



THE UNIVERSITY OF
NOTRE DAME
A U S T R A L I A

Procedure:

Human Research Ethics

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1 PURPOSE

- 1.1** The purpose of this procedure is to support the implementation of the *Policy: Human Research Ethics* (the Policy) by setting out:
 - 1.1.1 how human research is defined and how the degree of risk involved in human research is determined
 - 1.1.2 the processes by which the Notre Dame HRECs have oversight of human research conducted under the auspices of the University
 - 1.1.3 processes for ethics approval of human research, including requirements for applications, ethics review, exemption from ethics review and approval and/or authorisation, and
 - 1.1.4 requirements for monitoring and auditing of project's human research by Notre Dame HRECs and for referral of suspected breaches of research integrity for investigations.

2 RELATED POLICIES AND REGULATIONS

- 2.1** This procedure should be read alongside the *Policy: Human Research Ethics* and the policy's other supporting document: the *Human Research Ethics Committee Charter*, which it supports.
- 2.2** The procedure should also be read alongside the *Code of Conduct: Research* which sets out the research integrity obligations binding on those who conduct human research under the auspices of the University, on persons and committees who conduct ethics reviews, and on staff who support or facilitate human research at the University. The *Procedure: Managing Potential Breaches of the Code of Conduct: Research* states the process by which breaches of research integrity are investigated.

3 DETERMINING CONSISTENCY WITH THE OBJECTS OF THE UNIVERSITY

- 3.1** If the research activity may be inconsistent with the Objects of the University, a Research Ethics Officer will seek advice from the Notre Dame HREC Chairs and the Pro Vice Chancellor Research (or delegate). If the Notre Dame HREC Chairs and Pro Vice Chancellor Research consider that the application may be inconsistent with the Objects of the University, the Research Ethics Officer may be instructed to seek further information from the applicant or amendments for clarity. The Pro Vice Chancellor Research may appoint additional individuals to review the application to assist with further consideration and determination, as required.

4 DETERMINING WHAT CONSTITUTES HUMAN RESEARCH

- 4.1** Where there is a query over whether an activity constitutes human research, the details of the project will be submitted to a Notre Dame HREC for determination.
- 4.2** Examples of research activities that are deemed "human research" for the purposes of this procedure include:
 - 4.2.1 surveys, interviews or focus groups
 - 4.2.2 psychological, physiological or medical testing or treatment
 - 4.2.3 observational studies
 - 4.2.4 collection and use of biological materials

- 4.2.5 studies involving the opinions of persons published on the internet, including social media posts, tweets, self-generated 'lifelogging' data emitted from mobile phones and other 'smart' appliances, data or information generated through applications and devices related to personal pursuits, such as fitness activity, gambling, dating and web-based gaming
 - 4.2.6 research that involves sites of community, cultural, historical or religious significance to a definable group of humans
 - 4.2.7 research that involves human remains or cell lines, where these can be directly linked to living humans either on a direct familial or significant cultural basis, and
 - 4.2.8 findings which have a direct and significant impact upon the personal or professional affairs of a definable group of humans.
- 4.3** Examples of research activities that are not deemed "human research" for the purposes of the procedure include:
- 4.3.1 literature reviews that support the development or design of a research project
 - 4.3.2 research using data understood to be published in public domain and for which there is no reasonable expectation that the data is "private" and will not be used for research purposes. Examples include academic articles or treatises, government reports, court decisions, autobiographies, newspaper articles, historic artefacts (journals and possessions), and the opinions of individuals published with their consent by journalists or news providers. (Note that this does not cover research involving the opinions of persons published on the internet)
 - 4.3.3 research that only involves aggregate data
 - 4.3.4 consultation and engagement with potential participants, co-researchers and community representatives that: precedes the development, design or conduct of the research; is undertaken as pre-design planning for research and helps to ensure that the research and its priorities are guided by the people and communities with whom the research will take place and on whom the research will have an impact, does not pose a risk of harm to the persons involved, and will not be presented as "human research" in any publication or dissemination of research findings, and
 - 4.3.5 quality assurance and evaluation activities.

