HUMAN RESEARCH ETHICS POLICY
Approved by Council: 8 May 2019
Revised by Council: n/a

1. 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

The Privacy and Data Protection Act 2014 (Vic)

Regulation 1: General Provisions

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:

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

a) 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.

b) 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.

c) 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.

d) 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.

2.3.2 To facilitate high quality ethical research through efficient and thorough review processes developed in accordance with the *National Statement*.

2.3.3 To minimise the risk of harm arising from research studies involving humans.

2.3.4 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 and honorary researchers and to research projects undertaken by candidates for degrees and other 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 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. Human Research Ethics Committee

5.1 Membership

5.1.1 Membership of the Committee must meet the minimum standards of the *National Statement*.

5.1.2 The Committee must have at least nine members. As far as possible there should be equal numbers of men and women. At least one third of the members must be external to the University. The membership must include:

a) At least two lay people, one man and one woman, who have no other affiliation with the University and do not currently engage in medical, scientific, legal, or academic work;

b) At least two people with current research experience that is relevant to research proposals regularly considered by the Committee;

c) At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people;

d) At least one person who performs a pastoral role in the community, for example an Aboriginal elder or a minister of religion;

e) At least one lawyer, who is not engaged to advise the University.

5.1.3 All members are appointed by the University Council on the advice of the Governance and Nominations Committee for a term of up to three years. Persons so appointed are eligible for reappointment. No member may be appointed in more than one of the categories listed in section 5.1.2.

5.1.4 When a member is granted leave of absence for an extended period, the University Council must appoint an acting member in his or her place for the period of the leave of absence, and in the appropriate category of membership.

5.1.5 The Chair is responsible for the implementation of all decisions of the Committee and works in close consultation with the Research Office.

5.2 Chair

5.2.1 The Chair of the Committee is appointed by the University Council from the membership of the Committee. In the absence of the Chair, a member of the Committee is elected by the Committee as acting Chair for that meeting.

6. Ethics Review

6.1 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).

6.2 The level of review must be appropriate to the level of risk of the proposed study.

6.3 Proportional Review

6.3.1 Eligibility for Expedited Review

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.

6.3.2 The Expedited Review Panel

a) The **Expedited Review Application Form** is to be reviewed by a reviewer and the Chair of HREC and the Panel's decision communicated to the applicant within 10 working days of submission of application.

6.3.3 Incomplete applications, and applications submitted on out-of-date forms will not be considered.

6.3.4 All documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, should be approved by the Expedited Review Panel.

6.3.5 Elevation to Full Review

a) 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.

b) The full review requires the completion of the **Full Application Form**.

6.4 Full Review

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

6.4.2 A Primary Reviewer is appointed to lead the HREC review of the application.

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

6.4.4 Incomplete applications, and applications submitted on out-of-date forms will not be considered.

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

7. HREC Application Assessment Criteria

The criteria given consideration in the HREC assessment process are:

7.1 informed participant consent

7.2 voluntary participation and right of withdrawal without sanction

7.3 privacy and confidentiality of participants and records

7.4 secure storage of relevant data for a minimum period of five years after completion of a research project

7.5 clear, coherent expression of research proposals, including research scope, aims, questions and methods

7.6 research benefits outweighing the risks

7.7 that severity of the risks have been sufficiently minimised

7.8 that risks can be managed

7.9 regular monitoring of research outcomes

7.0 communication of research findings or results to participants

8. Amendments

8.1 Amendments to approved projects require written ethics 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 using the **Adverse Event/Progress/Final Report Form**.

9.2 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.

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

9.4 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.

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

9.6 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.

9.7 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 using the **Adverse Event Report**.

10.2 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**.

10.3 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.

11. Complaints and Non-Compliance

11.1 If complaints relate to activities that may have unexpected adverse effects, ethics approval may be withdrawn or suspended.

11.2 Complaints about the HREC review process – Where complaints concerning the HREC review of an application, amendment or report cannot be resolved by communication between the complainant and the HREC, the Director of Research is authorised to receive complaints in writing. If justified, the Director of Research may request that the HREC review its process in reaching the decision and reconsider its decision.

