Human Research Ethics Policy
DRAFT – 17 December 2024

1. Objectives

1.1. The objectives of this policy are to:

(a) ensure that the University's human research (i) recognises that each human being has intrinsic value; and (ii) carries significant potential benefit to the community through the advancement of knowledge;

(b) outline the University's commitment to ensuring that human research undertaken by its researchers is ethical and responsible; and

(c) prescribe the framework of ethical review, approval and monitoring to fulfil this commitment.

2. Scope

2.1. This policy, and the procedures for human research ethics review, applies to:

(a) all research conducted with or about human beings (including human embryos and foetuses), or their data or tissue (**Human Research**) including, but not limited to, the involvement of human beings through:

(i) taking part in surveys, interviews or focus groups;

(ii) undergoing psychological, physiological or medical testing or treatment;

(iii) being observed by researchers;

(iv) researchers having access to their personal information;

(v) the receipt, collection or use of their body, organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, cell lines, tumour and other biopsy specimens) or their exhaled breath;

(vi) access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database;

(vii) accessing Aboriginal and Torres' Strait Islander peoples' lands or waters, culture or knowledge, and artefacts or collections such as archives, datasets, information, or biospecimens;

(b) all Human Research conducted in the course of University activities, including:

(i) within Australia or overseas, taking into account local regulatory requirements;

(ii) at other institutions;

(iii) pursuant to a contract, grant or without funding;

(iv) as part of coursework, a student placement or internship;

(v) where the activity is assessed as higher risk, lower risk or exempt from human research ethics review; and

(vi) teaching or student-related data collection activities that fall under the definition of Human Research; and

(c) all University employees, Graduate Researchers, honoraries, visitors, volunteers, committee members (staff or otherwise) and students, who conduct, govern or support Human Research in their University capacity, and any non-University personnel who support the conduct of Human Research on behalf of the University.

3. Authority

3.1. This policy is made under the *University of Melbourne Act 2009* (Vic) and the Academic Board Regulation and aligns with:

(a) Australian Code for the Responsible Conduct of Research 2018;

(b) *AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research* 2020 (the AIATSIS Code) and *A Guide to Applying the AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research* 2020 (the AIATSIS Guide); and

(c) National Statement on Ethical Conduct in Human Research 2023 and associated guidelines.

4. Policy

4.1. The University is committed to Human Research that recognises and respects that each human being has value in themselves, meets ethical and scholarly or scientific standards and takes account of consumer and community perspectives. All personnel undertaking Human Research must:

(a) seek appropriate ethics approvals (or exemptions) under the National Statement on Ethical Conduct in Human Research (National Statement);
(b) comply with the terms of any ethics approval or exemption, this policy, the National Statement, relevant legislation, regulations, statutory guidelines, Codes, and other applicable University policies and processes;
(c) support appropriate monitoring of Human Research through submission of annual and incident reports in accordance with this policy;
(d) ensure that Human Research is within acceptable risk parameters in accordance with this policy; and
(e) ensure that Human Research is authorised under local Faculty governance processes.

4.2. Ethics approval or exemption for Human Research is necessary, but not sufficient, for such research to proceed. Where ethics approval or exemption has been granted, personnel must only conduct Human Research where it has been authorised by the relevant Faculty in accordance with local governance processes, taking into account applicable laws, regulations, policies and processes.

4.3. The Deputy Vice-Chancellor (Research) will:
(a) establish Human Research Ethics Committees (HRECs) and Lower Risk (LR) review entities to internally regulate human research against the National Statement through review, oversight and monitoring activities; and
(b) establish a Central Human Research Ethics Committee (CHREC) to support the University's commitment to the ethical conduct of human research by providing expert and strategic advice on human research ethics matters, and capability-building initiatives for ethics reviewers and researchers.

4.4. The University will provide training, resources, processes, and infrastructure to support researchers' and reviewers' understanding of human research ethics, and to facilitate the conduct of human research that meets the requirements of the National Statement.

4.5. Retrospective ethics approval cannot be granted.

4.6. The University provides an accessible, publicly available mechanism for individuals to raise concerns, issues or complaints about:
(a) the University's Human Research;
(b) researchers and/or the conduct of their research;
(c) ethics reviewers and/or the human ethics review process or outcome.

4.7. The University respects the right of its staff, graduate researchers, students and ethics reviewers to have and express conscientious objection to participating in the conduct or review of research involving human embryos, foetuses or embryonic or foetal tissue, and no adverse consequences will arise in relation to persons expressing such conscientious objection.