5 ASSESSING RISKS INVOLVED IN HUMAN RESEARCH ACTIVITIES

5.1 Risk Assessment

The University has established different pathways for the ethics review of human research, which are proportionate to the level of risks involved in the research. The University is committed to proportionate review of applications by reference to the risk profile of the research and requirements of the *National Statement on Ethical Conduct in Human Research (2025)* (the *National Statement*).

- 5.2** The *National Statement* outlines that risk in research exists on a continuum and categorised as minimal risk, lower risk, greater than low risk and higher risk.
- 5.3** *Minimal risk*: No risk of harm or discomfort; potential for minor burden or inconvenience;
- 5.4** *Lower risk*: No risk of harm, but a risk of discomfort (the project has "a low risk" profile), with or without a potential for minor burden or inconvenience;

- 5.5 *Greater than low risk:* A risk of harm (including physical, psychological, social, cultural, economic or legal harms or devaluation of self-worth), with or without a foreseeable burden;
- 5.6 *Higher risk:* A significant risk of harm (including physical, psychological, social, cultural, economic or legal harms or devaluation of self-worth), with or without a foreseeable burden.
- 5.7 The assessment of risks involved in human research will include consideration of risk posed to participants (either individually or collectively) and/or non-participants (such as family members, community and fetuses, whether the participants are pregnant or might become pregnant over the course of their participation).
- 5.8 The risks posed to researchers are not considered in the assessment of risks involved in human research for the purpose of ethics review and approval and these must be identified, managed and reported in accordance with the applicable University policies and procedures.

6 ETHICS REVIEW AND AUTHORISATION PATHWAYS

- 6.1 The University's pathways for approving human research have been developed to meet the requirements of the *National Statement* for the review, authorisation and monitoring of human research as follows:
 - 6.1.1 the Ethics Approval process
 - 6.1.2 the Ethics Exemption process
 - 6.1.3 the External Ethics Authorisation process, and
 - 6.1.4 the Permission Process for external research involving University staff, students or premises.
- 6.2 All Researchers undertaking Human Research must apply to a review, authorisation or permission process.
- 6.3 Determining which pathway applies to an application for ethics approval is based consideration of the type of human research proposed, its risk profile assessed in accordance with section 5, and whether ethics approval has already been obtained from an external NHMRC-accredited HREC or an equivalent ethics review body.
- 6.4 The University is required to maintain auditable records of ethics approval applications and their outcomes, and human researchers must keep records of all applications undergoing ethics review of their applications. This includes each member of the human research team having copies of all documents submitted to these processes and copies of all outcome letters.
- 6.5 Where additional documents or information are required to complete the assessment of an ethics approval application, the applicant must provide these within 3 months of the request. Where requested additional documents or information is not supplied within this time frame and no explanation is given, the applicant will be notified that the application has been rejected.

7 ETHICS APPROVAL AND EXEMPTION PROCESSES

Application requirements

- 7.1 The Ethics Approval process manages the review of all applications where a Notre Dame HREC will be the primary HREC.
- 7.2 Applications must be submitted by the Chief Investigator.

