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 Research Involving Humans (1999) issued by the National Health and Medical Research Council and endorsed by the Australian Vice-Chancellors’ Committee, the Australian Research Council, the Australian Academies of the Humanities, of Science and of Social Sciences 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 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 subjects.

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

1.4 To ensure that research projects involving human subjects 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 subjects.

1.6 To regularly report the Committees’ decisions to the Research Committee.

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 HREC or Faculty Committees. 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 or Faculty 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.
2. **MEMBERSHIP OF VICTORIA UNIVERSITY HREC**

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

**a. Core membership**
- Chairperson;
- Two members who are lay people, one man and one woman, who have no affiliation with Victoria University, and who are not involved currently in medical, scientific, or legal work;
- One member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;
- One member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- One member who is a minister of religion, or a person who performs a similar role in a community, such as an Aboriginal elder;
- One member who is a lawyer;

**b. Additional membership**
- The Chairperson (or Deputy Chairperson) of each Faculty Committee shall be ex officio members of the HREC.
- The Secretary of the Committee who shall normally be a staff member of the University Office for Research.

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 and Region) 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 Research Committee, acting on the advice of the Deputy Vice-Chancellor (Research and Region).

3.2 All appointments to the HREC shall be normally for a period of three (3) years, and may be renewed for a further period 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.

3.6 HREC members are required to provide the Secretary with current details of contact, including, as appropriate, telephone and fax 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.

4 FACULTY HREC’S

4.1 Faculty Committees, for the assessment of proposals of minimal risk will have an appropriate structure to review proposals and would normally have the following membership:
   a. Chairperson, who would normally be a senior member of Faculty staff;
   b. At least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the Committee and who would normally be a member of the Faculty [This membership takes cognisance of the fact that faculties involve multiple Schools and the research base of any one individual may not embrace the full range of activities that are likely to be handled by any single Faculty Committee];
   c. One member who is a member of the University other than that serviced by the Faculty Committee;
   d. At least one member, external to the University, who is a layperson, or a minister of religion or a lawyer, according to the definition used above.
   e. In addition, the Committee will appoint a Secretary who will normally be a member of the Faculty and who will have responsibility for the management of Committee business.

4.2 The Committee shall recommend the co-option of 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.

4.3 Appointments to Faculty Committees will be made by the Victoria University HREC taking into consideration advice from the relevant Faculty Executive Dean.

4.4 Conditions of appointment to Faculty HREC’s will be the same as those of the Victoria University HREC.

4.5 Faculty HREC’s will review only applications that are considered appropriate for expedited review. All decisions of Faculty HREC’s will be incorporated into the Agenda papers of the next meeting of the University HREC and presented for review and ratification. The University HREC may request
additional information and may approve, suspend or reverse any decision taken by a Faculty Committee.

4.6 The University HREC may seek specific advice from Faculty Committees to inform its decision making with respect to proposals that have not been through the process of review by a Faculty committee.

4.7 Faculty HREC’s will develop and maintain procedures and practices for the management of their own affairs that will be reviewed and approved by the University HREC on a not less than annual basis.

5 MEETINGS

5.1 Meetings of the HREC will be held at least six (6) 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 Office for Research homepage.

5.3 The Chairperson 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 the Office for Research. After use, papers will be disposed of through a confidential recycling bin. HREC members may leave papers for confidential disposal after meetings.

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 Subjects in Victoria University. Copies can be obtained from the Office for Research, or downloaded from the Office for Research homepage.

6.2 An application for research that is part of a multi-centre study may be submitted on the ‘Common Form’ developed by the Victorian Government Department of Human Services. Copies of the form are available from the University Office of Research homepage and from the Department of Human Services homepage.

6.3 No other application forms or procedures will be considered.

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

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 the Office for Research 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 through the Faculty Committees and which will require review by the University HREC (refer section 7.5). The Secretary of the HREC will stamp all incoming material with the date of receipt. 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.

7.2 The Secretary will be responsible for preparing a draft Agenda, which is to be approved by the
Chairperson, not less than 10 days prior to each meeting.

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

7.4 Draft Minutes of meetings will be distributed to members at the soonest opportunity following the
meeting; this day shall normally be within 14 days of the date of the 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
Faculty Committees or by HREC directly include the following:
   a. use of intrusive techniques
   b. causing discomfort 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 subjects (refer list in section 9.3)
   g. potential conflict of interest for researcher
   h. clinical trials
   i. other issues that Chairperson 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 rejected may be resubmitted for
reconsideration.

