Human Research Ethics Procedure

Section 1 - Context

(1) This procedure ensures that human research at RMIT is ethical, responsible and consistent with relevant legislation, regulations, guidelines and institutional policy and procedures.

Section 2 - Authority

(2) Authority for this document is established by the Research Policy.

Section 3 - Scope

(3) This procedure applies to all human research that is reasonably considered the responsibility of RMIT.

(4) It excludes activities not considered human research or which are exempt from ethical review according to the National Statement on Ethical Conduct in Human Research (National Statement), such as quality assurance activities, and some work integrated learning and internships.

Section 4 - Procedure

Human Research Ethics at RMIT

(5) Research that involves people, their data and/or bio-specimens will only be undertaken where it is ethical and conducted responsibly. All risks involved in human research will be assessed, minimised and managed to ensure that the welfare and interests of the participants, researchers and institutions are adequately protected throughout the research process.

(6) All human research at RMIT (undertaken by researchers at RMIT Australia, RMIT Europe or RMIT Vietnam) requires prior and appropriate ethics review and approval.

(7) The RMIT Human Research Ethics Committee (HREC) is responsible for reviewing, and where ethical, approving more than low risk and other human research at RMIT requiring HREC review, in keeping with the National Statement and institutional policy and procedures.

(8) The RMIT College Human Ethics Advisory Networks (CHEANs) are responsible for reviewing, and where ethical, approving negligible risk and low risk human research at RMIT in keeping with the National Statement and institutional policy and procedures.

(9) RMIT will provide professional development, resources, processes and infrastructure that support researchers to understand human research ethics and the gaining and maintaining of human research ethics approval, as well as the responsible conduct of research that complies with relevant legislation, regulations, guidelines and RMIT policy.

(10) In Australia, RMIT researchers will remain compliant with the National Statement and institutional policy at all

times, including when at other institutions. While outside Australia, RMIT staff members will remain compliant with the National Statement where possible. For advice on compliance for research outside Australia, contact the RMIT HREC.

Gaining Human Research Ethics Approval at RMIT

Risk Assessment

(11) Researchers will complete a risk assessment before applying for ethics approval and before starting any research activities involving human participants. The risk assessment will assist researchers in determining the level of risk.

(12) In line with the National Statement, human research is categorised by the level of risk. There are four categories:

a. exempt from review (research involving secondary analysis of non-identifiable data)
b. negligible risk (research in which there is no foreseeable risk of harm or discomfort)
c. low risk (research in which the only foreseeable risk is one of discomfort)
d. more than low risk (research that may lead to harm, including physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage).

(13) Projects that are exempt from review will not require ethics review and/or approval by a CHEAN or HREC. However, researchers will retain evidence that they have assessed their research project as exempt from review (i.e. keep a copy of the completed RMIT human research ethics risk assessment).

(14) Research projects that are negligible or low risk will be reviewed by:

a. the CHEAN most closely aligned with the area of research, or
b. for researchers based at RMIT Vietnam, to the CHEAN aligned to the relevant RMIT Vietnam School or Centre.

(15) Ethics applications for research activities that are more than low risk will be reviewed by the RMIT HREC.

(16) A CHEAN or HREC, or CHEAN or HREC Chairperson or Deputy Chairperson, and/or research governance staff may recommend a new risk assessment where they determine that the original assessment is inappropriate.

Standard Applications

(17) The Principal Investigator will complete the appropriate ethics application form and submit it to the appropriate ethics committee, via the REP.

(18) For honours, postgraduate or higher degrees by research (HDR) projects, the Supervisor will be named as Principal Investigator/Senior Supervisor on the application form.

(19) Relevant accompanying and supporting documentation will be submitted with the ethics application form (uploaded to the e-form as supporting documentation) including, as applicable:

a. recruitment materials (advertisements, posters, flyers, brochures etc.)
b. participant information and consent form/s
c. research instruments (questionnaire/s, survey/s and/or proposed interview/focus group outline
d. other material required as part of the application process.

(20) Submission dates for applications and meeting dates (where applicable) for the HREC and networks are published on the Researcher Portal.

a. DSC CHEAN and HREC generally review in-session

b. CoBL and SEH CHEANs generally review out-of-session on a rolling basis

(21) Applications that do not meet relevant submission dates or other governance requirements will be held over to a following meeting

(22) All applications will be vetted by research governance and/or other appropriate administrative staff for completeness and compliance with governance requirements. Incomplete, insufficient and/or unauthorised applications will not be accepted for review.

(23) Relevant ethics training will be completed before applicants apply for ethics approval.

