

James Cook University Human Research Ethics Committee

Operating Procedures

Membership

Human Research Ethics Committee

Membership of the JCU Human Research Ethics Committee (HREC) is prescribed in the National Statement and outlined in the HREC's Terms of Reference.

Executive

The Executive will consist of the Chair and one other member of the HREC.

Appointment of members

New members will be appointed for a term of three years by the Chair.

Internal (JCU) candidates for membership will generally be drawn from existing Human Ethics Advisors (HEA), or Lower Risk Panel members although if nobody from these sources puts themselves forward a request could be put to the colleges and institutes asking for a nomination of a suitable candidate or an expression of Interest will be sent around appropriate colleges.

External appointees will be sought through word of mouth, by recommendation from a previous member, by approaching an appropriate organisation or by posting an advertisement including to JCU Alumni.

Potential new members will submit a membership nomination form for review and a meeting with the Chair will be organised. The potential new member will be offered to attend a meeting as an observer and will complete a Confidentiality Agreement beforehand.

If the membership goes ahead, the new member will receive a formal notice of appointment which includes:

- The specification of the category of membership to which the person is appointed
- Notification that their term of membership is three years and may be renewed
- A statement that the University accepts legal liability for decisions and advice received from the Committee, and indemnifies members for any action taken against them in respect of Committee business
- Reference to the requirement in the *National Statement on Ethical Conduct in Human Research* (the National Statement) that all members be fully informed and have an opportunity to contribute to discussions and decisions of the committee their views on each application considered by the Committee
- Information on the Committee and its operations, including the committee's Terms of Reference, Operating Procedures, guides, and an electronic copy of the National Statement

Upon appointment to the Committee, members will also be required to sign the following:

- Confidentiality Agreement
- Volunteers Insurance Form (if not a JCU staff member)
- Conflict of Interest Declaration
- A statement declaring that they agree to abide by the committee's Terms of Reference and the National Statement

Orientation and training of members

On appointment, all members and the Chair will be provided with an induction acquainting them with the HREC's procedures, the National Statement, the HREC application guide and related documentation and will be provided with electronic copies or links to these documents where they exist.

New members will also be guided to complete JCU's mandatory online [Human Research Ethics Foundations](#) training modules.

Resignation or Termination of Membership

Resignation from the HREC by members should be made in writing to the Chair.

Termination of membership of the HREC will be made in writing by the DVC-R, in accordance with the Terms of Reference providing details of the reason for the termination.

Chair

The Chair will be appointed by the Deputy Vice Chancellor – Research (DVC-R) following a recommendation from Research and Innovation Services and will hold a senior position at the University.

The position of Chair will not have a fixed term, but the approximate term of service will be 5 years.

The Chair will receive a stipend for taking on the role.

The Chair will review amendments to approved protocols that don't raise serious ethical issues and responses to ethical review, not requiring revision and resubmission for re-review.

Deputy Chair

Three Deputy Chairs may be nominated or recruited through an Expression of Interest process sent to all JCU staff.

There will be two Deputy Chairs appointed from JCU- Australia staff and one from JCU-Singapore staff.

The position of Deputy Chair will have a term of three years, however when the term is ending the previous incumbent can renominate for the position with a maximum term of 6 years.

In addition to their membership of the HREC, Deputy Chairs will also be the lead reviewers for the three Lower Risk Panels, conducting the review of lower risk human research.

Human Ethics Advisors (HEAs)

HEAs will be appointed as delegates of the HREC and their roles will include:

- Providing advice to applicants on HREC processes and the National Statement
- Conduct a pre-review of applications to determine whether their level of risk is appropriate for the review pathway the application is seeking, and to provide feedback to the applicant on whether any changes are required in order to be approved
- Ensure that the application is completed correctly and thoroughly and contains all the relevant accompanying documentation

HEAs will have no fixed term of service and may serve as a source of members to the HREC.

Submission of New Applications

Application Documentation

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 and response to the report
- Any of the additional documentation as applicable to the research project (see below)

Additional Documentation

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 with the appropriate logo.

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.

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 or Forum/Focus Group Questions

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.

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.

Aboriginal and Torres Strait Islander Research

Research involving Aboriginal and Torres Strait Islander peoples, the additional Aboriginal and Torres Strait Islander form must be submitted.

Queensland Health/Townsville Hospital

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.

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.

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.

