HUMAN RESEARCH ETHICS POLICY

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Related documents

National Statement on Ethical Conduct in Human Research ("the National Statement") developed jointly by National Health and Medical Research Council, Australian Research Council, Universities Australia 2007 updated 2018

Australian Code for the Responsible Conduct of Research ("the Code")

Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research (National Health and Medical Research Council 2019)

Privacy Act 1988

Privacy and Data Protection Act 2014 (Vic)

Memorandum of Understanding between University of Divinity and Christian Research Association 2020

Australian Institute of Aboriginal and Torres Strait Islander Studies Code of Ethics for Aboriginal and Torres Strait Islander Research 2020 ("the AIATSIS Code of Ethics")

United Nations Declaration on the Rights of Indigenous Peoples 2007 ("UNDRIP")

1. Principles

1.1 The University of Divinity (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 and the Code.

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

1.3 The objectives of the University's HREC process 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, and their freedom of choice to participate or otherwise. 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 made accessible to participants in a way that is timely and clear.

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.

1.4 The University must ensure that all Aboriginal and Torres Strait Islander Research involving human participants is designed and conducted in accordance with the AIATSIS Code of Ethics, in addition to the National Statement and the Code, and that research with other Indigenous and cultural groups is designed and conducted in accordance with any such ethical frameworks as are applicable.

2. Scope

2.1 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.

2.2 Research conducted by the University's 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.

2.3 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, not including data collected from intentionally-selected vulnerable populations, such as Aboriginal and Torres Strait Islander or world Indigenous populations.

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

2.5 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.

3. Definitions

3.1 **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.

3.2 **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.

3.3 **HREC**: The University's Human Research Ethics Committee, which is the Human Research Ethics Committee of Christian Research Association, as per the Memorandum of Understanding (2020). The HREC 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.

3.4. **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.

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

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

3.7 **Prior review:** Research that has been reviewed and approved by another institution's HREC.

3.8 **Aboriginal and Torres Strait Islander Research:** All research that impacts or is of particular significance to Aboriginal and Torres Strait Islander peoples, including the planning, collection, analysis and dissemination of information or knowledge, in any format or medium, which is about or may affect Indigenous peoples, either collectively or individually.

4. Ethics Review

4.1 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).

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

4.3 Review applies to all documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets, social media posts and consent forms, which must be approved by the HREC.

5. Expedited Review

5.1 Expedited review is conducted as determined by the HREC.

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

a) Research projects that have received prior review, unless the University's HREC 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. Full Review

6.1 Full review applications are considered by the HREC.

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

7. HREC Application Assessment Criteria

Among the criteria given consideration in the HREC assessment process are:

a) informed participant consent with adequate attention to conflicts of interest, power imbalances, cultural sensitivity and vulnerable populations

b) voluntary participation and right of withdrawal without sanction

c) plain language information provided to participants, with materials provided in languages other than English where this is necessary for participants' understanding

c) privacy and confidentiality of participants and records

d) secure storage of relevant data for a minimum period of seven 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 has been sufficiently minimised

h) that risks can be managed

i) regular monitoring of research outcomes

j) communication of research findings or results to participants.

8. Amendments

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

8.2 The amended research must not commence until written ethics approval has been granted.

9. Reporting

9.1 Researchers must submit annual and final reports to the HREC.

9.2 Researchers must provide progress and final reports to Aboriginal and Torres Strait Islander and world Indigenous partners and contributors in a form that is culturally appropriate.

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

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

9.5 A final report is due within 60 days of the completion or discontinuation of the project, or of the expiry of the ethics approval, whichever is sooner.

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

10. Adverse Events

10.1 Researchers must report unexpected or serious adverse events to the HREC within one working day of the event occurring.

10.2 For projects approved by prior review applicants must submit a copy of the adverse event report submitted to the lead HREC and evidence of their approval.

11. Non-Compliance

11.1 Non-compliance with the National Statement and Code

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

11.2 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.

11.3 Non-compliance with reporting requirements

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 HREC, and after a further 15 working day interval, research approval must be withdrawn or suspended.

12. Appeals and Complaints

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

12.2 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.

12.3 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.

12.4 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.

13. Storage

13.1 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. Data storage should comply with the National Statement guidelines for the Management of Data.

13.2 All confidential research data must be stored on University premises, or in a secure, password-protected data storage facility owned by the University, for a minimum of seven 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.

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

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

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

14. Date of next review

14.1 This policy is to be reviewed no later than 31 December 2026