5. Procedural Principles

Implementing an Ethical Framework for Human Research

5.1. The Deputy Vice-Chancellor (Research) will determine efficient and proportionate processes in relation to Human Research to:
(a) assess whether an activity constitutes Human Research;
(b) assess the risk of Human Research to human participants;
(c) review and monitor Human Research;
(d) apply for an exemption from ethical review;
(e) register an ethics approval granted by an external ethics committee;
(f) register a conscientious objection to participating in the conduct or review of research involving human embryos, foetuses or embryonic or foetal tissue;
(g) support compliance with the AIATSIS Code; and
(h) any other processes relating to research and its impact on humans,

and such processes will be administered, documented and published by the Office of Research Ethics and Integrity as Ancillary Requirements.

Human Research Ethics Applications and Review

5.2. The Responsible Researcher will ensure that:
(a) in submitting a human research ethics application via the Office of Research Ethics and Integrity, all information contained in the application is factual, accurate and complete;
(b) where an exemption to human research ethics review has been granted, the activities subject to exemption are conducted in accordance with the principles of the National Statement; and
(c) in the case of any ethical approvals for human research obtained outside the University of Melbourne, such approvals are formally registered with the University through the Office of Research Ethics and Integrity.

5.3. For any Human Research proposing to access cadaveric Human Tissue from the University's ***Body Donor Program***, the Responsible Researcher must obtain in-principle approval [link]from the Department of Anatomy and Physiology prior to submitting a human research ethics application.

5.4. The HRECs and lower risk review entities will:
(a) work diligently to discharge the functions specified in their Terms of Reference in a timely and professional manner, and in accordance with the National Statement; and
(b) operate in accordance with the principles of procedural fairness.

5.5. All human research ethics reviewers will adhere to their relevant Terms of Reference (including the behaviours described in the Terms of Reference), this policy, and their specific terms of appointment in the discharge of their duties.

5.6. Deans will make staff available to serve as human research ethics reviewers in proportion to the number of applications submitted for human ethics review, considering the skills and expertise required to ensure that ethics reviews meet the requirements of the National Statement.

Respect, Consent, Privacy and Confidentiality

5.7. No researcher may conduct human research unless:
(a) in the case of adults, the participants have given prospective consent, explicit or implied, in accordance with the National Statement, or a waiver of the requirement to obtain consent has been approved by a HREC or LR review entity;
(b) in the case of participants who are aged under 18, in addition to any consent requirements determined through ethical review under the National Statement, consent from parents/legal guardians for their children to participate in Human Research is given in writing in accordance with the University's Child Safety policy; or
(c) in the case of embryos and foetuses, prospective consent from relevant parties has been obtained in accordance with the National Statement and approved through ethical review.

5.8. A waiver of the requirement to obtain consent may only be granted by a HREC or LR review entity under specific circumstances outlined in the National Statement, and may not be granted in relation to the requirement for parental/legal guardian consent under the University's Child Safety policy.

5.9. Researchers must respect the autonomy, privacy, confidentiality and cultural sensitivities of human research participants and, where relevant, of their communities. Any specific agreements made with the participants or the community should be documented and fulfilled.

5.10. (a) *Recruitment*: Researchers seeking to access personal or health information from health care providers or other organisations in order to identify recruitment pools, including:
(i) the contact details of potential research participants; or
(ii) screening health records, including electronic medical records, to identify potential participants meeting inclusion criteria,

must ensure that access to such information does not breach the *Privacy and Data Protection Act 2014 (Vic)*, *Privacy Act 1988 (Cth), Health Records Act 2001 (Vic)* or any other applicable privacy legislation. Access to personal or health information in these cases requires the provider or organisation to have appropriate privacy collection notices and suitable consent arrangements in place to enable such personal or health information (as the case may be) to be lawfully shared with researchers.

(b) *Recruitment*: Responsible Researchers must not propose or undertake, and Deans must not authorise the conduct of, research that recruits or screens potential research participants in breach of applicable privacy or health records laws. Waivers of consent granted by HRECs are not lawful in the context of Human Research recruitment activities.

(c) *Health Information-Based Research*: Researchers seeking to access health information from medical records or bio-banks for research purposes (but not merely for recruitment purposes) must ensure that access to such information does not breach the *Privacy and Data Protection Act 2014 (Vic)*, *Privacy Act 1988 (Cth), Health Records Act 2001* (Vic) or any other applicable legislation. If it is not practicable to seek consent from the persons to whom the health information relates, an application for a waiver of consent must be explicitly sought from the governing HREC by the Responsible Researcher.