- 7.3** Each human research project must have a Chief Investigator who is responsible for the governance of the project and who satisfies the following requirements.
- 7.3.1 The Chief Investigator is the governance lead on the project. The Chief Investigator does not need to be the lead author on any eventual publication.
 - 7.3.2 The Chief Investigator must be either:
 - 7.3.2.1 a Notre Dame staff member, or
 - 7.3.2.2 where the project has a Notre Dame student as Co-Investigator, one of the student's registered higher degree by research (HDR) supervisors (usually the Principal Supervisor).
 - 7.3.3 Where the human research project is being undertaken by a student as part of a University program or course
 - 7.3.3.1 the application may only be submitted by their registered Principal Supervisor (if the project is an HDR project) or by a Notre Dame staff member who is facilitating the student's work on the project or who has required the work to be done.
 - 7.3.4 The Chief Investigator's responsibility for the governance of the project covers the life cycle of the project, irrespective of their employment status at the University.
 - 7.3.5 It is the responsibility of the Chief Investigator to apply for either full committee review or low-risk subcommittee review.
 - 7.3.6 The Chief Investigator must ensure that the research project aligns with the Objects of the University.
- 7.4** The Chief Investigator must complete the application form and attach:
- 7.4.1 all relevant documentation which may include, but is not limited to, a Participant Information Sheet, Consent Form, copy of the data collection tool/s, other approvals, permissions, etc
 - 7.4.2 a Research Data Management Plan (RDMP) as outlined in the *Policy: Research Data Management* and *Procedure: Research Data Management*, and
 - 7.4.3 a low-risk subcommittee review checklist, where the Chief Investigator is seeking a low-risk subcommittee review.
- 7.5** The Chief Investigator and all other co-investigators must sign the application form and certify that they all have reviewed and approved the application.
- 7.6** When planning and preparing an application that involves Indigenous human research, the Chief Investigator must ensure the application also details that:
- 7.6.1 all researchers involved are culturally capable and competent to ensure cultural safety and have appropriate evidence to support this
 - 7.6.2 when planning Indigenous human research, the benefits of the research have been discussed with, and gained agreement from, Aboriginal or Torres Strait Islander research participants, communities and any relevant stakeholders during an engagement process, and ensure that the benefits are disseminated in a way that is agreed to by these participants/communities/stakeholders. When undertaking national or multi-centre human research, researchers must ensure that they gain local-level support for their research
 - 7.6.3 they have consulted and applied the NHMRC's *Ethical Conduct in Research with*

Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018) and *Keeping Research on Track II* (2018), as well as the *AIATSIS Code* and *A Guide to Applying The AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research* (2020) authored by AIATSIS, and

- 7.6.4 researchers conducting Indigenous health research in Western Australia must submit their ethics application to the Western Australian Aboriginal Health Ethics Committee (WAAHEC) and seek external ethics authorisation once WAAHEC have granted approval under Section 8 of this procedure.

7.7 Applications for health and medical human research also need to outline consideration for the involvement of consumers and community members in the development, conduct and communication of human research. This can include consideration of why the involvement of consumers and community members was excluded.

7.8 Administrative review by research ethics officers

- 7.8.1 All applications will be tracked and recorded in an applications register by the Research Ethics Officer.
- 7.8.2 All applications will be reviewed and vetted by the Research Ethics Officer to ensure:
 - 7.8.2.1 all required governance documents have been supplied
 - 7.8.2.2 there is a Research Data Management Plan that highlights how the Notre Dame researcher(s) are complying with the University's requirements for the management of data
 - 7.8.2.3 the human research is consistent with the Objects of the University, and
 - 7.8.2.4 where the research team is approved to directly recruit members of the University community (staff, students, guests, etc) via University communication channels or on University premises, or to gain access to University premises for observational studies or similar, that permission from the relevant Head of School or Institute Director (if any), has been obtained.
- 7.8.3 Incomplete and poor-quality applications, along with those in conflict with the Objects will not be accepted for review.
- 7.8.4 Once the application is complete, in the opinion of the Research Ethics Officer, it will be allocated to a Notre Dame HREC, and
 - 7.8.4.1 where a full committee review is needed, it will be added to the agenda of the committee's next scheduled meeting, or
 - 7.8.4.2 where a low-risk subcommittee review is appropriate, the Research Ethics Officer will allocate the application to a Low-risk Subcommittee for review, or
 - 7.8.4.3 where consideration for an exemption is appropriate, reviewed by the Research Ethics Officer.

