# TERMS OF REFERENCE

## VICTORIA UNIVERSITY
## HUMAN RESEARCH ETHICS COMMITTEE

### PREAMBLE

The primary role of a Human Research Ethics Committee (HREC) is to protect the welfare and the rights of participants in research, and the primary responsibility of each member is to decide, independently, whether, in his or her opinion, the conduct of each research proposal submitted to the HREC will so protect the participants. The guiding principles in making this decision are those of integrity, respect for persons, beneficence and justice. The National Statement on Ethical Conduct in Human Research (2007, updated 2018) issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia, provides guidance on the management of such research and the necessary administrative procedures.

### 1. ROLE OF THE HREC

1.1 To consider the ethical implications of proposed research projects[1] involving human participants that fall within the jurisdiction of Victoria University, and to certify with respect to those projects whether they satisfy ethical standards and codes in terms of safeguards for the wellbeing of the participants of the proposed research.

1.2 To establish and oversee procedures for the appropriate evaluation and certification of all proposals that fall within the jurisdiction of Victoria University for the conduct of research involving human participants.

1.3 To ensure that Victoria University has in place appropriate policies and practices for the administration of research involving human participants, and to oversee these practices.

1.4 To ensure that research projects involving human participants that fall within the jurisdiction of Victoria University are not conducted without the appropriate approval of the Committee.

1.5 To oversee the development and provision of education programs for staff and students of Victoria University on issues relating to the ethical conduct of research involving human participants.

1.6 To regularly report the Committees' decisions to the Research and Research Training Committee.

### 2. MEMBERSHIP OF VICTORIA UNIVERSITY HREC

**2.1** The University HREC will be constituted according to the following:

[1] Projects undertaken as part of undergraduate studies and/or laboratory classes are not considered generally to fall within the definition of activity that would require assessment by the University HRE. Projects undertaken as part of Honours, Graduate Diploma, Masters or Doctoral programs would generally be considered as falling within the definition of activity that would require assessment by the appropriate University committee. Projects undertaken as quality assurance in relation to healthcare, education or other field of endeavour would normally not fall within the ambit of the HREC, unless there was an intention to publish all, or part of, the obtained data.

**a. Core membership**

- a. A Chair, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under this National Statement;
- b. At least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
- c. At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
- d. At least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
- e. At least one lawyer, where possible one who is not engaged to advise the institution; and
- f. At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

**b. Additional membership**

- Up to three members of the Low Risk Human Research Ethics Panel shall be ex officio members of the HREC.
- The Secretary of the Committee who shall normally be a staff member of VU Research Services.

**2.2** The HREC shall have the power to co-opt additional members and/or seek additional advice as required; co-opted members shall have the same rights and responsibilities as members appointed to fill the positions described in Section 2.1 above.

**2.3** The Committee should endeavour to reach decisions by consensus that need not involve unanimity. In the event of lack of consensus, decisions can be made by formal vote of those present, in accordance with the Committee's Procedures (refer section 8.5).

**2.4** No Committee member shall adjudicate on research in which that member has any conflict of interest, including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research.

**2.5** The Deputy Vice-Chancellor Research & Impact may appoint one of the HREC members as Deputy Chair to undertake the role of Chair in the absence of that individual.

## 3 CONDITIONS OF APPOINTMENT TO THE VICTORIA UNIVERSITY HREC

**3.1** Appointments to the Victoria University HREC will be made by the Deputy Vice-Chancellor Research & Impact.

**3.2** All appointments to the HREC shall be normally for a period of three (3) years, and may be renewed for further periods of up to three (3) years. The preferred term of membership for any member shall normally be six (6) consecutive years.

**3.3** Members will be advised in writing of their appointment to the HREC and its conditions.

**3.4** Victoria University will provide legal protection for all HREC members, in respect of liability that may arise in the course of the bona fide conduct of their duties as HREC members.

**3.5** Members will not receive payment for membership of the HREC nor for attendance at meetings of the Committee. Members of the HREC who are not staff members of Victoria University will be eligible to be reimbursed for expenses incurred that are related directly to the business of the Committee. Victoria University recognises that participation in the HREC

involves considerable commitment from internal and external members, in terms of costs involved in foregoing wages and personal time.

a. The University will extend to external members of the Committee the provision of an honorarium to be set and managed through Research Services.

b. The University will recognise staff contributions by providing reasonable time allocation to assist them in their activities on the HREC.