5.11. Researchers seeking to collect, use or disclose personal information may be required to obtain a Privacy Impact Assessment (PIA). Where a PIA is required, this should be undertaken prior to submission of a human research ethics application.

5.12. Using material, human tissue (including cell lines), artefacts or data in Human Research acquired prospectively through professional or community activities (including through teaching, clinical practice or community engagement) is not permissible, even if that material has been legitimately accessed or acquired by a researcher as part of their academic or professional role, or community engagement, unless prospective ethics approval for the research, including acquisition of such material, human tissue (including cell lines), artefacts or data, has been granted.

Risk assessment

5.13. The University is committed to ensuring that all risks involved in human research are assessed and managed to ensure that the welfare and interests of the participants, researchers and institutions are protected throughout the research process.

5.14. Risks relating to:
(a) human research participants are assessed according to criteria drawn from the National Statement and embedded in the human ethics online application form;
(b) researchers and institutions are managed through relevant processes in accordance with authorisation governance processes.

5.15. Human research that is low risk is reviewed under an established LR pathway and human research that is higher risk is reviewed by an HREC.

5.16. Applications received via the LR review pathway but determined to be higher risk, must be referred to a HREC for review and approval.

Monitoring

5.17. Human research approved by the University is monitored through mechanisms aligned to the National Statement, including:
(a) annual progress and final reports for each approved project;
(b) internal and external audits of compliance with the approved protocols; and
(c) site visits and interviews with research participants.

5.18. Researchers must submit an annual report to the relevant approving body on every project that has human research ethics approval. The report includes:

(a) progress to date, or outcome in the case of completed research;
(b) the security of project-related data and information;
(c) compliance with the approved proposal; and
(d) compliance with any conditions of approval.

5.19. Failure to submit an annual report may result in suspension or withdrawal of ethics approval.

Incidents, Complaints and Grievances

5.20. All complaints will be managed via publicly available pathways and may involve review by the HREC and/or referral to the University's Research Integrity unit.

5.21. Where complaints raise the possibility of a breach of the standards governing the conduct of research, they are handled in accordance with the University's Research Integrity and Misconduct Policy and the Australian Code for the Responsible Conduct of Research.

5.22. Researchers must report all complaints received and unforeseen incidents by submitting an incident report via the ethics management system as soon as practicable following the event.

5.23. HRECs may suspend or withdraw ethics approval for human research where it is reasonable to believe that the research project may compromise the welfare or safety of any participant.

5.24. The DVCR can direct the suspension of research in the event of an issue, concern or complaint in relation to that human research being identified (in accordance with the requirements of the National Statement), irrespective of any approvals or authorisations under this Policy:
(a) pending investigation of the issue, concern or complaint;
(b) to minimise risk of further harm to people, animals, the environment or reputation; and/or
(c) where an ethics review body has decided to suspend or withdraw ethics approval.
In such an instance, the Responsible Researcher and relevant Dean must ensure that relevant research is suspended and not re-commenced without authorisation by the DVCR.

University approvals and authorisations

5.25. The Responsible Researcher must not commence Human Research unless authorisation has been given under local Faculty governance, taking into account whether all applicable processes, approvals and authorisations have been completed or granted including, without limitation, in relation to:
(a) Ethics review or ethics review exemption;
(b) Competency assessment or appropriate supervisory arrangements;
(c) Health and Safety risk assessment and approvals for University personnel; (Health and Safety policy)
(d) Travel approvals for University personnel; (Travel policy)
(e) Child safe processes and approvals; (Child Safe policy)
(f) University Clinical Trial Sponsorship processes and authorisation; (Clinical Trials Policy)
(g) Site Specific Approval; (Clinical Trials Policy)
(h) Medical Physics Radiation Dose and Risk Assessment (for projects involving ionising radiation);
(i) the University's Body Donor Program (cadaveric Human Tissue);
(j) Privacy Impact Assessment; (Privacy Policy)
(k) Data Management Plan; (Research Data Management Policy);
(l) IP licences or other permissions, such as social media terms of use; and
(m) any other requirements, approvals or authorisations for Human Research required by laws, codes or regulations.