7.9 Full review process

- 7.9.1 A full committee review of the application by a Notre Dame HREC at a meeting is required when any of the following apply:
 - 7.9.1.1 there is a risk of harm (i.e. a greater than low risk or a high risk profile)
 - 7.9.1.2 it is Indigenous human research
 - 7.9.1.3 the participants include person(s) under 18 years of age

- 7.9.1.4 it involves a waiver of consent for research using personal information in medical research or personal health information
- 7.9.1.5 there is direct recruitment of person(s) with issues that affect their voluntary informed consent to participation (for example, cognitive impairment, intellectual disability, mental illness, highly dependent on medical care, unconscious)
- 7.9.1.6 the participants are arguably in dependent or unequal relationships with the researchers themselves or with those supporting or advocating for the human research
- 7.9.1.7 the human research involves active concealment or planned deception;
- 7.9.1.8 there is opt-out approach taken for human research to which the section 95 or 95A Guidelines apply
- 7.9.1.9 the human research aims to expose illegal activity
- 7.9.1.10 there is collection of human biospecimens (this does not include the use of stored biospecimens)
- 7.9.1.11 genomic research, unless no information that can identify an individual is used and no linkage of data is planned
- 7.9.1.12 animal-to-human xenotransplantation, and
- 7.9.1.13 other circumstances as set out in the *National Statement* and determined by the Research Ethics Officer, in consultation with the Notre Dame HREC Chair(s).
- 7.9.2 Where the Notre Dame HREC requires additional information or modifications to the project to ensure that the human research is compliant with the *National Statement*, University policies and procedures, and/or relevant codes and documents, the Chief Investigator must return a copy of the application with track changes and with written responses to the concerns identified.
- 7.9.3 The Notre Dame HREC will inform the Chief Investigator in writing of the outcome of the review via the Research Ethics Officer
 - 7.9.3.1 where the research includes a Notre Dame student researcher, a copy of the outcome will also be sent to the student, and
 - 7.9.3.2 where possible, such notification will be made within seven business days of the meeting.
- 7.9.4 Where an application is declined (not approved), the Notre Dame HREC will ensure that the Chief Investigator is provided with appropriate feedback or advice including whether or not a revised proposal can be submitted to the HREC.

7.10 Low risk review process

- 7.10.1 Applications determined as low risk will be reviewed by a subcommittee of the Notre Dame HREC (low-risk subcommittee review).
- 7.10.2 The Notre Dame HREC will inform the Chief Investigator in writing of the outcome of the review via the Research Ethics Officer
 - 7.10.2.1 where the research includes a Notre Dame student researcher, a copy of the outcome will also be sent to the student.
- 7.10.3 Where an application is not approved, the Low-risk Subcommittee will ensure that the

Chief Investigator is provided with appropriate feedback or advice including whether or not a revised proposal can be submitted to the HREC.

- 7.10.4 The Notre Dame HREC will note, at its next scheduled committee meeting, the low risk applications that were either approved or not approved since the last meeting.

7.11 Full and Low risk approval conditions

- 7.11.1 Full and low risk applications that are successfully approved will be granted on the basis of conditions that will be provided to the Chief Investigator on the basis that:
- 7.11.1.1 the Ethics Approval is only valid so long as the project maintains approval from the relevant ethics review body
 - 7.11.1.2 the research must be conducted in accordance with conditions of the ethics approval, and
 - 7.11.1.3 reporting and notification obligations.

7.12 Ethics Exemption process

- 7.12.1 Exemptions from ethics review are allowed, under the *National Statement*, in restricted circumstances. The University will consider providing an exemption only when the research carries a minimal or low risk profile, and one (1) or more of the following conditions apply:
- 7.12.1.1 the research involves the use of collections of information or data from which all personal identifiers have been removed prior to being received by the researchers and where the researchers explicitly agree
 - a) not to attempt to re-identify those with whom the information or data is associated
 - b) to take all reasonable steps to prevent re-identification of the information or data for unauthorised purposes or access to the information or data by those who are not authorised
 - c) that any sharing of any research data during or after the project will not create any additional risks of re-identification of the information or data
 - 7.12.1.2 the research is restricted to surveys and observation of public behaviour using information that was or will be collected and recorded without personal identifiers and is highly unlikely to cause distress to anyone associated with the information or the outcomes of the research
 - 7.12.1.3 the research is conducted as part of an educational training program in which the research activity is for training purposes only and where any outcomes or documentation are for program use only, or
 - 7.12.1.4 the research uses only information that is publicly available through a mechanism set out by legislation or regulation and that is protected by law, such as mandatory reporting information, information obtained from registries of births and deaths, coronial investigations or reports of the Australian Bureau of Statistics.
- 7.12.2 The human research project is reviewed by the Research Ethics Officer, with assistance and oversight from a Notre Dame HREC, in accordance with the

requirements of the *National Statement*.