**3.6** HREC members are required to provide the Secretary with current contact details, including, as appropriate, telephone numbers, email and postal addresses. All communications with individual committee members will be made through this contact information.

**3.7** Any individual's membership of the Committee may be withdrawn by the University at any time during the proposed period of appointment, such decision being advised in writing by the Chair. Membership may also be withdrawn in the instances where members:

a. are unable to attend consecutive meetings and do not provide feedback on applications in advance of the meeting date without reasonable justification.

b. are unable to attend three consecutive meetings and do not provide justification to the Committee for their non-attendance.

## 4 Low Risk Review Process

**4.1** The Low Risk Reviewers, for the assessment of proposals of that do not fall under the high risk criteria as set out in the National Statement, will have an appropriate structure to review proposals.

**4.3** The Committee shall recommend the co-option of additional members and/or seek additional advice as required

**4.4** Appointments to the Low Risk Panel will be made by the Victoria University HREC taking into consideration advice from the relevant College Dean or Head of Group.

**4.5** Conditions of appointment to the Low Risk Panel will be the same as those of the Victoria University HREC.

## 5 MEETINGS

**5.1** Meetings of the HREC will normally be held up to 11 times per year.

**5.2** Meetings will be held at dates and times to be determined by the Committee. Normal meeting dates will be set by the end of each calendar year for the ensuing 12 months. These dates will be published on the VU Research homepage.

**5.3** The Chair may call additional meetings of the HREC, should a situation call for such additional meetings, provided that 14 days notice is given to the Committee.

**5.4** All matters relating to protocols and Committee proceedings are confidential. Project files will be kept in Research Services, in Research Master secure database and on the VU Y Drive under the Ethics folder as appropriate.

## 6 PRESENTATION OF RESEARCH PROPOSALS

**6.1** All applications for research to be considered by the HREC should be submitted on the Victoria University Application for Approval of Project Involving Human Participants in Victoria University through the Quest (ResearchMaster) online system.

**6.2** No other application forms or procedures will be considered.

**6.3** No fees are charged for consideration of research proposals from VU staff.

**6.4** The Primary Chief Investigator shall be responsible for the presentation of the research proposal and related administration.

## 7 PREPARATION AND DISTRIBUTION OF MEETING AGENDAS AND MINUTES

**7.1** Research proposals or other material for inclusion in the Agenda may be submitted through Research Services at any time. The Secretary of the HREC, in collaboration with the Chair of the University HREC, will decide which applications will be handled by expedited review and which will require review by the University HREC (refer section 7.6). Material received less than 14 days prior to any scheduled meeting of the University HREC will not be guaranteed of inclusion in the Agenda for the immediate next meeting. Material requiring pre-review must be received 21 days prior to any scheduled meeting of the University HREC.

**7.2** The Secretary will be responsible for preparing a draft Agenda, which is to be approved by the Chair.

**7.3** Agendas will be sent to all members at their nominated address physically or by email not less than 7 clear days before the meeting date.

**7.4** Draft Minutes of meetings will be formally confirmed at the following meeting.

**7.5** Agenda papers and minutes of meetings are to be stamped 'CONFIDENTIAL'

**7.6** Issues that will be taken into consideration for determining whether proposals are reviewed by the HREC directly include the following:

a. use of intrusive techniques

b. causing discomfiture in participants beyond normal levels of inconvenience

c. examination of potentially sensitive or contentious areas

d. use of therapeutic techniques

e. seeking disclosure of information which may be prejudicial to participants

f. involving special groups of participants (refer list in section 9.3)

g. potential conflict of interest for researcher

h. clinical trials

i. other issues that Chair or Secretary consider require consideration by the full HREC.

## 8 METHODS OF DECISION MAKING

**8.1** The HREC may approve, require amendment to or reject a research proposal on ethical grounds. Any proposal that requires modification or has been withheld may be resubmitted for reconsideration. A research proposal that has been rejected on ethical grounds cannot be resubmitted.

**8.2** Committee members who are unable to attend a meeting may be requested to forward comments and feedback to the Committee Secretary prior to meeting for consideration by the Committee.

**8.3** The HREC will endeavour to reach decisions that need not involve unanimity by consensus. Failure to reach an agreement may require an extension of time to reconsider the research proposal and its possible amendment, especially when any member is not satisfied that the welfare and rights of participants are protected

**8.4** If clarification of any proposal is required, the HREC may invite the investigator(s) to appear before it in person to answer specific questions.

