University of Victoria

RESEARCH INVOLVING HUMANS

University Policy No.: RH8105
Classification: Research
Approving Authority: Board of Governors
Effective Date: September, 2012
Supersedes: May 2005
Last Editorial Change: March 2021
Mandated Review: September, 2017

Associated Procedures
Procedures for Conducting Human Research

PURPOSE

1.00 The purpose of this policy is to:

a) set out provisions to ensure Research Involving Human Participants at the university conforms with the highest ethical standards;
b) promote awareness and understanding of how the core principles of respect for persons, concern for welfare and justice are applied in accordance with the most current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* and the relevant university policies and procedures; and
c) establish the human research ethics review process.

DEFINITIONS

For the purposes of this policy:

2.00 **Human Participants** are those individuals whose data or responses to interventions, stimuli or questions by the researcher are relevant to answering the research question.

3.00 **Research Involving Human Participants** means an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation involving Human Participants and includes:

a) research involving living human participants; or
b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells, whether derived from living or deceased individuals.

4.00 **Members** and **Associated Members** include but are not limited to university faculty, emeritus faculty, staff, sessional instructors, clinical professors, administrators, students, visiting or adjunct scholars, fellows, and paid or unpaid associates.

5.00 The **Human Research Ethics Board** (HREB) means the body established under this policy and associated procedures to review and approve the ethical acceptability of Research Involving Human Participants.

6.00 The **Human Research Ethics Appeal Tribunal (HREAT)** means the body appointed under this policy and associated procedures to hear appeals of decisions of the HREB.

7.00 **Ethics Approval** means the research ethics approval granted by the HREB in accordance with this Policy.

8.00 **Researcher** means the principal investigator and the leader of the research team who is responsible for the conduct of the research, and for the actions of the team.

9.00 **TCPS** means the most recent edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

SCOPE

10.00 This policy applies to Research Involving Human Participants not explicitly exempted by the TCPS that is:

a) conducted by Members or Associated Members of the university acting in their university capacity as the Researcher; and/or
b) conducted within space that is under the administration of the university.

POLICY

11.00 The University will regulate Research Involving Human Participants in accordance with the TCPS as the minimal standard.

12.00 The responsibility for implementing and upholding the TCPS is entrusted on behalf of the university to the Vice-President Research and Innovation.

13.00 The Vice-President Research and Innovation will establish the HREB to conduct ethics reviews and reconsiderations.

14.00 The Vice-President Research and Innovation will appoint members of the HREAT to hear appeals from HREB decisions.

15.00 The Vice-President Research and Innovation will provide administrative support for the ethics review process, approvals and ongoing regulatory activities.

16.00 The Vice-President Research and Innovation will establish committees and other mechanisms for on-going regulatory activities and for educating the university community about human ethics.

17.00 Ethical review and approval by HREB is required before Research Involving Human Participants commences, unless the research is exempt from HREB review by reason of protections available by other means, as described in the TCPS.

ACCOUNTABILITY

18.00 HREB is mandated to review and maintain ongoing oversight on behalf of the university of all proposed or ongoing Research Involving Human Participants, by applying the core ethical principles to such review and oversight.

19.00 HREB is accountable to the Vice-President Research and Innovation for the ethics review process and ongoing regulatory activities.

20.00 HREB may review and grant ethics approval.

21.00 The Vice-President Research and Innovation is responsible for the determination of the financial and administrative resources that are required for the HREB to fulfill its duties and to ensure that these resources are provided.

22.00 The Vice-President Research and Innovation is responsible for ensuring that processes are in place so that, for Research Involving Human Participants, research accounts are not opened or spending authorized unless an ethics approval has been granted.

23.00 The Researcher is responsible for taking appropriate action to determine whether the research that the Researcher, their research team or the students under their direction are proposing to undertake constitutes Research Involving Human Participants according to this policy.

24.00 The Researcher is responsible for ensuring that:

a) ethics approval has been granted before commencing Research Involving Human Participants;
b) ongoing ethics approval is in place, including the annual renewal process and any required modifications; and
c) any other regulatory or other approvals are in place before Research Involving Human Participants commences.

25.00 Failure to adhere to this policy will result in an investigation and possible disciplinary action in accordance with the Policy on Scholarly Integrity (AC1105).