Coursework or Labwork Applications

(24) RMIT staff can apply for coursework or labwork human research ethics approval for common and clearly defined human research activities that are being undertaken:

a. for coursework approvals - by multiple students in a coursework context (either undergraduate, postgraduate or vocational); or
b. by multiple members (staff or students) in a labwork context.

(25) Coursework and labwork research ethics approvals will generally only apply to negligible risk or low risk human research activities. Where coursework or labwork-related research activities are assessed as more than low risk, the applicant will consult the HREC regarding the provision of human research ethics approval.

(26) Coursework applications will be prepared and submitted by the relevant Course Coordinator, convenor or person responsible for the conduct of the course or program via the REP. This person will be named as the Principal Investigator on the Coursework and Labwork Human Research Ethics Application Form.

(27) Labwork applications will be prepared and submitted by the relevant Lab Group Leader responsible for the conduct of the related human research ethics activities via the REP. This person will be named as the Principal Investigator on the Coursework and Labwork Human Research Ethics Application Form.

(28) The completed Coursework and Labwork Human Research Ethics Application Form will be reviewed by the relevant CHEAN, most closely aligned with the course or lab group, for review and approval.

(29) For coursework, this human research ethics approval covers all students enrolled in the relevant course or program, to carry out the common and defined research activities, for the designated approval period.

(30) For labwork, this human research ethics approval covers all students or staff named in the lab group, to carry out the common and defined research activities, for the designated approval period.

Registering an Externally Approved Human Research Ethics

(31) Where an RMIT staff member or student has an external approval for a research project the relevant RMIT HREC or CHEAN will be notified.

(32) The RMIT researcher will submit a registration notification via REP, in line with the instructions, guidance and/or schedule of dates provided on the Researcher Portal.

(33) This registration will be reviewed and a formal acknowledgement will be issued to the researcher by the relevant RMIT HREC or CHEAN.

Multi-centre Research and Minimising Duplication of Review

(34) RMIT University seeks to avoid duplication of ethics review, in line with the National Statement.

(35) RMIT University accepts human research ethics approvals from Human Research Ethics Committees registered with the Nationl Health and Medical Research Council (NHMRC) and accepts multi-centre research proposals where RMIT University researchers are involved but the Principal Investigator is from another institution. All such projects will be registered with the respective HREC or CHEAN (see section 2.4).

(36) For transfers of an externally approved human research ethics project or activities to RMIT an RMIT application will be required.

Aboriginal and Torres Strait Islander Research

(37) Research involving Aboriginal and Torres Strait Islander Peoples will be reviewed and approved by the RMIT HREC.

(38) In determining whether research involves Aboriginal and Torres Strait Islander Peoples consider:

a. the scope of the project
b. the demographics of participants
c. the research topic, social phenomena and/or the illness or health burden being studied
d. their historical, social and cultural context and connections.

(39) Researchers and ethics review bodies will consider and apply the values and ethics guidelines contained in the National Statement and other relevant guidance documents including:

a. Guidelines for Ethical Research in Indigenous Studies [AITSIS]
b. Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders [NHRMC] including the six core values of: Spirit and integrity, Cultural continuity, Equity, Reciprocity, Respect and Responsibility.
c. Keeping research on track II [NHMRC]

(40) HREC review of research involving Aboriginal and Torres Strait Islander Peoples will include assessment by and/or advice from:

a. people who have networks with Aboriginal and Torres Strait Islander Peoples and/or knowledge of research Aboriginal and Torres Strait Islander Peoples; and
b. people familiar with the culture and practices of the Aboriginal and Torres Strait Islander Peoples with whom participation in the research will be discussed.

(41) Researchers will not collect data or commence recruitment activities without first receiving formal notification of ethics approval. Scoping and other pre-research planning activities may proceed prior to approval.

Ethics Review and Approval

(42) The HREC and CHEAN will review all applications for human research ethics at RMIT on behalf of the institution and in line with relevant codes, guidelines, legislation and RMIT policy and procedures.

(43) The HREC or CHEAN will inform the Principal Investigator of the outcome of the review in a timely manner.

(44) Applications will be approved for a minimum of six months and for a maximum of three years, although extensions can be requested for beyond the initial three-year approval period up to a maximum of five (5) years.

Amending a Human Research Ethics Approval

(45) Amendments are required where researchers plan to vary any aspect of their approved project, including changes to the Principal Investigator or other investigators (including student investigators taking a leave of absence from their program), research participants, recruitment methods, research methods, research sites/locations, or an extension of approval.

(46) Researchers will gain approval for an amendment prior to implementing the change.

(47) Researchers will seek approval for an amendment to extend ethics approval before the approval period has expired. Research activities that require ethics approval will not continue when such approval has expired.