**8.5** The HREC will communicate reasons for requesting amendment for or rejection of research proposals in writing. Proposals that require amendment may be given provisional approval, pending amendment. Such amendments are to be approved by the Chair, or other Committee member determined by the Committee, and shall be ratified by the next full meeting of the Committee.

**8.6** Should it be necessary to make a decision by formal vote at a meeting, a motion will be carried by simple majority of members present at the meeting. The Chair of the meeting shall have a deliberative vote and in the event of there being an equality of votes on any question, the Chair of the meeting shall also have a casting vote.

**8.7** Expedited review of proposals by any procedure other than that specifically noted in these terms of reference is not allowed.

## 9 REVIEW OF RESEARCH PROTOCOLS

**9.1** It is acknowledged that each research proposal will be unique, and will entail potentially unique ethical issues for consideration. Thus it may be neither possible nor appropriate to apply a ‘checklist’ approach to the consideration of specific proposals.

**9.2** Issues that the Committee should include in its deliberations, but are not limited to:

- The research credentials of the investigators;
- The merit[2] and integrity of the research;
- Respect for persons involved in the research, including the dignity, welfare, rights, beliefs, perceptions, customs and cultural heritage of participants;
- The likelihood and level of harm or discomfort to participants;
- The burden of participation on individual participants or identified groups;

[2] Where prior peer review has judged that a project has research merit, the question of research merit is no longer subject to ethical judgement.

- Any source of financial, or in kind support, to researchers and/or participants, in particular where conflicts of interest may arise or be evident;
- Confidentiality of participants and of all material relating to participants;
- Security of data during and following completion of the project;
- Documents and material used to inform participants and obtain informed consent;
- Any necessity for advocates and or interpreters;
- Appropriate supervision of student researchers in the conduct and reporting of the research.

**9.3** In consideration of research proposals relating to, or including, individuals from the following groups;

a. children and young people;

b. persons with a cognitive impairment, an intellectual disability or mental illness;

c. persons highly dependent on medical care;

d. persons in dependent or unequal relationships;

e. collectives;

f. Aboriginal and Torres Strait Islander Peoples;

g. persons who may be involved in illegal activities;

h. persons in other countries;

i. women who are pregnant and the human foetus.

the HREC will pay consideration to the general principles laid out in the National Statement on Ethical Conduct in Human Research (2007, updated 2018).

**9.4** Proposals that involve;

a. multi centre research;

b. clinical trials;

c. innovative therapy or intervention;

d. epidemiological research;

e. human genetic research;

f. the use of human tissue samples;

g. ionising radiation;

h. assisted reproductive technology; or

i. research that involves deception of participants, concealment or covert observation;

are all to be reviewed in light of the specific guidelines and requirements set out in the National Statement on Ethical Conduct in Human Research (2007, updated 2018).

**9.5** If the proposed research requires unsupervised access to individuals from a group such that a police check or Working with Children check of the researchers is required, evidence of that check must be declared in the research proposal.

**9.6** For any proposals involving individuals or research of the kind described in 9.3 or 9.4 above, the Secretary will include a reference in the Agenda papers to the relevant section of the National Statement on Ethical Conduct in Human Research (2007, updated 2018) to assist members in their deliberations.

## 10 APPLICATIONS BY INDIVIDUALS WHO ARE NOT STAFF MEMBERS OF VICTORIA UNIVERSITY

**10.1** External research requiring review and approval from the Victoria University HREC

Victoria University will consider applications for research involving human participants from individuals who are not staff members of VU and who require access to the cohort of VU staff or students to undertake their research. Such research proposals would normally be 'sponsored' by a member of staff, who would be required to take responsibility for all interactions with the University and the HREC in relation to ethics issues and their management.

Unless specific alternative arrangements have been made by the Victoria University HREC, external research associates will be required to have their research reviewed through the VU ethics approval process if: (1) their research uses VU as the administering institution for the purpose of grant administration, as per NHMRC requirements; or (2) their research is a collaboration with a VU staff member who holds a position of Chief Investigator on the project.

