Human Research Ethics Procedure

Section 1 - Preamble

(1) This Procedure is effective from 19 August 2024.

Section 2 - Purpose

(2) This Procedure sets out how the University ensures that all research involving human research participants, or their data or tissue is ethically designed, reviewed, and conducted.

Section 3 - Scope

(3) This Procedure applies to all persons conducting University business who intend to conduct or review human research, including:

a. Deakin staff and students, regardless of where the research is carried out, and
b. Research collaborators and visitors listed on a Deakin human research ethics application.

Section 4 - Policy

(4) This Procedure is pursuant to the Research Conduct Policy.

(5) Deakin upholds the principles of the National Statement on Ethical Conduct in Human Research (the National Statement) which help to shape a relationship of trust, mutual responsibility and ethical equality between researchers and participants. These principles are:

a. Research Merit and Integrity
b. Justice
c. Beneficence and
d. Respect.

Section 5 - Procedure

Human research ethics

(6) Deakin staff, students and external associates and visitors who intend to conduct human research must comply with the National Statement, all other relevant national guidelines, Commonwealth, State, and international Statutory Regulations and, where applicable, with any other specialised ethics guidelines and codes of practice.

(7) Deakin staff and students who intend to conduct human research must undertake education and training and demonstrate their competency in accordance with Deakin's human research ethics training requirements.

(8) Deakin staff and students who intend to conduct human research must obtain ethics approval or an exemption from ethics approval at Deakin as outlined in this Procedure. No human research may commence, nor approved research be modified, without ethics approval or confirmation of exemption from ethics review.

(9) Deakin staff and students who intend to conduct the research above must follow the approved processes and timelines and submit the appropriate forms described on the human research ethics website via ResearchPoint.

Deakin University Human Research Ethics Committee (DUHREC)

(10) Under the authority of the Deputy Vice-Chancellor Research and Innovation, Deakin's Human Research Ethics Committee (DUHREC) has been established and is constituted in accordance with the DUHREC Terms of Reference, responsible for ensuring human research complies with the National Statement and is ethically acceptable.

(11) DUHREC is responsible for reviewing all higher risk human research and all human research involving:

a. Women who are pregnant and the human foetus
b. People highly dependent on medical care who may be unable to give informed consent
c. People with a cognitive impairment, an intellectual disability, or a mental illness
d. Aboriginal and Torres Strait Islander peoples or issues
e. Opt-out consent in relation to the collection or use of potentially identifiable health or sensitive data or information from participants
f. People who may be involved in illegal activities, where the research is designed to expose the illegal activity, or likely to discover it
g. Clinical trials
h. Human genomics except where no information that can identify an individual is used, no linkage of data is planned, and the research is otherwise 'low risk'
i. Human biospecimens including any derivative of human biospecimens, such as human cell lines (see the Low Risk Human Research Ethics Application Form for further details)
j. Overseas travel to regions classified as Levels 2, 3 or 4 by the Department of Foreign Affairs and Trade (DFAT) (except where researchers live in the region, their research only involves travel to areas they would normally visit and the project does not involve sensitivities that elevate the normal risks associated with living and working in that region)
k. Active concealment or planned deception of participants
l. Collection or use of potentially identifiable health or sensitive data or information, without permission from the person identified
m. Animal to human xenotransplantation or
n. Exposure to ionising radiation.

(12) Deakin staff and students who intend to conduct research described in clause 11 must submit an ethics application via ResearchPoint.

(13) Deakin staff and students who intend to conduct research described in clause 11d will, in addition to the instruments described in clause 2, undertake consultation with Aboriginal and/or Torres Strait Islander communities prior to designing their projects as such consultation should inform project design. They should also consider and apply the values and ethics guidelines contained in:

a. AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (the AIATSIS Code)
b. Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
c. Keeping research on track II.

Human Ethics Advisory Groups (HEAGs)

(14) Deakin has established Human Ethics Advisory Groups (HEAGs) which are responsible for the ethical review of lower risk human research projects in accordance with the National Statement and the HEAG Terms of Reference.

(15) Deakin staff or students who intend to conduct lower risk human research must submit an ethics application via ResearchPoint to the HEAG.

Exemption from ethics review

(16) Research may be eligible for an exemption from ethics review where it carries a lower risk to participants or the community and satisfies one or more conditions of the National Statement 5.1.17.

(17) Deakin staff or students who intend to conduct human research that is eligible for exemption from ethics review must submit an application for exemption via ResearchPoint. Such research must not commence until formal acknowledgement of exemption is received. If the project receives such acknowledgement i.e. it meets National Statement 5.1.17a-d, the researchers will have four years to conduct their project. If the project project does not meet the eligibility criteria for exemption as per National Statement 5.1.17 a-d, a new ethics application will be required.

