

EXTERNAL HUMAN ETHICS APPROVAL PROCEDURES 2013

Issued by: *Deputy Vice Chancellor Research*

Date: *1 July 2013*

Signature:

Name: **Professor Jill Trehwella**

1 Purpose and application

- (1) These procedures:
 - (a) give effect to the [Research Code of Conduct](#);
 - (b) minimise unnecessary duplication of ethical reviews; and
 - (c) prescribe the process for managing approval by external human research ethics committees.
- (2) These procedures apply to research conducted by staff, affiliates or students of the University where:
 - (a) ethical approval has been given by an external human research ethics committee; and
 - (b) that committee has stated in writing its willingness to be responsible for all sites at which the research is to be conducted.

2 Commencement

These procedures commence on 15 July 2013.

3 Interpretation

Chief Investigator means the researcher responsible for the conduct of the study. In the case of student projects, the chief investigator is the supervisor of the student.

IRMA means the Integrated Research Management Application, which is the system used to collect and manage information about researchers and research at the University and to manage the human ethics application process.

Low Risk Subcommittee	means a subcommittee of a University HREC created within a school, faculty or division consistently with the requirements of the National Statement on Ethical Conduct in Human Research (2007). Note: As at the date of these procedures, this document is available at http://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hreecs/human-research-ethics-committees-hreecs/national .
NHMRC	means National Health and Medical Research Council, which is Australia's peak body for supporting health and medical research.
FWA Program	means the Federal Wide Assurance Program of the Office of Home Research Protections in the United States Department of Health and Human Services, in which the University participates.
student	means a person who is currently admitted to candidature in an award course of the University.
University HREC	means a human research ethics committee convened and administered by the University.

4 Recognition of external HREC findings

- (1) The University recognises the ethical assessment and approval of a research project by an NHMRC-registered ethics committee. In this circumstance researchers are not required to submit an application for review by a University HREC.
- (2) Research which has been approved by an ethics committee not registered with the NHMRC and which is to be conducted wholly or partly in Australia must undergo full assessment by a University HREC.
 - (a) Such research may be assessed by a relevant Low Risk Subcommittee, where available and appropriate.
- (3) Where research which has been approved by an ethics committee not registered with the NHMRC is to be conducted wholly overseas:
 - (a) full assessment by a University HREC is required if it is funded by a grant administered by the University.
 - (i) If the approving ethics committee is from a member of the FWA Program, the research may be assessed by a relevant Low Risk Subcommittee where available.
 - (b) no application for review by a University HREC is required if there is no University grant funding. In such cases, it is the researchers' responsibility to:
 - (i) inform themselves about the local requirements for conducting such research; and
 - (ii) ensure that it is conducted in accordance with all applicable laws, regulations and codes.

5 Approval process

- (1) Researchers must submit requests for approval online using IRMA, for allocation to the appropriate committee.
- (2) An application for approval of a project may be completed by any University of Sydney researcher (staff, affiliate or student) who is involved in the project.
- (3) The application must:
 - (a) nominate a staff member or affiliate as Chief Investigator; and
 - (b) name all researchers involved in the project.
- (4) Each researcher named in an application must provide their approval of that application.
 - (a) Staff, students and affiliates of the University may do so online through IRMA.
 - (b) Researchers external to the University must sign and submit an [External Researcher Approval form](#).
- (5) The Dean (or Dean's nominee) of the Chief Investigator's faculty must provide approval of the application through IRMA.

NOTES

External Human Research Ethics Approvals Procedures 2013

Date adopted: 1 July 2013

Date commenced: 15 July 2013

Administrator: Director of Research Integrity.

Review date: 15 July 2018

Related documents: [Research Code of Conduct 2013](#)

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

[National Statement on Ethical Conduct in Human Research \(2007\)](#)

AMENDMENT HISTORY

Provision	Amendment	Commencing
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