11.3 Appeals against the HREC decision – Appeals are to be made on the **Appeal Notification Form** and follow the appropriate Appeals Process.

11.4 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 will be investigated in accordance with *The Code* and the disciplinary processes of the University.

11.5 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, the Research Office, and the College responsible for the governance of the project.

11.6 Non-compliance with the annual and final reporting requirement – If a report is 15 working days overdue, the Research Office will provide a reminder with a 15 working day deadline for completion. Failure to submit the report will result in the Director of Research providing another reminder with a 15 working day deadline for completion. A continued failure to meet reporting obligations requires the Director of Research to inform the appropriate Head of College and the University of Divinity HREC, and

after a further 15 working day interval, research approval will be withdrawn or suspended.

12. Storage

12.1 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.

12.2 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 Research Office when the project is complete.

12.3 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.

12.4 The destruction of research data and records should be authorised by the Director of Research and the HREC Chair, and the approval advice should be maintained on an HREC register.

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

13. Date of next review

31 December 2022

SCHEDULE A:

University of Divinity Human Research Ethics Committee Level of Risk Checklist

This Checklist is to be used as a guide to determine if an activity requires ethical review and, if so, what Level of Ethical Review

Checklist

*1. If the answer to the following is 'yes' then the application is eligible for Expedited Review. Proceed to complete the **Expedited Review Form** and attach the relevant documentation (proof of approval from the other HREC, and the complete the application materials approved by that HREC).*

	Yes	No
Has ethics approval been granted by another Human Research Ethics Committee?	☐	☐

*2. If the answer to any of the following is 'yes' then the application is not 'negligible' or 'low' risk. Proceed to complete the **Full Application Form**.*

	Yes	No
Will the proposed research activity target as participants women who are pregnant?	☐	☐
Will any participants be people with a cognitive impairment, an intellectual disability, or a mental illness?	☐	☐
Will any participants be highly dependent on medical care and not be able to provide consent?	☐	☐

3. If the answer to any of the following is 'yes' then the application may not be 'negligible' or 'low' risk. Proceed to seek advice from the University of Divinity Human Research Ethics Committee.

	Yes	No
Will any participants be under the age of 18?	☐	☐
Will any participants be people in dependent or unequal relationships?	☐	☐
Will any participants be Aboriginal and Torres Strait Islander peoples?	☐	☐
Will the proposed activity target as participants people who may be involved in illegal activities?	☐	☐
Will the proposed activity cause any level of discomfort for the participants (beyond minimal inconvenience or simple discomfort)?	☐	☐
Will the proposed activity breach the confidentiality of the participants' personal information (e.g., identifying participants, disclosing information to a third party)?	☐	☐

If the answer to all the questions in 2. and 3. is 'no', then proceed to complete the Expedited Review Form.

SCHEDULE B:
Human Research Ethics Application Expedited Review Process Form

Level of Risk

The University of Divinity applies a review of risk level to applications for ethics approval. This considers the ethical issues and possible risks to research participants presented by the proposed research protocol as assessed against the requirements of the National Statement on Ethical Conduct in Human Research (National Statement) and the *Australian Code for the Responsible Conduct of Research* (Code). *Risk is the potential for harm, whether it is physical, psychological, social, economic or legal, or the potential to cause people to think they have been treated disrespectfully.*

Only negligible and low risk research is permitted to be reviewed under an expedited process; see chapter 2.1 and paragraphs 5.1.6 – 5.1.8 of the National Statement.

- *E1 expedited review = Negligible or no appreciable risks or ethical issues*
- *E2 expedited review = Low risk and ethical issues addressed by the research design*
- *E3 full HREC review = Potential for significant risk, i.e. does not qualify for E1 or E2 review*

Further details about the levels of review and response times are available from the Human Research Ethics webpage [URL].