Victoria University HREC may consider research proposals on behalf of organisations not having their own properly-constituted HREC's, on conditions to be set from time to time by the University HREC. Such applications would not require a VU 'sponsor', as the HREC would only be acting in an advisory role. All proposals from non-VU staff will be submitted on the Victoria University form Application for Approval of Project Involving Human Participants in Victoria University, or, if part of a multi-centre trial, on the 'common' Australian Department of Human Services form.

An administration fee may be charged for the management of proposals by non-VU staff, at a level to be fixed from time to time by the HREC.

**10.2** Research that has been reviewed and approved by an external HREC

Research by external individuals will not be required to undergo review through the VU ethics approval process if: (1) the research has received approval from a properly-constituted HREC that is external to the University; and (2) the research is sponsored by a VU member of staff. In this case, both the approved ethics application, associated documentation and letter of approval from the administering HREC are required to be submitted to the Victoria University HREC. Copies of this documentation will be kept on file.

## 11 RECORDING OF DECISIONS

**11.1** Research Services, on behalf of the HREC, will maintain a record of all research protocols received and reviewed that will include:

a. project identification number;

b. name of Chief Investigator;

c. title of project;

d. ethical approval or non-approval with date;

e. approval or non-approval of any changes to the protocol;

f. the terms and conditions, if any, of approval of any protocol;

g. whether approval was by expedited review, and if so by which Committee

h. whether the opinion of another HREC was considered;

i. action taken to monitor the research;

j. the relevance, if any, of the *Guidelines for the Protection of Privacy in the Conduct of Medical Research.*

**11.2** For multi-centre proposals, the following information shall also be recorded:

a. details of other centre(s) involved;

b. approval status of the study at each centre;

c. details of amendments required by any other centre.

**11.3** The University shall retain on file a copy of each research protocol and application for approval, including information sheets, consent forms or correspondence in the form in which they are approved.

## 12 NOTIFICATION OF DECISIONS

**12.1** All decisions will be communicated to the Primary Chief Investigator in writing at the earliest opportunity. Normally, such decisions shall be advised to the Primary Chief Investigator, within 14 days of the date of meeting at which the decision was taken.

**12.2** Letters of notification of accepted proposals will include instructions in relation to length of approval, compliance, reporting, monitoring of adverse outcomes and complaints procedures.

**12.3** No research may commence until the applicant has received formal notification of approval from the relevant Ethics Committee or Panel, as appropriate, depending upon which committee has reviewed the proposal.

## 13 MONITORING

**13.1** Primary Chief Investigators will provide the HREC via Research Services with a written report annually, and upon completion of the research project. The Annual/Final report will incorporate the following information;

a. Progress to date;

b. Security of records;

c. Compliance with protocols;

d. Compliance with any specific conditions of approval;

e. Additional information appropriate to the specific protocol.

Reports should be submitted using the Annual/Final Report form that is available on the VU Research Ethics website.

**13.2** Failure to provide a report may place at risk the continuation of the project. Research Service will:

a. Send the Primary Chief Investigator a written request to submit an Annual/Final Report on an annual basis.

b. If an Annual/Final Report is not received by Research Service within one (1) month of the initial request, a follow-up reminder will be sent to 1) the Primary Chief Investigator.

c. If an Annual/Final Report is not received within two (2) months of the initial reminder, the following actions will be taken:

- Research Services will notify the Chair of the approving HREC and College Dean or head of Flagship Group of the non-response.

- The Chair will advise the Primary Chief Investigator of the breach of ethical conduct and suspend approval for the project which will require all work to cease until such time as the required Annual Report is provided.

- The Chair will advise the HREC. The HREC may resolve to take additional action.

**13.3** The HREC may require additional reports, either in writing or verbally as requested, if it deems that the research should be monitored more often. The HREC may adopt any additional procedures for monitoring research that it considers is appropriate.

**13.4** Researchers will immediately report to the Secretary of the HREC any other changes or events that may warrant review of the ethical approval including:

a. proposed changes to the protocol;

b. unforeseen events.

**13.5** At the completion of the project, the applicant will provide a final report to the HREC. The report should include a description of how the project has progressed against the stated aims, the outcome(s) of the study and include a description of how the results will be used.

**13.6** If for any reason, a project is discontinued, the researcher will advise the Secretary of the HREC immediately in writing. Upon receipt of such advice, the Secretary shall advise the Chair, who will determine the relevant course of action for notifying Committee members and for follow-up.