3. Roles and Responsibilities

Role/Decision/Action	*Responsibility*	*Conditions and limitations*

Deputy Vice Chancellor (Research)	Establishes and oversees the CHREC, the HRECs and LR Review entities: • Determines CHREC, HREC and LR review Terms of Reference • Appoints and dismisses the CHREC and HREC Chairs Determines processes for approving, monitoring and overseeing human research. Suspends human research.	
Director, OREI by delegation from Deputy Vice Chancellor (Research)	Establishes and administers procedures and processes relating to Human Research, including to support the functions of the HRECs, risk assessment of Human Research, LR review processes, exemption review processes, and monitoring of human research. Makes available guidance to researchers and ethics reviewers on the ethics application and review processes. Maintains a complete record of all human research proposals received and reviewed by HRECs and LR review entities. Maintains a record of external human research ethics approvals registered with the University. Maintains a record of all human research projects granted an exemption from human research ethics review. Administers the HREC annual reporting to the NHMRC.	
Director, OREI by delegation from the Deputy Vice Chancellor (Research)	Directs the suspension of research in the event of an issue, concern or complaint in relation to that human research being identified (in accordance with the requirements	(a) Pending investigation of the issue, concern or complaint; (b) To minimise risk of further harm to people, animals, the

	of the National Statement), irrespective of any approvals or authorisations under this Policy	environment or reputation; and/or (c) Where an ethics review body has decided to suspend or withdraw ethics approval.
Director, OREI	Receives complaints, issues, incidents or concerns in relation to the conduct of human research or the conduct of an HREC or LR review entity.	
Responsible Researcher	Obtains all required approvals and authorisations for conducting human research under this policy. Complies with all conditions of human research ethics approval or exemption.	
Human Research Ethics Committee (HREC) and Lower Risk (LR) review entities	Review and monitor human research activities in accordance with the Terms of Reference and Human Research Ethics Operating Procedures.	
Central Human Research Ethics Committee (CHREC)	Develop and deliver training and guidance materials to support researchers and ethics reviewers understanding of the principles of human research ethics.	
Deans	Implements governance processes to authorise Human Research. Establishes and implements local Faculty processes, to ensure that personnel act in accordance with this Policy, that risks are assessed and authorised, and that ethics training is completed.	
Deans	Make staff available to serve as human research ethics reviewers in proportion to the number of applications submitted for human ethics review, considering the skills and expertise required to ensure that ethics reviews meet the requirements of the National Statement.	

	Supports CHREC to develop and deliver training and guidance materials relevant to their local contexts.	

4. Definitions

Ancillary Requirements means the detailed activities, requirements, guidance, roles and responsibilities authorised by the Deputy Vice-Chancellor (Research) under this policy and maintained and published by Office of Research Ethics and Integrity.

Burden or inconvenience means a minor negative accompaniment or effect of research, less serious than discomfort. Examples may include such activities as filling in a form or participating in a street or phone survey, or simply giving up time to participate in research

Discomfort means a negative accompaniment or effect of research, less serious than harm. Examples might include minor side-effects of medication, the discomforts related to measuring blood pressure, or anxiety introduced by being interviewed.

Harm means that which adversely affects the interests or welfare of an individual or a group. Harm includes physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage. Examples may include, but are not limited to, the following:

- physical harms - injury, illness, pain;
- psychological harms - feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease;
- devaluation of personal worth - being humiliated, manipulated or in other ways treated disrespectfully or unjustly;
- social harms - damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status;
- economic harms - discovery and prosecution of criminal conduct.

Higher Risk Research means research in which there is:

- Risk of harm +/- foreseeable burden (Greater than Low); or
- Risk of significant harm +/- foreseeable burden (High)

Human Research means research involving people, their data or their biospecimens. Human participation in research therefore includes, but is not limited to, the involvement of human beings through:

(a) taking part in surveys, interviews or focus groups;
(b) undergoing psychological, physiological or medical testing or treatment;
(c) being observed by researchers;
(d) researchers having access to their personal documents or other materials;
(e) the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
(f) access to their information (in individually identifiable, re-identifiable or nonidentifiable form) as part of an existing published or unpublished source or database;
(g) accessing Aboriginal and Torres' Strait Islander peoples' lands or waters, culture or knowledge, and artefacts or collections such as archives, datasets, information, or biospecimens.

Lower Risk Research means **research in which there is:**

- No risk of harm or discomfort; potential for minor burden or inconvenience (minimal risk); or
- No risk of harm; risk of discomfort +/- foreseeable burden (low risk)

Responsible Researcher means the researcher who is the primary named person with responsibility for the conduct of the project and obtaining the relevant approvals.

POLICY APPROVER
[Position title of policy approver]

POLICY STEWARD
[Position title of policy steward]

REVIEW
This policy is due to be reviewed by [insert date not more than 3 years from date of approval].

VERSION HISTORY

Version	Approved By	Approval Date	Effective Date	Sections Modified
1	[Position title of policy approver]			N/A