- 7.12.3 The Research Ethics Officer will not organise supplementary scientific or technical reviews of the research.
- 7.12.4 Notification of the outcome of the review of the application will be provided to the relevant Notre Dame HREC at its next scheduled meeting and recorded.
- 7.12.5 Successful applicants obtain an Ethics Exemption and are approved by the University to commence work on the project on the basis that the research is conducted in accordance the conditions that provided the basis for the exemption being granted.
- 7.12.6 The life cycle of the project is not monitored by the Notre Dame HREC, however research integrity breach investigations related to the project may nevertheless be undertaken if integrity breach concerns are raised.

8 EXTERNAL ETHICS AUTHORISATION

- 8.1** This process is intended to minimise unnecessary duplication of ethics review for Notre Dame researchers who are seeking to commence human research that has received ethics approval from an external ethics review body. It is not intended for a Notre Dame HREC to be the primary HREC.
- 8.2** Projects that previously received Cross-Institutional Approval from a Notre Dame HREC are deemed to have received External Ethics Authorisation and are bound by the Policy, this Procedure and the HREC Charter.
- 8.3** The applicant must complete the relevant application form with the following attachments:
 - 8.3.1 a copy of the original ethics application and all supporting documentation, and
 - 8.3.2 a copy of the ethics approval received from the external ethics review body.
- 8.4** For student projects, the applicant must be the registered Principal supervisor of the HDR student or the Notre Dame staff member who is requiring the human research to be undertaken.
- 8.5** For student projects, the applicant must:
 - 8.5.1 ensure that the student is named as an Investigator on the ethical approval received from the external ethics review body, and
 - 8.5.2 either
 - 8.5.2.1 ensure that they are named as an Investigator on the ethical approval received from the external ethics review body, or
 - 8.5.2.2 ensure the supervision plan clearly outlines oversight mechanisms to support the student in meeting their obligations as they are set out in the ethical approval provided by the external ethics review body.
- 8.6** Where a Notre Dame staff member who is facilitating a student's work on a human research project or who has required that work to be undertaken is not also named on the ethical approval received from the external ethics review body, they may provide academic or supervisory guidance, including feedback on research design, analysis and publications, but must not be involved in participant recruitment, participant interactions, consent processes, or have access to research data or participant information.

- 8.7** Applications will be accepted where the human research has received ethics approval from:
- 8.7.1 an external NHMRC-registered HREC
 - 8.7.2 a lower risk approval process administered by a TEQSA-registered institution, or
 - 8.7.3 an overseas ethics review body with processes and standards that are equivalent to those described in the *National Statement*.
- 8.8 Determining equivalency of external ethics review bodies to NHMRC-registered HRECS**
- 8.8.1 The applicant must provide evidence that the external ethics review body operates in a manner that is equivalent to an NHMRC-registered HREC.
 - 8.8.2 The Research Ethics Officer, in consultation with the Notre Dame HREC Chairs, determines whether an external ethics review body operates in a manner that is equivalent to an NHMRC-registered HREC and hence can be accepted for review.
 - 8.8.3 Determinations are made on a case-by-case basis. Key considerations in the determination of equivalency include, but are not limited to:
 - 8.8.3.1 evidence provided by the researcher of the constitution of the external ethics review body, the criteria by which they assessed the human research project in question, and the criteria for approval
 - 8.8.3.2 whether the external ethics review body operates in a manner that is consistent with relevant legislative requirements binding on Australian researchers, and
 - 8.8.3.3 consistency with the Objects of the University.
- 8.9** The application for External Ethics Authorisation is reviewed by a research ethics officer, with advice from a Notre Dame HREC Chair or member, if required.
- 8.10** Once an application has been reviewed and authorisation recommended, it is allocated to a Notre Dame HREC for noting and maintenance of any ongoing reporting requirements.
- 8.11** Successful applicants obtain an External Ethics Authorisation from the Notre Dame HREC to which the project has been allocated and are authorised by the University to commence work on the project subject to any stated conditions.
- 8.12** Unsuccessful applicants may not commence work on the project. They may apply for Ethics Approval or an Ethics Exemption from a Notre Dame HREC.

