstanding matters the HREC will include this in the approval notification. These outstanding matters need to be addressed and provided to the ethics team as soon as possible.

Once approved, you are required to conduct it according with the *National Statement* and any conditions placed on the research by the HREC.

Amendments to Approved Research

Where there are outstanding matters the HREC will include this in the approval notification. These outstanding Once approved, you may find it necessary to make changes to aspects of the research plan. If you need to make changes to your plan from what was approved, you will need to submit an amendment and cannot implement the changes until you receive approval from the HREC.

Amendments to research are usually reviewed by the HREC"s Executive in 5-7 business days, however if the proposed changes are major or raise additional ethical issues, they may need to undergo full HREC review. Additionally, if there are significant changes to the research, a new application may be required.

Note: amendments to research plans may also require that other documentation needs to be amended also, including the Information Sheet, Consent Form or Trial Protocol. Please ensure that all necessary documentation is submitted with your amendment.

Annual Progress and Final Reporting

The *National Statement (See Section 5.5.5)* requires researchers to report annually and at the completion of the research using the [Annual/Final Progress Report Form](#),

You will receive reminder emails nearing the anniversary of the date of initial approval and a report needs to be submitted by the deadline. A failure to submit a report may result in the HREC suspending your project.

If you finish your project before the approval ends you can submit your Final Report early to save you from receiving further requests for reports. If you receive a reminder for a Final Report but your research is not yet complete, you can apply for an extension by submitting an amendment.

Adverse Events

An adverse event is any incident that has the potential adversely affect research participants or the progress of the progress. Adverse events should be reported using the Adverse Event Form, as soon as possible after they occur, and may mean that the project needs to be amendment to prevent further occurrence.

Complaints

If you have any concerns or wish to lodge a complaint about:

- The conduct of a JCU researcher or student undertaking human research.
- A JCU human research project.
- A decision made by the JCU Human Research Ethics Committee.
- JCU human research that you feel may not have HREC approval or being conducted outside of the conditions of approval.
- JCU human research that may be in breach of legislation.

You can raise these concerns or lodge a complaint confidentially by contacting the ethics team via email, by phoning +61 7 4781 5011, or by writing to:
Chair of the JCU Human Research Ethics Committee
Research and Innovation Services
James Cook University
Queensland 4811

If there is evidence supporting the veracity of the complaint, the matter will be referred to the Chair and HREC and may result in referral to the University for further action.

Appealing a HREC Decision or Process

If an applicant is concerned by the way a human ethics application was processed or by a decision of the HREC, in the first instance, please contact the Human Ethics Officer or the Human Ethics Advisor of the project. If concerns remain unresolved after discussing the issue with the Human Ethics Officer or Human Ethics Advisor, the matter may be referred to the Chair, HREC for advice and action. If still unresolved, a meeting may be called where the Chair, HREC and Senior Deputy-Vice-Chancellor will discuss the matter with the applicant.
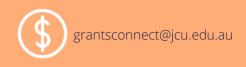
Contact Research and Innovation Services

Research and Innovation Services opens doors across our campuses in Australia and Singapore, making it easier for you to connect with the right people, expertise, facilities, resources, and advice.

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