(48) For amendments to projects approved by an RMIT ethics review body:

a. The Principal Investigator will submit an application for an amendment via REP, in line with the instructions, guidance and/or schedule of dates provided on the Researcher Portal. Applications which fail to meet applicable submission dates will be held over to a future meeting.
b. Requested amendments to an approved project will not be implemented by the Principal Investigator until the request is approved by the relevant CHEAN or HREC.
c. The CHEAN or HREC Executive may review and approve amendments out-of-session. During the review they may seek additional advice from the Principal Investigator. Any amendments approved out-of-session will be ratified at the next regular CHEAN or HREC meeting.

(49) For amendments to projects approved externally:

a. The Principal Investigator will submit an application for an amendment electronically, in line with the requirements of the external ethics committee that approved the project.
b. Requested amendments to an approved project will not be implemented by the Principal Investigator until the request is approved by the relevant external ethics committee.
c. Once approved the Principal Investigator will forward a copy of the amendment and the approval to the relevant RMIT CHEAN or HREC for noting.

Reporting

(50) The Principal Investigator will submit an Annual Report on the anniversary date of approval for the life of the project or program (regardless of the duration of human research ethics approval), via REP, in line with the instructions, guidance and/or schedule of dates provided on the Researcher Portal.

(51) The annual reports will detail the project progress over the past 12 months including any progress made towards the objectives of the study and any adverse events or incidents over the reporting period.

(52) Ongoing approval of a project is conditional upon the submission of annual reports.

(53) In the final year, the Principal Investigator will submit a final report within six months of the end of the approval period via REP, in line with the instructions, guidance and/or schedule of dates provided on the Researcher Portal.

(54) The Final Report will provide a conclusion statement on the outcomes of the project or activities and should also outline any publications (either submitted or in progress) resulting from the project or activities and if any further avenues of research have arisen as a result. Final reports must be submitted within six months of the end of the approval of the project or as soon as possible after a research project has concluded.

(55) Annual and final reporting will be undertaken using the RMIT Committee approved forms, via REP, in line with the

instructions, guidance and/or schedule of dates provided on the Researcher Portal.

(56) Reports are still required even where an approved project has not commenced or has been abandoned.

(57) The HREC/CHEAN may decide not to review new applications from a Principal Investigator, whilst annual and final reports for previous projects remain outstanding.

Adverse Events

(58) Any adverse event will be reported promptly by the Principal Investigator to the approving ethics review body at RMIT (HREC/CHEAN) within 24 hours of it being identified or coming to the attention of the researcher/s.

(59) Adverse events are to be reported via REP, in line with the instructions, guidance and/or schedule of dates provided on the Researcher Portal.

(60) Adverse events will be reviewed by the relevant HREC/CHEAN with support from the Research Ethics, Integrity and Governance team.

(61) The Principal Investigator, line manager and any other appropriate persons/bodies will be notified of the outcome of this review, including any related findings and/or recommendations.

Monitoring and Withdrawal of Approval

(62) Monitoring and auditing ethically approved research is the responsibility of the institution.

(63) As per the National Statement monitoring is conducted through various mechanisms including:

a. reports from researchers
b. reports from independent agencies
c. review of adverse events
d. audits or inspections of research sites, data, or documentation
e. interviews with research participants or other forms of feedback.

(64) The HREC/CHEAN may request an audit of research projects that have human research ethics approval. Results of any audits will be reported back to the relevant HREC or CHEAN.

(65) The HREC/CHEAN may withdraw approval for any project, before or after an audit, when they have reason to believe that the research project continuing would compromise the welfare of participants, researchers or others.

(66) Where a HREC/CHEAN withdraws approval for a project, the HREC/CHEAN will notify the researcher(s), as well as the relevant line manager and/or Head of School/College/Centre, and may also notify other parties, including participants, as possible and appropriate.

(67) Where the HREC/CHEAN considers that urgent suspension of approval for a research project/s is necessary before the complaints process described in Section 8 is undertaken, they may stop the research.

(68) In reviewing cases of non-compliance or situations in which participant welfare has been compromised, the HREC/CHEAN may refer the matter to the institution (the Designated Person at RMIT), for consideration under the Management of Breaches of Research Integrity Procedure.

Complaints

(69) Staff, students, members of the public, or any other concerned persons may make a complaint concerning human research projects or activities at RMIT.