Submission of Documentation

Once the Dean has signed the application, it can be forwarded to ethics@jcu.edu.au as a single PDF document.

Validation of Applications

After receipt the HEO will review and validate the documents and ensure:

- All documents relevant to the particular application have been submitted
- The Ethics Advisor Report has been completed and submitted. Ensure that any review changes are highlighted and the Principal Investigator's response to Ethics Advisor review is completed.
- All necessary signatures are in place

If applications are missing any of the documentation necessary for review, the HEO will contact the Principal Investigator and the application will not be submitted to the HREC until these are received.

Research Review Pathways

Lower Risk Human Research

Lower risk human research will be conducted by the Lower Risk Panels.

Higher Risk Research

Research that meets the criteria of higher risk research, is research whose potential risk is greater than discomfort.

Other Research Review

If the research involves any of the subjects or participants below, it will also be reviewed by the full HREC:

- Human biospecimens in laboratory-based research
- Genomic research
- Animal-to-human xenotransplantation
- Women who are pregnant and the human foetus
- People highly dependent on medical care who may be unable to give consent
- People with a cognitive impairment, an intellectual disability or mental illness
- People who may be involved in illegal activities (except for those projects that only involve the collection of non-identifiable data and involve negligible risk)
- Aboriginal and Torres Strait Islander Peoples
- People in other countries (except where the risk to participants is low/negligible risk and/or the project does not involve participants who could be considered a vulnerable group in the context of the project)

Lower risk research that requests a waiver of consent or uses an opt-out consent process will also require review by the full HREC.

Full HREC Review – Research Involving More Than Lower Risk

Research involving more than lower risk or meeting the above criteria, will be reviewed by the full HREC.

Aboriginal or Torres Strait Islander Research

All research involving Aboriginal or Torres Strait Islander people must accord with the *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018* if it:

- Involves or will be conducted in an Aboriginal and Torres Strait Islander community;
- If the target participants of the study are Aboriginal and Torres Strait Islander peoples;
- If the recruitment population of the study is likely to include a significant number of Aboriginal and Torres Strait Islander peoples, i.e. health population studies, certain school populations.

All research involving Aboriginal or Torres Strait Islander meeting the above criteria will be reviewed by an Aboriginal or Torres Strait Islander Ethics Advisor, then reviewed by the full HREC.

Clinical Trials

Clinical trials will be reviewed by the Townsville Hospital and Health Service HREC by agreement.

Research Approved by an External HREC

The JCU HREC will accept approvals granted by external HRECs as long as they are registered with the NHMRC or where the reviewing body and review aligns with the standards of the National Statement, see also the External Human Ethics Approval Procedure.

Research Using Student Information from JCU Student Databases

Research that plans to use student information where specific consent was not provided when the information was collected, must be first approved by the Privacy Officer and then the full HREC, as it involved a waiver of consent.

Research Being Conducted in Queensland Health Facilities

Any research being conducted in Queensland Health Facilities, patients or data must be approved by the appropriate Queensland Health HREC according to the Queensland HREC procedures.

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 (schools, etc)

Research taking place in Queensland Department of Education (DoE) facilities (schools) must obtain JCU HREC approval, and also apply to the DoE Research Services as outlined on their [website](#). The two processes can be initiated at the same time but the final DoE Research approval is contingent on the HREC approval.

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 should approach the educational institution directly to find out their requirements for their participation in research.

Exempt Human Research

Research involving humans will be given exemptions to ethics review if it meets the requirements of the National Statement Sections 5.1.15-18.

Application Forms

All ethics submissions must be submitted through the online forms in GECO, including:

- Requests for exemption to ethics review
- Requests for external acknowledgement of external ethics approvals
- Applications for review of both lower and higher risk research

An auditable record of all research classified as exempt will be kept in GECO.

Meetings

There will be 11 scheduled meetings of the HREC, scheduled for the second Tuesday of every month except for January.

Meeting dates for the next year will be determined and uploaded onto the HREC's web page in early December to allow for forward planning by researchers.

Where possible meetings will be scheduled so that all members can attend, however members who are unable to attend will leave their feedback in the online meetings platform.

If, for some reason, a meeting has to be postponed or cancelled, researchers with items to be considered at that meeting will be notified and kept up to date on when next their items can be reviewed.

Distribution of Agenda Documents

All agenda items will be electronic, linked from the online meeting platform LearnJCU to the GECO application forms.