9 PERMISSIONS PROCESS FOR RESEARCH INVOLVING UNIVERSITY STAFF, STUDENTS or PREMISES

- 9.1** This permission process applies to external human research who are seeking to directly recruit members of the University community (staff, students, guests, etc.) via University communication channels or on University premises, or to gain access to University premises for observational studies or similar.
- 9.2** External researchers must provide evidence of ethics approval from an NHMRC-registered HREC or equivalent ethics review body for the human research project.
- 9.2.1 This process does not apply to teams with Notre Dame researchers who must follow one of the pathways identified in s 6.

- 9.3** Permission must be obtained from the relevant National Head of School or Institute Director (if any), with advice from the Research Ethics Officer, if required.
- 9.4** In weighing whether permission should be given, considerations may include (but are not limited to):
- 9.4.1 the University's support for ethical human research that contributes to knowledge and benefits communities
 - 9.4.2 the alignment of the research with University priorities and the Objects of the University
 - 9.4.3 the need to protect staff and student wellbeing and cultural safety, and
 - 9.4.4 applicable privacy obligations and/or, where the students in question are under 18 years of age, applicable child-safe obligations.
- 9.5** The National Head of School or Institute Director may, at any time, withdraw the permission granted to an external research team on any ground.

10 HREC MONITORING, AUDITS AND INTEGRITY REFERRALS

10.1 Monitoring of projects with Ethics Approval via annual and final progress reporting

- 10.1.1 Each Notre Dame HREC shall monitor human research it has provided Ethics Approval via the Annual Reports and Final Reports to be submitted by the Chief Investigator.
- 10.1.2 The Research Ethics Officer shall review and approve Annual Reports and Final Reports, recording the outcome of the reviews on the application register and notifying the relevant Notre Dame HRECs on those outcomes.

10.2 HREC Audits are led by the Research Ethics Officers and may – depending on the level of complexity and risk, involve participation by the HREC Chairs, Deputy Chairs, Research Integrity Officers, Research Integrity Advisors and other persons, as appropriate.

10.3 The HREC Audits may include:

- 10.3.1 interviews or meetings with researchers
- 10.3.2 review of research documentation (whether written, audiovisual, etc)
- 10.3.3 random or targeted inspections by sponsors, collaborative research organisations or regulators that assess research sites, data integrity and security, or project documentation and records
- 10.3.4 commissioning reports, or seeking advice, from external experts or expert bodies
- 10.3.5 interviews with research participants or other forms of feedback from participants
- 10.3.6 review of published results
- 10.3.7 review of the dissemination of outcomes, or
- 10.3.8 any other activity required to complete the audit.

10.4 HREC Audit Outcomes

- 10.4.1 The full details of the outcome of a HREC Audit will be notified to the researchers involved in the human research that is the focus of the HREC Audit.
- 10.4.2 Where the HREC Audit has been undertaken in response to a complaint or concern that has been raised by a person(s) external to the research team involved in the human research, the overall outcome (and not the full details of the outcome) will be notified

to that external person(s).

- 10.4.3 Where the outcome of a HREC Audit is that there are problems with the ethical acceptability of the human research and its governance, those involved with the research will be required to undertake steps (where possible) to rectify the problems and ensure the ongoing ethical acceptability of the human research.
- 10.4.4 The outcome of a HREC Audit in relation to an Ethical Approval may include a recommendation to the Pro Vice Chancellor Research (or delegate) that that Ethical Approval be restricted, suspended or withdrawn.
- 10.4.5 The outcome of a HREC Audit in relation to an External Ethics Authorisation or Ethics Exemption may include a recommendation to the Pro Vice Chancellor Research (or delegate) that the External Ethics Authorisation or Ethics Exemption be restricted, suspended or withdrawn.
- 10.4.6 The outcome of a HREC Audit may include a research integrity breach investigation referral(s), pursuant to the *Procedure: Managing Potential Breaches of the Code of Conduct: Research*.
- 10.4.7 Situations that may warrant restriction, suspension or withdrawal of an Ethics Approval / External Ethics Authorisation / Ethics Exemption granted by a Notre Dame HREC include, but are not limited to:
 - 10.4.7.1 where there are or have been substantial deviations from the method and aims outlined in the approved application
 - 10.4.7.2 where the risk profile of the project has changed, such that continuation of the research may comprise the welfare of participants and/or those who are indirectly affected by it, or
 - 10.4.7.3 where there is evidence that the Ethics Approval / External Ethics Authorisation / Ethics Exemption should not have been granted.

