HUMAN RESEARCH ETHICS POLICY

Current version in effect from: 5 Dec 2019
Approved by Council: 8 May 2019
Revised by Council: 4 Dec 2019

Related documents

National Statement on Ethical Conduct in Human Research ("the National Statement")
Australian Code for the Responsible Conduct of Research ("the Code")
Privacy Act 1988
Privacy and Data Protection Act 2014 (Vic)
Regulation 1: General Provisions, Determination 6: Human Research Ethics Committee

2. Principles

2.1 The University must ensure that all research involving human participants is designed and conducted in accordance with The Code and ethically reviewed and monitored in accordance with the National Statement.

2.2 The University conducts this ethics review and monitoring through the Human Research Ethics Committee which operates in accordance with the National Statement.

2.3 The objectives of the University’s HREC are:

a) To protect the rights and welfare of research participants by ensuring that research projects are designed in accordance with the following values:

i) Respect for human beings – individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to protection. This requires respect for the privacy, confidentiality and cultural sensitivities of research participants. All people involved in research have the right to make informed decisions about matters that affect them. People must be protected and empowered if their capacity to make informed decisions is impaired.

ii) Research merit and integrity – research must be worthwhile and have value to the community. This requires the use of methods, facilities and resources that are appropriate to achieve the aims of the research. Benefits of research must be justified, it should be supervised by researchers with appropriate expertise, and findings reported accurately and responsibly.

iii) Justice – in planning research, who ought to receive its benefits and bear its burdens should be addressed and resolved. Ensuring justice requires procedural fairness in the recruitment of participants and review of research. Research aims should be achieved using 'just' means that do not unfairly burden particular groups. The benefits of research should be distributed fairly between participants and the wider community, and research findings should be provided within a reasonable time.
iv) Beneficence – there is an obligation to maximise possible benefits and minimise possible harms. This requires a sensitivity to the welfare and interests of participants, and the cultural and social implications of the research. The likely benefits to participants or the wider community must justify any risk of harm or discomfort to research participants.

b) To facilitate high quality ethical research through efficient and thorough review processes developed in accordance with the National Statement

c) To minimise the risk of harm arising from research studies involving humans

d) To promote the development of an ‘ethical consciousness’ through education of the academic and professional community.

3. Scope

3.1 This Policy applies to all research conducted by the University’s academic staff (including honorary researchers) and to research projects undertaken by students enrolled in awards of the University.

3.2 Research conducted by University academic staff, honorary researchers, and students that has been approved through a prior review process of another institution also requires approval from the University’s HREC.

3.3 The following research is exempt from an ethics approval application: negligible risk research that only involves access to existing collections of non-identifiable data or records about humans.

3.4 Human research data collection cannot begin prior to HREC approval.

3.5 Retrospective ethics approval for a research project cannot be granted. Any data collected from human participants prior to HREC approval cannot be used in the research project. It is the researcher’s responsibility to ensure that ethics approval has been obtained before commencing any research.

4. Definitions

4.1 The National Statement: The National Statement on Ethical Conduct in Human Research consists of a series of Guidelines made in accordance with the National Health and Medical Research Council Act 1992. It is intended for use by researchers conducting research with human participants, HREC members reviewing that research, those involved in research governance, and potential research participants.

4.2 The Code: The Australian Code for the Responsible Conduct of Research guides institutions and researchers in responsible research practices and promotes integrity in research for researchers. The Code clarifies how to manage breaches of The Code and allegations of research misconduct, how to manage research data and materials, how to publish and disseminate research findings, including proper attribution of authorship, how to conduct effective peer review and how to manage conflicts of interest. It also explains the responsibilities and rights of researchers if they witness research misconduct.
4.3 **HREC**: The University’s Human Research Ethics Committee, as constituted by Regulation 1: Determination 6, which reviews and monitors the research of the University’s academic staff and honorary researchers, and the research projects undertaken by candidates for degrees and other awards of the University in accordance with the National Statement and The Code.

4.4 **Negligible risk**: Negligible risk research means that it involves no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience.

4.5 **Low risk**: Low risk research means the only foreseeable risk that it involves is one of discomfort.

4.6 **More than low risk**: More than low risk research means the foreseeable risk that it involves is more than inconvenience and discomfort.

4.7 **Prior review**: This means research that has been reviewed and approved by another institution’s HREC.

4.8 **Reviewer**: The person appointed to lead the review of applications.

5. **Ethics Review**

5.1 Student applications are to be submitted only after successful peer-review progress has been achieved (approval of the Minor Thesis Approval Form for Minor Thesis projects, or confirmation of candidature for Higher Degree by Research students).

5.2 The level of review must be proportionate to the level of risk of the proposed study.

6. **Expedited Review**

6.1 The following categories of research projects are eligible for expedited review:

a) Research projects that have received prior review, unless the University’s HREC Expedited Review Panel determines that the ethics review was not in accordance with the requirements of the *National Statement* or when the ethics review body previously granting approval will no longer be involved in monitoring the project

b) Negligible risk research projects

c) Low risk research projects.

6.2 The Expedited Review Panel is comprised of the Chair and another member of HREC.

6.3 The Expedited Review Application Form is to be reviewed by the Expedited Review Panel and the Panel’s decision communicated to the applicant within 10 working days of submission of application.