Members will have access to all relevant documentation and have an opportunity to contribute their views in the decision-making process on each application in LearnJCU.

Confidentiality of Proceedings

All HREC and Executive documents including applications, agendas, minutes and personal notes from meetings are confidential and must be archived securely in TRIM.

Discussions at meetings are also confidential and their details cannot be communicated outside of the committee and administration staff.

Attendance of the Applicants at Meetings

The HREC may invite applicants to meetings to discuss their applications and answer any questions the committee may have.

Advice from External Experts

The HREC may seek advice from an external expert to help in considering a proposal. The expert would be bound by the same confidentiality and conflict of interest requirements as the committee members.

Conflicts of Interest

Members will complete the Conflict-of-Interest Declaration upon joining the committee and declare any financial, personal or other conflicts of interest.

Each member, or expert advisor whose advice the HREC seeks, will declare any actual or potential conflicts of interest related to any of the agenda items at the beginning of each meeting, and leave the meeting so as not to be involved in decisions made about that item. They may remain in the meeting room for as long as it takes to discuss the item and answer any questions related to the item, if required.

If an expert advisor declares a conflict of interest the HREC will seek to find another advisor and if one cannot be found, request them to provide written advice.

All conflicts of interest and how they were managed will be documented in the minutes.

Decision Making

Each member will read the submissions and decide whether, in their judgment, an application submitted to the HREC meets the requirements of the *National Statement* and is ethically acceptable.

Decisions by the HREC about whether a research proposal meets the requirements of the *National Statement* must be informed by an exchange of opinions from each of those who constitute the minimum membership. This exchange should, ideally, take place at a meeting with all those members present.

All members will be allowed reasonable opportunity to express relevant views on matters on the agenda.

Members unable to attend may submit their comments using LearnJCU, by email or using another written form. These will be viewed or tabled and discussed in the meeting.

If members of the Committee are absent from a meeting, the Chair must be satisfied, before a decision is reached, that the minimum membership has received all papers, had an opportunity to contribute their views, and that the views of those absent have been received, recorded and considered.

The HREC will endeavour to reach a decision by general agreement, this may not involve unanimity.

Outcomes of review

The HREC will, on ethical grounds:

- Approve a proposal, with the resulting communication being in writing and clearly stating that it meets the requirements of the National Statement
- Approve the application pending minor clarification
- Defer the application, request amendment to a proposal either communicating the decision in writing or informally, or
- Not approve a research proposal, with the resulting communication

If an application is not approved, it may be re-submitted after changes are made that address the issues.

Duration of HREC approval

Project applications can be approved for up to three years, however approval is contingent on the submission of a satisfactory Annual Report, so if the Annual Progress Report is not submitted, the HREC approval may be withdrawn or suspended.

Projects can be approved for longer if there is sufficient justification and resources available for that length of time.

Notification and Communication of HREC Decisions

After the HREC's consideration of submissions, researchers will be notified promptly in writing of the HREC's decisions by the end of the meeting week.

Feedback to researchers about their submissions will wherever possible, refer to the appropriate sections of the *National Statement* or other documents and will be explained as clearly as possible.

While communication between researchers and the committee will initially be in writing, face-to-face and phone conversations and meetings will also be used as appropriate, especially where misunderstandings have arisen. Communication to researchers should not be adversarial.

Documentation and Record Keeping

Record Keeping

Records of ethics applications and other submissions will be kept in the GECO online system. Meetings will be facilitated through the online meeting portal LearnJCU, where members also leave their review feedback before the meeting. Once finalised ethics applications and amendments will be downloaded from GECO and archived in TRIM.

Agendas, minutes, submission documents, correspondence, approval notifications and other project-related documents will be stored on the secure server until they are archived in TRIM.

Agenda

Following the closing date for submission of applications for approval, the HEO will prepare an agenda for the meeting in consultation with the Chair.

The Agenda will include:

- Apologies
- Confirmation of minutes of the previous meeting
- Business arising from the minutes
- Matters not yet finalised
- Correspondence and matters listed for the information and consideration of the committee
- Research and teaching involving human participants:
 - Amendments approved since the previous meeting
 - Executive approvals granted since the previous meeting
 - Applications for full HREC review
- General Business

Minutes

The Human Ethics Officer will prepare minutes of the HREC meeting for confirmation at the next meeting as soon as possible after the meeting.