11 COMPLAINTS AND APPEALS

- 11.1** Complaint reporting mechanisms, including an anonymous complaint reporting mechanism, shall be advertised on the university website.
- 11.2** Where information is given to a human research participant about a project that has received Ethics Approval or Ethics Exemption, and that information shall include complaint reporting mechanisms.
- 11.3 Complaints and concerns about the conduct of human research at the University**
 - 11.3.1 The University will ensure that complaint reporting mechanisms are made available to the public, as well as to human research participants during recruitment and consent-taking processes (if any).
 - 11.3.2 Complaints and concerns about the conduct of human research at the University can be made directly to the [Research Integrity](#) mailbox.
 - 11.3.3 Notre Dame researchers, as well as University staff and students generally, are obliged to forward to the [Research Integrity](#) mailbox or otherwise notify the Research Integrity Officer of any and all complaints or concerns raised in relation to human research conducted under the auspices of the University. This includes complaints and concerns raised by participants of the research, complaints/concerns raised by

people unrelated the research, and complaints/concerns that the recipient believes to be vexatious.

- 11.3.4 Complaints and concerns received will be reviewed by the Research Integrity Officer, in consultation with the Research Ethics Officer and the HREC Chairs, using a risk-based approach, to determine the most appropriate pathway for managing the complaint/concern. This pathway may involve:
 - 11.3.4.1 the commencement of a HREC Audit
 - 11.3.4.2 preliminary assessment as a potential breach of the *Code of Conduct: Research*
 - 11.3.4.3 the commencement of a HREC Audit and preliminary assessment as a potential breach of the *Code of Conduct: Research*, or
 - 11.3.4.4 another pathway if the complaint is unrelated to the conduct of research.
- 11.3.5 Where there is reason to believe that continuance of a research project will compromise the welfare of human research participants, or if the conditions of ethics approval for the project (including the reporting requirements) are not being adhered to, the Research Ethics Officer, in consultation with a HREC Chair will immediately seek to establish whether ethics approval and/or authorisation or exemption for the project should be restricted, suspended or withdrawn. The University will ensure, in this process, that all persons connected to that project (researchers, participants, stakeholders, etc) are treated with procedural fairness and in a manner that respects their dignity.
- 11.3.6 As per the *Code of Conduct: Research*, where complaints/concerns are assessed by the research integrity officer as vexatious, they will be dismissed.

11.4 Appeals and complaints in relation to the conduct of an ethics review process

- 11.4.1 Complaints about decisions of the HREC in relation to applications for Ethics Review, and about the decisions of research ethics officers in relation to applications for External Ethics Review or Ethics Exemptions can be made to the Research Integrity and Ethics Lead.
- 11.4.2 To preserve clear and respectful communication between the Notre Dame HREC and Notre Dame researchers, the University will seek to facilitate resolutions to complaints and concerns by engaging the complainant and the relevant Notre Dame HREC Chair in direct dialogue. Other relevant personnel may be included in the discussion, including – for example – the Director Research Services, Associate Deans, Research, Heads of School, Program Coordinators, the HDR Lead, the Research Grants Manager, etc.
- 11.4.3 The University cannot override a decision of a Notre Dame HREC as to the ethical acceptability of a human research project.
- 11.4.4 The University can conduct a procedural fairness review (a HREC Process Audit), to ensure that all ethics reviews are conducted in a procedurally fair manner and in a manner that is respectful, consistent and supportive of Notre Dame researchers and their collaborators in human research.
- 11.4.5 Where the outcome of a procedural fairness review is that the complainant was not afforded procedural fairness, the issues that were identified in the review will be notified to the decision-maker (the Notre Dame HREC in relation to applications for Ethics Approval, the Research Ethics Officer in relation to applications for External Ethics

Review and Ethics Exemptions) for a second review.