Previous approval from external ethics committees within Australia

(18) Deakin staff or students who have obtained approval to conduct research from the Human Research Ethics Committee (HREC) of another Australian institution, must submit an application via ResearchPoint to register the project. Work must not commence until notification from Deakin is received.

Human research projects conducted in a country other than Australia

(19) Prior to commencing human research projects that involve any Deakin staff or students and will be conducted in a country other than Australia (by any member of the research team including collaborators) must:

a. comply with the National Statement
b. comply with any required local ethics review processes and other legal and/or cultural requirements and
c. obtain ethics approval from DUHREC or another Australian HREC. If approval was obtained from another Australian HREC, DUHREC will note this in accordance with clause 18.

Modifying an approved project

(20) Applications to modify approved human research must be submitted to the Deakin ethics review body that approved the project originally i.e. DUHREC or a HEAG.

(21) An application to modify a project must be submitted to DUHREC, even if a HEAG approved the original application, if the modification:

a. involves a request to waive the requirement for consent for access to potentially identifiable health or sensitive data or information;
b. involves an opt-out consent process for access to potentially identifiable health or sensitive data or information; or
c. is higher risk or meets any of the criteria listed in clause 11 a) to n).

(22) A project must not be modified until approval is obtained from DUHREC or a HEAG, or the external Australian HREC that has ethical oversight for the project (i.e. previously approved projects), has provided approval for the change.

Annual and final reporting

(23) An annual report must be submitted via ResearchPoint for each human research project approved by Deakin for noting or action as appropriate.

(24) Annual Reports are not required for:

a. human research projects that are exempt from ethics review as per clause 16; or
b. human research projects approved by another Australian HREC and noted by DUHREC as per clause 18.

(25) A final report must be submitted via ResearchPoint:

a. at the conclusion of data collection, or when a final report is submitted to the original approving Australian HREC; or
b. if the project is discontinued prior to the expected completion date.
c. Final reports are no longer required for projects that are exempt from ethics review. These projects will be automatically closed after four years. To continue such research beyond four years, Deakin researchers must submit a new application for exemption via ResearchPoint.

Quality assurance or evaluation activities

(26) Quality assurance (QA), evaluation and research exist on a continuum of activity. In all cases, the activity must be conducted in a way that is ethical as described in Ethical Considerations in Quality Assurance and Evaluation Activities (2014). Such projects may be eligible for an exemption from ethics review as per National Statement 5.1.17 and may therefore be submitted via the Exemption for Ethics Review form in ResearchPoint as per clause 16. However, ethics approval may be required in some instances, depending on the nature of the ethical issues involved.

(27) Where ethics approval is required, an application must be submitted to DUHREC or a HEAG via ResearchPoint.

Adverse events, incidents, or reactions

(28) Researchers are responsible for taking immediate action to ensure the welfare of participant/s who experience adverse events, incidents or reactions. The principal investigator should be contacted by research team members to assist in assessing and determining the immediate actions required.

(29) As soon as practical after the participant/s immediate welfare needs and any other risks are addressed, the researchers must notify Research Ethics and Integrity.

(30) Where the research is a clinical trial, only serious adverse events, incidents, or reactions caused by the research must be reported to Research Ethics and Integrity.

(31) Clinical trials involving therapeutic goods must adhere to the specific safety monitoring and reporting requirements of the NHMRC Guidance Safety reporting and monitoring in clinical trials involving therapeutic goods.

(32) Upon receipt of a notification, DUHREC may immediately suspend ethics approval for the research where there is reason to believe that the continuance of the project will compromise the participant welfare.

(33) The principal investigator must promptly complete an Adverse Event Form and submit the report, via ResearchPoint.

(34) DUHREC will review the Adverse Event Form and may determine additional actions for the project. Actions may include but are not limited to:

a. modifying the project
b. withdrawing approval for the project or activity.

(35) DUHREC will notify the principal investigator of the outcome and any recommended actions.

(36) Where ethics approval for a research project has been withdrawn:

a. the researcher, the University and, where possible, the participants should be informed of the withdrawal;
b. the researcher must promptly suspend the research and make arrangements to meet the needs of participants; and
c. the research may only resume upon approval from DUHREC.

Allegations of research integrity breaches

(37) Allegations of research integrity breaches will be managed in accordance with the Deakin Human Research Ethics Breach process and the Research Integrity Breaches Procedure.

