External Human Ethics Approval Procedure

Intent

This procedure gives effect to the process of formally recognising the approvals from non-JCU (external) ethics reviews of human research. The procedure outlines the process for assessing the external approval (including approval by overseas review bodies) of human research to determine whether that review process meets the standards of the Australian National Statement, while avoiding the duplication of ethics review wherever possible.

Scope

This procedure applies to all James Cook University (JCU) staff, students and adjuncts conducting human research under the JCU's auspices.

Definitions

Ethics review body	A committee, panel or other mechanism constituted to conduct the ethics review of human research regardless of its local name
HREC	Human Research Ethics Committee
LRP	Lower Risk Panel
National Statement	*National Statement on Ethical Conduct of Human Research*
RIS	Research and Innovation Services

Introduction

The National Statement Chapter 5.5 encourages institutions to avoid duplication of ethics review wherever possible and Sections 5.5.3-4 cover the acceptance of ethics reviews conducted by overseas ethics review mechanisms.

JCU formally recognises the approvals from external ethics reviews of human research that meet certain criteria and provides guidance on whether the external review meets the standards of the National Statement.

The National Statement section 4.6.1 states that when Australian researchers conduct research overseas, they must adhere to the requirements of the National Statement. When accepting the approval of an overseas ethics review body, JCU must be sure that the review meets the standards of the National Statement also, with respect to guidance provided in the National Statement Chapter 4.6.

It assists Research and Innovation Services to manage associated grants, contract research and funding.

The recognition process lies outside of JCU's ethics review framework and part of the University's research governance framework. In applying for external ethics recognition, a project will not be reviewed by an ethics committee and will not receive an ethics approval letter from JCU.

The external ethics committee will remain solely responsible for the ethical conduct of the research and its ongoing monitoring, and researchers will need to comply with the terms and conditions of the approving ethics committee. Researchers will, however, receive documentation from JCU that formally recognises the approving committee's decisions.

Procedure

Projects approved by external ethics review

(1) The University recognises the ethics review and approval of human research by external ethics review mechanisms if they meet the standards of the National Statement.

(2) Researchers who have obtained approval from an acceptable external ethics review body are not required to have their research reviewed again by the JCU HREC or other ethics review body if the approving review body meets certain criteria.

Criteria for recognition of external ethics approvals

(3) JCU staff and students who are working under the ethics approval of another review body are required to request JCU recognition of that ethics approval.

(4) JCU will accept external ethics approvals that meet the following criteria:

(a) approvals from an Australian NHMRC-registered research ethics body;

(b) approvals from other ethics review bodies, including overseas ethics review bodies that are based on the provision of information on the elements of research and apply ethics principles to the National Statement where:

(i) The review and application include the elements and principles of:

- Research scope, aims, themes, questions and methods
- Recruitment
- Voluntary informed consent
- Benefit and risk identification and management
- Data management, information privacy and security
- Dissemination of results, including communication of research findings to participants

(ii) The review body consists of qualified personnel that includes people independent to the review body's own institution.

(c) Guidance on which overseas ethics review bodies are likely to meet the criteria of acceptance are listed in Schedule 1, which is a living document and is updated as new information becomes known.

Notification, receipt and assessment of request to recognise external ethics approvals

(5) Researchers named on the research project must use the external ethics approval form or clinical trial form (for clinical trials) in GECO to notify the University of:

(a) The external ethics approval;

(b) Approval of any associated amendments to the project;

(c) Progress, final or incident reports submitted to the approving body (submitted as an attachment in GECO);

(d) Complaints or non-compliance.

(6) The PI must be a JCU staff member, student or associate (adjunct) and be listed as an approved researcher in the ethics application and on the approval document (this is even if a non-JCU researcher is the project's PI on the external approval).

(7) Each request form must:

(a) Identify one of the named JCU researchers as the lead JCU researcher and primary JCU contact;

(b) Have the lead JCU researcher on the approval be the Principal Investigator (PI) on the GECO recognition request form even if they are not the PI on the external approval so they will receive all project-related correspondence;

(c) Have uploaded in the GECO form's Attachments and Comments tab:

(i) The approved external application, and all approved supporting documents (Information Sheet Consent Form, surveys, interview guides etc);

(ii) The external approval notice or letter;

(iii) Any other documents reviewed by the approving ethics review body;

(iv) Current human ethics training records for all JCU investigators.

Responsibilities of JCU – Research & Innovation Services

(8) JCU will delegate responsibility for recognition of external ethics approvals to the Manager, Research Ethics & Compliance, Research & Innovation Services

(9) JCU will determine the criteria that must be satisfied to accept an ethics review conducted by an entity external to JCU (including overseas review bodies) and make these criteria publicly available.

