

# EXTERNAL HUMAN ETHICS APPROVAL PROCEDURES 2024

Issued by: Deputy Vice-Chancellor (Research)

Dated: 14 May 2024

Last amended:

Signature:

Name: Professor Emma Johnston

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## 1 Purpose and application

- (1) These procedures give effect to:
  - (a) the [Research Code of Conduct](#); and
  - (b) the [National Statement on Ethical Conduct in Human Research 2023](#) ("National Statement")
- (2) These procedures:
  - (a) apply to research conducted by staff, students, affiliates, or other researchers of the University; and
  - (b) set out the process for notifying the University of external ethics approvals.

## 2 Commencement

These procedures commence on 14 May 2024.

## 3 Interpretation

- (1) Words and phrases used in these procedures and not otherwise defined in this document have the meanings they have in the [Research Code of Conduct](#).

**HREC** means a Human Research Ethics Committee registered by the NHMRC.

**Note:** See [Research Code of Conduct](#) for more detail.

**international ethics review mechanism** means a framework through which human research is ethically assessed in another country, where University researchers or students are collaborating.

**lower-risk research** has the meaning given in the [National Statement](#). At the date of this document that is:

research with no risk of harm where the only foreseeable risk is discomfort.

**low-risk subcommittee** means a subcommittee of a University HREC established to review low-risk research.

**myResearch Ethics** means the University's research information management application. It is used to:

- collect and manage information about researchers and their research; and
- manage the human ethics submission process.

**NHMRC** means the National Health and Medical Research Council.

**student** has the meaning given in the [University of Sydney \(Student Discipline\) Rule](#). At the date of this document that is:

means a person who:

- is currently admitted to candidature in an award course at the University; or
- is a non-award student, exchange student or study abroad student enrolled in a unit of study at the University.

#### 4 Projects approved by external HRECs

- (1) The University recognises the ethical assessment and approval of a research project by an external HREC.
- (2) Researchers who have obtained approval from an external HREC are not required to seek approval from a University HREC.
- (3) The approving external HREC is responsible for:
  - (a) maintaining oversight of the project;
  - (b) monitoring activities under its oversight; and
  - (c) any errors in the decision-making process about the project.
- (4) Researchers named on the research project must use the External Approval Notification Form in myResearch Ethics to notify the University Human Ethics Manager promptly of:
  - (a) the approval; and
  - (b) approval of amendment or modification to it.
- (5) Each notification must:
  - (a) identify one of the named researchers as the primary University contact;



- (b) identify all University researchers involved in the project who have not previously been identified;

**Note:** Researchers only need to be identified once. After initial identification, further notification is needed only when adding or removing researchers.

- (c) attach:
  - (i) the approved external application, and its attachments;
  - (ii) the external approval letter;
  - (iii) any additional agreements entered into about the external approval process; and
  - (iv) any protocol amendments or modifications since the last notification.

**Note:** These include changes to or withdrawal of the approval, and adding or removing a University researcher.

- (6) The Human Ethics Manager may:
  - (a) accept the notification;
  - (b) request further information, and defer considering the notification; or
  - (c) decline to accept the notification.
- (7) The Human Ethics Manager will contact the primary University contact about any decision to defer or decline a notification, and any request for further information.

## 5 Projects approved by approved external international ethics review mechanisms

- (1) The Director, Research Integrity and Ethics Administration may approve external international ethics review mechanisms for the purposes of these procedures.
  - (a) Research Integrity and Ethics Administration will publish a list of approved international ethics review mechanisms at [Application process - Intranet - The University of Sydney](#)
  - (b) Researchers may request the Director, Research Integrity and Ethics Administration to approve an international ethics review mechanism.
- (2) The University will recognise the ethical assessment and approval of a research project by an approved external international ethics review mechanism.
- (3) Researchers who have obtained approval from an approved external international ethics review mechanism are not required to seek approval from a University HREC.
- (4) An approving international ethics review mechanism is responsible for:
  - (a) maintaining oversight of the project;
  - (b) monitoring activities under its oversight; and
  - (c) any errors in the decision-making process about the project.
- (5) Researchers named on the research project must use the External Approval Notification Form in myResearch Ethics to notify the Human Ethics Manager promptly of:
  - (a) the approval;
  - (b) approval of amendment or modification to it; and

- (c) addition or removal of University researchers from the project.
- (6) Notifications must be provided using the External Approval Notification Form in myResearch Ethics.
  - (a) They must include the same information and provide the same attachments as required for external HREC approvals, as specified in clause 4(5).
- (7) The Human Ethics Manager may:
  - (a) accept the notification;
  - (b) request further information, and defer considering the notification; or
  - (c) decline to accept the notification.
- (8) The Human Ethics Manager will contact the named primary University contact about any decision to defer or decline a notification, and any request for further information.

## 6 Projects approved by other external bodies

- (1) Projects which have not been approved under clause 4 or clause 5 must be assessed by a University HREC if the research:
  - (a) will be conducted wholly or partly in Australia; or
  - (b) is funded by the University or by a grant administered by the University.
- (2) If the Human Ethics Manager deems a project to be low-risk, they may refer it for assessment to a low-risk subcommittee.
- (3) If the research project:
  - (a) will be conducted wholly overseas; and
  - (b) is not funded by the University or by a grant administered by the University;the researchers must:
  - (c) comply with chapter 4.8 of the [National Statement](#);
  - (d) inform themselves about the local requirements for conducting such research; and
  - (e) conduct the research in accordance with all applicable laws, regulations, and codes, including other University policies and procedures.

## 7 Adherence to approvals

Researchers named on any externally approved a research project must promptly inform the Research Integrity Office of:

- (a) any alleged misconduct; or
- (b) breaches of the relevant codes, guidelines, and legislation.

**Note:** This includes serious breaches of good clinical practice (GCP) or the protocol for clinical trials of therapeutic goods.

## 8 Rescissions and replacements

This document replaces the External Human Ethics Approval Procedures 2013, which is rescinded as from the date of commencement of this document

## NOTES

### External Human Ethics Approval Procedures 2024

Date adopted: 14 May 2024

Date commenced: 14 May 2024

Administrator: Director, Research Integrity and Ethics Administration

Review date: 14 May 2027

Rescinded documents: External Human Ethics Approval Procedures 2013

Related documents: [Research Code of Conduct](#)

[Australian Code for the Responsible Conduct of Research 2018](#)

[National Statement on Ethical Conduct in Human Research 2023.](#)

## AMENDMENT HISTORY

Provision	Amendment	Commencing
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