Complaints concerning DUHREC or HEAG processes or decisions

(38) As per Deakin's website, researchers can put forward an alternative view on the outcome of their ethics application, making reference to the National Statement principles and any other relevant guidelines. If the researcher is unsatisfied with the final decision of either DUHREC or a HEAG, the researcher can make a formal complaint to the Pro Vice-Chancellor Research Planning and Governance. The Pro Vice-Chancellor Research Planning and Governance will review the complaint and provide the complainant with written notification of the resolution of the matter and reason(s) for the decision.

(39) If a complainant remains dissatisfied with the resolution of their complaint about a decision made by DUHREC or the HEAG, they may make a further complaint to the Victorian Ombudsman.

Complaints concerning a Deakin human research project

(40) Complaints about the conduct of a Deakin human research project may be made in writing by a research participant or any other interested party to Research Ethics and Integrity as per the Human Research Ethics public webpage.

(41) Complaints will be managed in accordance with the complaints handling process published on Deakin's Human Research Ethics public webpage.

Organisational consent

(42) Organisational consent for research involving Deakin University staff and students as participants must be obtained prior to seeking human research ethics approval. Approval will only be given where staff and student participation is appropriate and necessary for the research and other options are not available. Such research will minimise the number of Deakin University staff and students involved. Where the research is by an external party it must also be of benefit to the University and relevant results provided to the staff or students involved.

(43) Organisational consent must be obtained from one of the following:

a. the Head of Academic Unit for staff and students enrolled in an Academic Unit (including participants in combined courses where the research relates to their enrolment in that Academic Unit)
b. the Faculty Executive Dean or Institute Director for staff and students in more than one Academic Unit
c. the Dean of Students for students in two or more Faculties or Institutes.

d. the Deputy Vice-Chancellor Research and Innovation or delegate/nominee for staff in two or more Faculties, Institutes or Portfolios.

(44) Where the proposed research is changed as a result of the ethics approval process, approval for any amendments affecting staff or student experience, including the plain language statement and consent form, must be reconfirmed by the responsible person/s in clause 43.

(45) Where more than 200 students are to be surveyed, researcher(s) will also consult with Institutional Research and Surveys prior to scheduling the research. While consultation with Institutional Research and Surveys may occur prior to or after ethics approval is obtained, the research may not be scheduled until after ethics approval is provided.

Conscientious objection

(46) Researchers who conscientiously object to being involved in conducting research with human embryos, foetuses, embryonic or foetal tissue will not be obliged to participate in such research, nor will they be put at a disadvantage because of their objection.

Section 6 - Definitions

(47) For the purpose of this procedure:

a. Adverse incident:
    i. Any unexpected adverse occurrence for which there was no mitigation plan in place, or
    ii. An expected adverse occurrence that was more severe than anticipated and/or for which the mitigation plan proved ineffective

    Which has a possible, probable or definite causal relationship with the research project.
b. Adverse event: any untoward medical occurrence in a research participant with a possible, probable or definite causal relationship with the research project.
c. Clinical trial: any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
d. Clinical trials involving a therapeutic good: clinical trials involving investigational medicinal products and investigational medical devices for trials conducted under the Clinical Trial Notification (CTN) scheme.
e. Discomfort: is considered less serious than harm. It can involve physical or psychological impacts, e.g. minor side-effects from medication or mild anxiety associated with being interviewed. However, where a participant's reaction exceeds discomfort (e.g. distress or physical pain) this should be viewed as a harm.
f. Human Ethics Advisory Group (HEAG): A faculty committee of peers responsible for reviewing and approving low risk human research.
g. Higher risk research: research in which the risk for participants or others is greater than discomfort and carries a risk of harm to research participants, researchers, or others. Harm may include (but is not limited to) physical harm, psychological harm, devaluation of personal wealth, social harm, economic harm, cultural harm and legal harm. Higher risk research requires review by DUHREC.
h. Life-threatening: refers to an event in which the participant was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe.
i. Lower risk research: includes research that is of:
    i. Minimal risk, i.e. where there is no risk of harm or discomfort but where there may be a potential for minor burden or inconvenience (e.g. time given up to participate in research, filling in forms, costs related to travel to a research site).
    ii. Low risk, i.e. projects where there is no risk of harm but where there is a risk of discomfort. Where the

risk, even if unlikely, is more serious than discomfort, the research is not lower risk. Lower risk research is reviewed by a HEAG.

j. Principal investigator: A paid Deakin staff member who is responsible for obtaining ethics and other approvals prior to the commencement of research and ensuring that all conditions of any approvals are adhered to during the course of the research.
k. Researcher: Any person conducting research including but not limited to staff and students.
l. Serious adverse event or reaction: an event that results in death, is life-threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is a medically important event or reaction that may require medical or surgical intervention to prevent one of the other outcomes.

Status and Details

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Responsible Executive	Matthew Clarke Deputy Vice-Chancellor Research and Innovation +61 3 924 43979
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