12 DEFINITIONS

12.1 For the purpose of this procedure, the definitions set out in the policy apply.

12.2 In addition, the following definitions apply to this procedure:

Annual Report means the report required annually in a format prescribed by Research Services.

Chief Investigator means the definition set out in the *Code of Conduct: Research*.

Child means an individual under the age of 18.

Co-Investigator means researchers who are officially listed as researchers on an ethics review application, aside from the Chief Investigator.

Discomfort means the definition set out in the *National Statement*.

Fetus means the developing human being, whether alive or dead at delivery, inclusive of an embryo that has been transferred to a uterus.

Fetal tissue means membranes, placenta, umbilical cord, amniotic fluid, and other biospecimens that contain the genome of a fetus. Fetal tissue is regarded as part of the fetus prior to separation of the fetus from the pregnant woman.

Final Report means the report required in a format prescribed by Research Services.

Full committee review means review by a Notre Dame HREC at a meeting. It is a review by the full committee, in contrast to review by a subcommittee.

Genomic research means research about generating, gathering, collecting, conveying or using genomic data or information that has hereditary implications and/or is predictive of future health in research involving participants, relatives and other family members. The source material for the research is irrelevant when it comes to defining “genomic research”.

Harm means the definition set out in the *National Statement*.

Human biospecimens means any biological material obtained from a person including tissue, blood, urine and sputum. It also includes any derivative of these, such as cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person.

Investigators means both Chief Investigators and Co-Investigators on a human research project.

Low risk profile means the human research carries no foreseeable risk of harm but does carry a risk of discomfort.

Low-risk subcommittee review means a review conducted by a subcommittee of a Notre Dame HREC, formed in compliance with the conditions set out in the Charter.

Minimal risk profile means the human research carries no foreseeable risk of harm, no foreseeable risk of discomfort, but does carry a potential for minor burden or inconvenience.

Minor inconvenience or burden means the definition set out in the *National Statement*.

Personal information means information or an opinion about an identified individual, or an individual who is reasonably identifiable: (a) whether the information or opinion is true or not; and (b) whether the information or opinion is recorded in a material form or not. An individual

is defined as a 'natural person'.

Principal supervisor means the definition set out in the *Procedure: Higher Degree by Research Supervision*.

Quality assurance and evaluation activities means activities where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation. It includes, but is not limited to, the following activities: peer review; quality assurance; quality improvement; quality studies; audits; and the systematic collection and analysis of information to make judgments about the effectiveness, efficiency and/or appropriateness of procedures, activities, resources, policies, and/or strategies

RDMP means Research Data Management Plan.

Registered Supervisor means the person(s) appointed by the University to act as a supervisor to a Higher Degree by Research (HDR) student and who is registered as per the *Policy: Higher Degree by Research Supervision* and related procedure.

The Charter means the *Human Research Ethics Committees: Charter*.

The Policy means the *Policy: Human Research Ethics*.

Xenotransplantation means any procedure that involves the transplantation, implantation or infusion of *live* cells, tissues or organs from another species, or body fluids, cells, tissues or organs that have ex vivo contact with live cells, tissues or organs from another species.

Young person means an individual under the age of 18.

Version	Date of Approval	Approved by	Amendment
1	7 October 2026	Vice Chancellor	Effective date – new Procedure to support the <i>Policy: Human Research Ethics</i> , and replacing the <i>Procedure: Applying For Ethics Approval (Course Clearance)</i> ; <i>Procedure: Applying For Ethics Approval (Cross-Institutional Approval)</i> ; <i>Procedure: Applying for Ethics Approval (Full Ethical Review)</i> ; <i>Procedure: Applying for Ethics Approval (Low risk)</i>