6.4 Incomplete applications, and applications submitted on out-of-date forms are not considered.

6.5 All documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, must be approved by the Expedited Review Panel.
6.6 The HREC Expedited Review Panel may request that the application be elevated to a full review on the basis of the Panel’s determination of the level of risk involved in the research project. The full review requires the completion of the Full Application Form.

7. **Full Review**

7.1 Full review applications are considered by the University of Divinity HREC.

7.2 A Primary Reviewer is appointed by the Chair from the HREC membership to lead the HREC review of the application.

7.3 The HREC decision is reported to the applicant within 10 working days of the HREC meeting at which the application is reviewed.

7.4 Incomplete applications, and applications submitted on out-of-date forms are not considered.

7.5 All documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, must be approved by the HREC.

8. **HREC Application Assessment Criteria**

The criteria given consideration in the HREC assessment process are:

a) informed participant consent  
b) voluntary participation and right of withdrawal without sanction  
c) privacy and confidentiality of participants and records  
d) secure storage of relevant data for a minimum period of five years after completion of a research project  
e) clear, coherent expression of research proposals, including research scope, aims, questions and methods  
f) research benefits outweighing the risks  
g) that severity of the risks have been sufficiently minimised  
h) that risks can be managed  
i) regular monitoring of research outcomes  
j) communication of research findings or results to participants.

9. **Amendments**

9.1 Amendments to approved projects require written HREC approval. Revised versions of all relevant application documentation are required, with all changes clearly highlighted.

9.2 The amended research must not commence until written ethics approval has been granted.
10. **Reporting**

10.1 Researchers must submit annual and final reports using the Adverse Event / Progress / Final Report Form.

10.2 For projects approved via the prior review pathway, applicants may submit a copy of the report submitted to the lead HREC and evidence of its approval for the report.

10.3 Annual reports are due within one year from the date of ethics approval.

10.4 A final report is due within 30 days of the completion of the data collection, of the expiry of the ethics approval, or of the discontinuation of the project.

10.5 Reports for projects originally approved via the full review pathway must be reviewed by the HREC.

10.6 Reports for projects originally approved via an expedited pathway may be reviewed by an Expedited Pathway Panel, unless departure from the approved protocol, an adverse participant experience resulting from the research, non-compliance with the conditions of approval, or unforeseen ethical issues are reported, in which case the HREC must review the report.

10.7 Compliance may also be monitored by any other means deemed necessary or appropriate, such as random audits or more frequent reporting requirements.

11. **Adverse Events**

11.1 Researchers must report unexpected or serious adverse events to the HREC within one working day of the event occurring using the Adverse Event Report Form.

11.2 For projects approved via the prior review pathway, applicants may submit a copy of the adverse event report submitted to the lead HREC and evidence of their approval for the report instead of the University of Divinity Adverse Event / Progress / Final Report Form.

11.3 In cases where a researcher is not able to complete the relevant form within one day of the adverse event occurring, the event should be reported to the Research Office by email, until such time the relevant form can be submitted.

12. **Non-Compliance**

12.1 Non-compliance with the National Statement

Researchers who fail to comply with the provisions of the National Statement risk facing serious professional and legal consequences and are to be investigated in accordance with The Code and the disciplinary processes of the University.

12.2 Non-compliance with ethics review decisions

Any non-compliance with ethics review or HREC decisions should be reported to the HREC Chair. The Chair considers appropriate actions and reports the non-compliance to the HREC, and the College responsible for the governance of the project.

12.3 Non-compliance with the annual and final reporting requirement
If a report is 15 working days overdue, the Office of the Vice-Chancellor must provide a reminder with a 15 working day deadline for completion. On further failure to submit the report the Office of the Vice-Chancellor must provide another reminder with a 15 working day deadline for completion. A continued failure to meet reporting obligations requires the Office of the Vice-Chancellor to inform the appropriate College Principal and the University of Divinity HREC, and after a further 15 working day interval, research approval must be withdrawn or suspended.

13. **Appeals and Complaints**

13.1 If the University receives a complaint about research conducted with HREC approval and the complaint relates to activities that may have unexpected adverse effects, ethics approval may be withdrawn or suspended immediately by the Chair of HREC while further investigation takes place.

13.2 A researcher may apply for a review of a decision of the HREC by lodging a completed Review Request Form with the University Secretary within five working days of receiving notification of that decision.

13.3 The University Secretary must refer the Review Request Form to the Chair of HREC. The Chair of HREC must provide a response to the researcher within ten working days of receiving the Review Request Form.

13.4 A researcher who has requested a review of a decision of the HREC and received a response and who has reasonable grounds for believing that there has been a failure of the process set out in this Policy or in the National Statement may have recourse to the Appeals Policy.

14. **Storage**

14.1 Researchers must ensure that proper arrangements have been made for the security and storage of, and controlled access to, confidential research data collected in the course of research projects involving human participants. For the electronic storage of data and records, precautions are to be taken to secure the materials and restrict access. The proposed arrangements must be outlined in the application for ethics clearance.

14.2 All confidential research data must be stored on University premises, for a minimum of five years. The researcher and supervisor (if applicable) must ensure that all records are transferred to the Office of the Vice-Chancellor when the project is complete.

14.3 All confidential research data created as part of research activities within the institution which involve minors must be stored for 7 years after the child reaches the age of 18.

14.4 The destruction of research data and records must be authorised by the HREC Chair, and the approval advice recorded on an HREC register.

14.5 The retention and future use of research data must be approved by the HREC and consented to by participants.

15. **Date of next review**

15.1 This policy is to be reviewed no later than 31 December 2022