(10) On behalf of the University, RIS will:

(a) Maintain the schedule of approved overseas ethics review mechanisms (Schedule 1) and publish this list on its webpages and in guidance material;

(b) Review the submitted documents and information provided and assess the external review against the criteria for acceptance of external reviews, and on a case-by-case basis either:

(i) Accept the request for recognition;

(ii) Request further information or documentation, and defer consideration until the information is provided;

(iii) Seek advice on whether the approval can be recognised from the HREC Chair;

(iv) Reject the request and inform the applicant that a full ethics application be submitted for ethics review by the JCU HREC or a LRP (note the outcome of these requests will be rejected in GECO and the request will be archived as with approved requests – meaning an entirely new ethics application must be started).

(c) Not recognise exemptions to ethics review by overseas ethics review bodies since the requirements for what research requires ethics review varies considerably between jurisdictions.

Responsibilities of the JCU researchers working under an accepted external approval

(11) JCU Researchers and students working under the approval of an external ethics review body must:

(a) Inform JCU of their involvement and comply with JCU's procedures to request JCU recognition of this approval,

(b) Provide the documentation to JCU as outlined above via GECO,

(c) Provide information relevant to the external approval to JCU on any existing national or international programs, protocols, policies, standards and guidance that may be relevant to the institutional decision to accept the review.

(d) The ethics review process and ethics standards applied so JCU can decide whether it will accept the external ethics approval.

(e) Notify JCU of any amendments to ethics approvals and any progress or final reports endorsed by the approving ethics review body,

(f) Inform JCU of any complaints, decisions to suspend or deny approval of research.

Responsibilities of the approving external ethics body

(12) Approving ethics review bodies will be responsible for:

(a) Maintaining oversight of the project;

(b) Monitoring activities conducted for the project;

(c) Handling any issues that arise during the conduct of the project.

(13) Any complaints raised to JCU concerning an externally approved project will be referred to the approving ethics review body.

Transfer of ethics approval from an external ethics review body to JCU

(14) Ethics approvals from overseas or unregistered Australian review bodies will not be accepted for transfer and a new application needs to be submitted to JCU.

(15) To action the transfer, the researcher must request the transfer by emailing the Ethics Office and then if accepted, request the recognition of the external approval in GECO as above.

(16) The request and GECO entry will be reviewed by the HREC Chair to determine whether:

(a) JCU can accept the transfer of approval; or

(b) Any amendments to the approval or supporting documents need to be made before it can be accepted; or

(c) A new application needs to be submitted for review by the JCU review body.

(17) Once transferred, JCU will be the primary approving institution, and all future amendments and reporting will be through JCU.

(18) Notification of the institution holding the original approval, any co-investigators, submitting a final report and closing the approval at that institution is the responsibility of the investigator requesting the transfer.

Related policy instruments

Code for the Responsible Conduct of Research - Policy

Schedules

Schedule 1 – Accepted overseas ethics review bodies by country

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Administration

NOTE: Printed copies of this procedure are uncontrolled, and currency can only be assured at the time of printing.

Approval Details

Policy Domain	Research Ethics and Governance
Policy Sub-domain	Research Governance
Policy Custodian	Manager, Research Ethics and Compliance
Approval Authority	Deputy Vice Chancellor Research
Date for next Major Review	

Revision History

[Use the table below to record information regarding changes to this procedure. Version control should be applied, for example major or minor amendments (approved by the Policy Sponsor) should be numbered 23-1, 23-2 and so on (the first two digits = year, the last digit = version number)].

***NOTE**: A minor amendment will not result in a change of the next major review date.*

Approval date - the date the Policy Sponsor approved the establishment, minor or major amendment or disestablishment

Implementation Date - the date the procedure was published in the Policy Library and is the date the procedure takes effect

Version	Approval date	Implementation date	Details	Author
1.0	29/10/2026	29/10/2026	Procedure established	Manager, Research Ethics and Compliance

Keywords	External HREC, External ethics approval, Human ethics, Research governance
Contact person	Manager, Research Ethics and Compliance

Schedule 1 – Accepted overseas ethics review bodies by country

Approvals from the following overseas ethics review bodies will be accepted in place of another review by the JCU HREC. Review bodies not listed below will be assessed on a case-by-case basis.

Country	Acceptable committees	Notes
Australia	Any NHMRC-Registered review bodies	
Canada	Any Ethics Review Board	
Fiji	Fiji National University Human Health Research Ethics Committee	
Indonesia	University Research Ethics Committees	
New Zealand	Any university or health human ethics committee	
Papua New Guinea	Institute of Medical Research Institutional Review Board	
Singapore	Any university or health Institutional Review Board	
South Korea	Hospital Institutional Review Boards	
Taiwan	Hospital Institutional Review Boards	
Thailand	University Research Ethics Committees	
Tonga	National Health Ethics and Research Committee	
United Kingdom	Any human research ethics committee	
United States	Any certified Institutional Review Board	