(70) Complaints about an RMIT human research project

a. The complaint will be forwarded to the Research Ethics, Integrity and Governance team via humanethics@rmit.edu.au.
b. The Secretary will acknowledge receipt of the complaint and inform the HREC Chairperson, Manager, Research Ethics & Governance and Senior Manager, Research Ethics & Integrity.
c. The HREC Chairperson and Research Ethics, Integrity and Governance team team will consider the complaint and as appropriate:
    i. form a working party to investigate the complaint and report to the HREC;
    ii. refer it onto the appropriate institutional process (this includes the Research Misconduct Process); or
    iii. if unfounded, determine that no further action is required.
d. The working party will consist of the Chairperson (or delegate) and two members of the committee and may include others. Where the complaint relates to a project approved by a CHEAN, the relevant CHEAN Chairperson (or delegate) will join the working party.
e. The report will detail the investigation and any findings and recommendations for further action.
f. The HREC decides on any required actions and informs the relevant parties.
g. Where investigation finds that the complaint involves a breach of the National Statement, the working party will work with the relevant CHEAN and/or School/College/Centre to avoid a recurrence.
h. Where the investigation finds that the breach of the National Statement may also represent a breach of the Australian Code or research misconduct, the working party will refer it to the Designated Officer who will handle it in line with the Management of Breaches of Research Integrity Procedure.
i. Where the working party or the HREC Chairperson dismisses a complaint, the reason/s for dismissal will be provided to the complainant and to the HREC.
j. Where the working party or the HREC Chairperson finds that the complaint should be dealt with under other institutional provisions, they will refer it on as appropriate.

Complaints Regarding the Conduct of the HREC or CHEAN

(71) Where the complaint cannot be readily resolved by communication between the complainant and the review body, the complaint may be submitted to the Director, Research Services in writing.

(72) Following receipt of a complaint, the Director, Research Services or nominee shall seek further information from the relevant HREC/CHEAN Chairperson, and other staff as necessary to establish the veracity of the complaint, and whether any RMIT policies or procedures have been compromised.

(73) The Director, Research Services or nominee will provide a report to the relevant committee and the complainant on the outcome of the investigation of the complaint and include a recommendation for any further actions.

(74) As per the National Statement, researchers cannot appeal an ethics review body’s decision to reject an application.

Section 5 - Definitions

ARC	Australian Research Council.
Adverse event	Any adverse event or unexpected incident which affects or impacts a participant’s welfare and/or the ethical acceptability of the project.

Biospecimen	Defined broadly, as any biological material obtained from a person including tissue, blood, urine and sputum; it also includes any derivative of these, such as cell lines.
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.
Code	the Australian Code for the Responsible Conduct of Research.
Consent	A person's or group's agreement (based on adequate knowledge and understanding of relevant material) to participate in research.
CHEAN	College Human Ethics Advisory Network. Note: RMIT Vietnam Schools and Centres are all aligned to RMIT Australia Colleges.
Co-investigator	Other investigators (in addition to the Principal Investigator) involved in a research project for which ethics approval is sought. Single or multiple co-investigators can be included on an ethics application and may not necessarily be RMIT staff or students.
Coursework human research activity	Common and clearly defined human research activities that are being undertaken by multiple students in a Coursework context (either undergraduate, postgraduate or vocational).
Data	In a human research context, data refers to bits of information in their raw form. Data can refer to raw data, cleaned data, transformed data, summary data and metadata (data about data). It can also refer to research outputs and outcomes. See also 'databank'.
Databank	A systematic collection of data (see above).
External approval	An ethics approval for human research granted by a non-RMIT HREC or other human research ethics review body.
Genomic research	Research with the potential for hereditary implications, which may range from single gene genetic research to whole genome sequencing and any other 'omic' research (e.g. exomic, proteomic, etc.) with potential hereditary implications. Genomic research includes the full scope of 'genetic' research.
HREC	Human Research Ethics Committee, constituted in accordance with the National Statement.
Identifier	Details attached to data, such as name and/or contact information, that identify an individual.
Intervention	An intentional change in the circumstances of research participants, with the aim of evaluating the impact of that change on one or more outcome measures. An intervention can be a health-related procedure or process or a behavioural, educational or social modification. It can also involve a policy change, a therapeutic strategy, a change in service provision or an approach to provision of information that is introduced and manipulated, controlled or directed by the researcher.
Labwork human research activity	Common and clearly defined human research activities that are being undertaken by multiple members of a lab group (staff or students) in a labwork context.
Low risk research	Research in which the only foreseeable risk is one of discomfort.
Negligible risk research	Research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is of inconvenience only.
Principal Investigator	The Principal Investigator will be an RMIT staff member who has overall responsibility for the conduct of the project.
REP	Research Ethics Platform
Sponsor	An individual, company, institution or organisation that takes responsibility for the initiation, management, and/or financing of research.

Status and Details

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Enquiries Contact	Research Services