## 14 REPORTING OF ADVERSE EVENTS

**14.1** The University HREC will oversee procedures for responding to adverse events, including procedures for intervention to protect patient's or participant's rights and the University's legal liability.

**14.2** Procedures for reporting adverse events will be incorporated into notification of approval to the Primary Chief Investigator.

**14.3** Any adverse events relating to research arising from research proposals must be reported immediately to the Secretary of the HREC, who will immediately advise the Chair of the University HREC. Such adverse events and any action taken by the Chair, and outcomes, shall be reported to the next meeting of the University HREC.

## 15 COMPLAINTS PROCEDURES

**15.1** Complaints from researchers

a. Any complaints from researchers in relation to decisions made by the HREC or in relation to the working procedures of the HREC should be discussed initially with the Secretary of the University HREC, who will advise the Chair. The Secretary or Chair may request that the complaint be made in writing, and will take such formal complaints to the next full meeting of the HREC. If the Chair considers it necessary, a special meeting of the Committee may be convened, at the earliest opportunity.

b. The University HREC shall review the complaint and make a decision about its management. As appropriate, the complainant may be required to attend the meeting. Any decisions taken by the Committee in relation to the complaint will be communicated to the complainant in writing, as soon as practicable, but normally within 14 working days.

c. Any complaint concerning decisions or procedures of the Low Risk Panel should in the first instance follow the procedures outlined in 15.1.a above, i.e. to the Secretary of the University HREC.

**15.2** Complaints from research participants

a. Procedures for the receipt of complaints, including details of contact must be provided to all participants at the time of recruitment into the study.

b. Any complaints from participants should normally be made to the Secretary of the University HREC who will advise the Chair of the University HREC at the earliest opportunity.

c. The Chair will consider any complaint at the earliest opportunity and will take appropriate action immediately. This action may include direct discussion with the complainant and/or direct contact with the researcher and may require the suspension of the research until the complaint is resolved. At all times, subject confidentiality will be a major consideration.

d. Complaints will be discussed at the next full meeting of the Committee, as appropriate. Should it be deemed necessary by the Chair, a special meeting of the Committee may be called under item 15.1 above.

**15.3** Complaints from other parties

a. Any complaint from other interested parties would be managed normally according to section 15.2 above 'Complaints from research participants'.

**15.4** Resolution of complaints

a. Any complaint that cannot be resolved under section 14.1 – 14.3 will be reviewed by a full meeting of the Committee, and shall be advised to the complainant at the earliest opportunity, but wherever possible within 14 days of the Committee's decision.

## 16 SUSPENSION OR DISCONTINUATION OF RESEARCH

**16.1** If the HREC is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not and will not be protected, the Committee may withdraw approval, inform the Primary Chief Investigator of such withdrawal, and advise that the project has been discontinued, suspended or advise of other steps to be undertaken.

**16.2** A researcher must not continue the research if ethical approval has been withdrawn and must comply with any special conditions required by the HREC.

**16.3** In the circumstance where a project has been approved by Low Risk Ethics process, but the full University HREC does not ratify that approval at its next scheduled meeting for any reason, the Primary Chief Investigator must be advised immediately to discontinue the research until the specific issues have been resolved.

## 17 COMPLIANCE

**17.1** Researchers are required to comply with conditions advised by the HREC.

**17.2** In turn, the HREC, or the University, will provide information from its records as required to the NHMRC or other mandated authority, provided at all times that the rights and welfare of researchers and participants is respected.

**17.3** The HREC will report annually to the NHMRC, or other mandated party, information relevant to its procedures that is requested by the NHMRC or that party.

## DEFINITIONS

**Primary Chief Investigator:**

The Primary Chief Investigator is an authorised and appropriately trained researcher[3] who takes intellectual, ethical and administrative responsibility for a research project from its conception to completion and the communication of outcomes.

The Primary Chief Investigator is the first named applicant on an ethics application.

The Primary Chief Investigator is responsible for obtaining ethical approval for the research project and any other clearances where relevant.

The Primary Chief Investigator shall ensure that all members of the research team comply with the National Statement on Ethical Conduct in Human Research.

Where the research team includes one or more students, the Primary Chief Investigator must ensure that any student involvement in the design, conduct and reporting of the research is appropriately supervised. A student may not be the Chief Investigator of a research project.

[3] In accordance with the Australian Code for Responsible Conduct of Research