Minutes will be reviewed at the next scheduled meeting and any corrections noted before the final version is accepted.

After the meeting, the HEO will update and record the Committee decisions in the database and draft the notifications and feedback on each application.

Monitoring approved research projects

The HREC will monitor the conduct and progress of approved projects in a number of ways, as outlined below.

Annual Progress and Final Reports

Researchers must complete a progress report annually on the anniversary of the project's approval date and a final report on the completion of data collection and analysis. Reports also need to be submitted if a project is abandoned before commencing.

Amendments

An application to amend the approved protocol must be submitted prior to implementing the changes.

Reporting of Adverse Events

The Principal Investigator must immediately report to the Committee anything which might warrant review of ethical approval of the project, including:

- Serious or unexpected adverse effects on participants
- Proposed changes in the protocol
- Unforeseen events that might affect continued ethical acceptability of the project

Adverse event reports will be reviewed by the Chair, who will then decide whether the incident warrants being escalated to the HREC, or if any action needs to be taken immediately in order to protect participants.

Complaints

The HEO will maintain a record (the Complaints Register) of all complaints received regarding the activities of the Committee and the outcomes of those complaints, a record of all complaints received regarding research projects and the outcomes of those complaints, and a record of all possible breaches of the JCU's human research ethics procedures, the *National Statement* or an HREC approval.

Complaints concerning the conduct of a project

Concerns about the conduct of approved research projects may be raised by anyone, including potential participants or participants in the research, other members of the University, members of the general community, the researcher or the research supervisor.

These can be raised anonymously, or confidentiality can be requested, although the identity of the complainant may, at some stage, become apparent to the subjects of the complaint due to details provided and

Concerns about research conducted by staff or by students undertaking research degrees should be raised in the first instance with the Principal Investigator of the project or other project contact whose details are provided on the Participant Information Sheet. In projects for higher degrees by research, the research supervisor provides a secondary point of reference.

If discussions with the researcher and/or research supervisor do not resolve the problem to the complainant's satisfaction, they can be directed to the Chair through the HEO, and all those raised will be registered in the Complaints Register, investigated and reported to the HREC.

In accordance with the *National Statement*, contact details for the HREC as the recipient of complaints will be provided to all participants in research involving human participants.

The HEO will notify the Chair as soon as possible after its receipt so that an investigation can commence.

Suspension or Withdrawal of HREC Approval

Where the conduct of research has the potential to cause serious harm to participants, the institution or community, and the ethical approval for a research project is suspended or withdrawn by the HREC or the Chair, the researcher and the institution will be informed immediately in writing detailing the reason for requesting suspension or withdrawal of approval.

In the event an ethics approval is suspended or withdrawn the HREC will also immediately notify any other HRECs mentioned in the application of that withdrawal.

Complaints concerning HREC Decisions or Processes

The HEO will maintain a record (the Complaints Register) of all complaints received regarding the activities of the Committee and the outcomes of those complaints, a record of all complaints received regarding research projects and the outcomes of those complaints, and a record of all possible breaches of the JCU's human research ethics procedures, the National Statement or an HREC approval.

Complaints will be brought to the attention of the HREC at their next meeting.

Accountability and Reporting

The Committee will provide an annual compliance report to the National Health and Medical Research Council (NHMRC) on matters specified in the National Statement. The Committee will provide other information to the NHMRC or ARC on request.

The Committee will report annually to the University through the DVC-R.

Information in the report will include:

- Membership/membership changes
- Number of meetings
- Number of research projects reviewed, approved and rejected
- Monitoring procedures for ethical aspects of research in progress and issues identified by the HREC in undertaking its monitoring role
- Description of any appeals, complaints or non-compliance issues received and their outcome
- Description of any research where HREC approval has been suspended or withdrawn and the reasons for this action
- Training and professional development opportunities provided to the HREC members, researchers or administrative staff
- General issues including advice on strategies to promote awareness of the ethical conduct of human research in the institution
- Resources required to assist the HREC in fulfilling its role

The annual report to the HREC Executive will also include an evaluation of the performance of the HREC identifying any factors that have affected or may affect the integrity and efficiency of the HREC's performance. The HREC Chair is responsible for the conduct of this evaluation.

The HREC completes and submits reports on behalf of the University to the Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC, as well as any other reports as required.

The Chair of the HREC will review and approve any reports of activities of the HREC.