8.2 Committee members unable to attend meetings are to forward comments and feedback to the
Committee Secretary prior to meetings for consideration by the Committee.

8.3 The HREC will endeavour to reach decisions by consensus that need not involve unanimity. Failure
to agree 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 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 Chairperson, 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 Chairperson of the meeting shall have a deliberative vote and in the event of there being an equality of votes on any question, the Chairperson of the meeting shall have a casting vote also.

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:

- Scientific validity;
- The research credentials of the investigators;
- The 'value' of the research to health and healthcare delivery, or other field of endeavour;
- Respect for persons involved in the research, including the dignity, welfare, rights, beliefs, perceptions, customs and cultural heritage of subjects;
- The likelihood and level of harm or discomfort to participants;
- The burden of participation on individual participants or identified groups;
- Any source of financial, or in kind support, to researchers and/or subjects;
- The source of funds to support the project, including an assurance by the investigators that sufficient resources are available or have been committed to ensure that the study can proceed to its agreed end-point(s);
- Confidentiality of subjects and of all material relating to subjects;
- Security of data during and following completion of the project;
- Documents and material used to inform subjects and obtain informed consent;
- Any necessity for advocates and or interpreters;
- All applications are signed by all investigators.

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

a. children or young people;
b. persons with an intellectual or mental impairment;
c. persons highly dependent on medical care;
d. persons in dependent or unequal relationships;
e. collectivities;
f. Aboriginal and Torres Straight Islander Peoples;

the HREC will pay consideration to the general principles laid out in the NSEC.

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 NSEC.

9.5 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 NSEC to assist members in their deliberations.

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

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

10.1 Victoria University will consider applications for research involving human subjects 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.

10.2 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.

10.3 Any affiliate or associate of Victoria University who uses the University as the administering institution for the purpose of grant administration will come under the jurisdiction of the VU HREC, unless specific alternative arrangements have been made by the HREC.

10.4 Research associates, not employed by VU will be required to submit proposals through the VU process only if their research uses VU as the administering institution; postgraduate students of the University are involved in the research or the research requires access to the VU cohort of students or staff.

10.5 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’ DHS Form.

10.6 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.
11 RECORDING OF DECISIONS

11.1 The Research Office, 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 principal researcher;
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 Faculty 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 Chief Investigator in writing at the earliest opportunity. Normally, such decisions shall be advised to the Chief Investigator by post, 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 Faculty Ethics Committee or the HREC itself, as appropriate, depending upon which committee has reviewed the proposal.

13 MONITORING

13.1 Investigators will provide the HREC through the Office for Research with a written report annually, that 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 made on the form Annual Report for Research Involving Human participants, that is available on the Office for Research homepage.

13.2 Failure to provide a report may place at risk the continuation of the project. The Office for Research will send a reminder to the investigator within one month of the due date, if no report Terms has been received. If no report is received within a further two months, the HREC may advise the applicant that the project will be suspended immediately.

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 Aims and the outcome(s) of the study, including a description of how the results will be used.

13.6 If for any reason, a project is discontinued, the researcher will advise immediately in writing the Secretary of the HREC. Upon receipt of such advice the Secretary shall advise the Chairperson, 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 the patient’s or subject’s rights and the University’s legal liability.

14.2 Procedures for reporting adverse events will be incorporated into notification of approval to the 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 Chairperson. The Secretary or Chairperson 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 Chairperson 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 Faculty committees 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 be made normally to the Secretary of the University HREC who will advise the Chairperson of the University HREC at the earliest opportunity.

c. The Chairperson 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 Chairman, a special meeting of the Committee may be called under item 5.3 above.

15.3 Complaints from other parties

a. Any complaint from other interested parties would be managed normally according to section 14.2 above ‘Complaints from 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 chief investigator of such withdrawal, and advise that the project has been discontinued, suspended or other steps 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 a Faculty Ethics Committee, but the full University HREC does not ratify that approval at its next scheduled meeting for any reason, the Chief Investigator must be advised immediately to discontinue the research until the specific issues have been resolved. The Chair of the Faculty Committee and the Head of the investigator’s School will similarly be advised immediately.

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 by the NSEC 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, in accordance with the NSEC or its equivalent at the time.