***NOTE**: It is the responsibility of the researchers and their supervisors to ensure that all facets of human research meet the requirements of the National Statement and the Code and to ensure that a realistic assessment of risk is made when submitting applications to the HREC for expedited review.* ***Failure to make an accurate assessment of risk may lead to significant delays in the processing of an expedited review application and may necessitate withdrawal and submission to the full HREC**.*

Please tick one of the following

☐	Negligible Risk
☐	Low Risk

Main applicant details

Personal details	
Name	
Researcher Status (HDR student, academic staff member, honorary researcher)	

College	
Project Title	
Email	
Name of Supervisor (if applicable)	

Explanation of the project

Project Duration	
Name of Chief Investigator	
Contact Person (*if different from the above*)	
Research Team (*identify all researchers involved in the project, and their affiliation if different from the above-listed College*)	
Date of Confirmation Panel approval (*if the research has not been subject to a Confirmation Panel, or has been subject to a peer-review process other than a Confirmation Panel, provide details*)	

Expedited Review eligibility checklist

If the answer to any of the following is 'yes' then the application will not be eligible for expedited review.

	Yes	**No**

Will the proposed research activity target as participants women who are pregnant?	☐	☐
Will any participants be people with a cognitive impairment, an intellectual disability, or a mental illness?	☐	☐
Will any participants be highly dependent on medical care and not be able to provide consent?	☐	☐

If the answer to any of the following is 'yes' then the application may not be eligible for expedited review.

	Yes	**No**
Will any participants be under the age of 18?	☐	☐
Will any participants be people in dependent or unequal relationships?	☐	☐
Will any participants be Aboriginal and Torres Strait Islander peoples?	☐	☐
Will the proposed activity target as participants people who may be involved in illegal activities?	☐	☐
Will the proposed activity cause any level of discomfort for the participants (beyond minimal inconvenience or simple discomfort)?	☐	☐
Will the proposed activity breach the confidentiality of the participants' personal information (e.g., identifying participants, disclosing information to a third party)?	☐	☐
If the answer to any of these questions is 'yes', then outline ways by which participants' special situations will be taken into account in your research, particularly to address/manage the inevitable inequalities in relationship between you as researcher (or your delegates) and research participants, and the level of discomfort. Explain how you have assessed the level of discomfort. *(maximum 300 words)*		

Project

Project Summary
Please succinctly outline in plain, non-technical language the nature, potential significance, and aims of the research project. In brief, what is the project and why is it worth doing? *(maximum 300 words)*

Participants
Please explain how the data will be collected, who will be recruited, and how (including the issue of participant consent). *(maximum 250 words)*
Approvals Required
Please list the approvals required for conducting the data collection (e.g., from schools, churches, etc.) and whether the approvals have been granted at the time of application.

Research Outputs and Reporting

Please explain the anticipated outputs of the project (including any relevant publications, seminars and conference papers, or reports). *(maximum 300 words)*

Privacy Act	**Yes**	**No**
Will the Privacy Act apply?	☐	☐
Declaration		
I / We, the undersigned, accept responsibility for the conduct of the research detailed above in accordance with the principles outlined in the *National Statement on Ethical Conduct in Human Research* (2007), the *Australian Code for the Responsible Conduct of Research*, and any other conditions required by the University of Divinity's Human Research Ethics Committee. I / We, the undersigned, agree that if any changes to the approved research design or methodology are proposed after the Committee's consent has been obtained, then HREC will be immediately informed by the Chief Investigator in writing.		

I / We, the undersigned, further agree that no research actions varying from those approved will be undertaken until further approval is received from the University's HREC.

I / We, the undersigned, agree that should the research project be discontinued, then the University's HREC will be informed in writing, with reasons, and that data collected will be retained securely on the same terms as if the research project had been completed.

Signatures

Chief Investigator			
Signature		Date	
Name *Write SURNAME in capitals*			
Principal Supervisor (for HDR student applications)			
Signature		Date	
Name *Write SURNAME in capitals*			

Please attach a copy of the *Participant Information and Consent Form (PICF)*, recruitment flyers, and approvals from third parties, proposed interview questions, and any other documentation to be used in conjunction with the research.

Please note that provided the version is clearly identified and no more than nominal variations are applied, it is not necessary to submit copies of standard tests, scales, or questionnaires unless requested specifically by the HREC.