RECIPROCAL ETHICS REVIEW AGREEMENTS WITH OTHER INSTITUTIONS OR ORGANIZATIONS

26.00 In order to facilitate collaborative research projects involving researchers, data or participants from more than one institution, the university may enter into agreements to accept reviews undertaken by an external HREB.

AUTHORITIES AND OFFICERS

i) Approving Authority: Board of Governors
ii) Designated Executive Officer: Vice-President Research and Innovation
iii) Procedural Authority: Vice-President Research and Innovation
iv) Procedural Officer: Associate Vice-President Research Operations

RELATED POLICIES:

Research Policy (RH8100)
External Research Funding Agreements (RH8200)
Policy on Scholarly Integrity (AC1105)

University of Victoria

PROCEDURES FOR CONDUCTING HUMAN RESEARCH

Procedural Authority: Vice-President Research and Innovation
Procedural Officer: Associate Vice President Research Operations

Effective Date: September, 2012
Supersedes: NEW
Last Editorial Change: March 2021

PURPOSE

1.00 The purpose of these procedures is to set out the appropriate process for ensuring that all Research Involving Human Participants at the university is conducted in accordance with the most current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).

GENERAL

2.00 The university is committed to ensuring that Research Involving Human Participants meets the highest scientific and ethical standards that respect and protect the Human Participants. The primary way Human Participants are respected and protected is through the application of ethical principles. The university has adopted TCPS as the minimal standard. Researchers and supervisors are encouraged to regularly review the guidelines that are available on the Office of Research Services website.

3.00 The Associate Vice President Research Operations (AVPRO) maintains the following organizational bodies for administering its policies on human research and as a resource to researchers:

a) the Human Research Ethics Board (HREB);
b) the Human Research Ethics Advisory Committee (HREAC); and
c) the Human Research Ethics Appeals Tribunal (HREAT).

In the following section, the terms of reference, membership, procedures and policies of these committees are detailed.

HREB MANDATE AND AUTHORITY

4.00 The mandate of HREB is to determine the ethical acceptability of Research Involving Human Participants that is conducted under the auspices of, or by Members and Associated Members of the university.

5.00 The HREB may approve, reject, propose modifications to, or terminate any proposed or ongoing Research Involving Human Participants.

6.00 While the primary purpose of HREB is to ensure that the Human Participants in research, and their communities, are respected and protected, the HREB will fulfill its mandate in a way that is supportive and educative for the university.

RESPONSIBILITIES OF THE HREB

7.00 The HREB shall:

a) provide impartial, fair and reasoned review of the ethical acceptability of proposed and ongoing research in an efficient and timely manner on behalf of the university;
b) ensure that HREB decisions are communicated clearly to the Researchers;
c) provide continuing research ethics review of research that it has approved on an annual basis at a minimum;
d) provide prompt reconsideration of decisions as requested by the Researcher;
e) review and approve applications for in-principle approvals, to support the initial exploratory and consultative phases of research or other phases of research that do not involve contact with human participants, for purposes such as the release of research funding;
f) prepare and maintain comprehensive records, including all documentation related to the projects submitted to the HREB for review, attendance at all HREB meetings, and accurate minutes reflecting HREB decisions.
g) report the outcome of an ethical review to the Researchers (approval, approval with revisions, resubmission) and the HREB records shall include the reasons for the outcome.

MEMBERSHIP AND MEETINGS

8:00 All members of the HREB are appointed by the Vice-President Research and Innovation for a period of up to three years, with the possibility of one renewal for a further term up to three years; terms of individual appointments will be staggered to ensure continuity of the HREB expertise; members will be drawn from different faculties and opportunities will be provided for the various departments and programs to be represented over time.

9.00 The AVPRO has administrative responsibility for:

a) providing administrative support for the HREB;
b) offering education to the university community about human research ethics; and
c) providing administrative support for the HREAT.

10.00 The Chair of the HREB is a faculty member appointed by the Vice-President Research and Innovation, normally for a period of up to two years, with the possibility of one renewal of up to two years.

11.00 The Vice-President Research and Innovation may appoint a Vice-chair, for a period of up to two years, after which it is expected that the Vice-chair will serve as Chair to provide continuity of expertise to the Board.

COMPOSITION OF HREB

12.00 a) The HREB will consist of at least five members, including both men and women, of whom:

i. at least two members have expertise in relevant research disciplines, fields and methodologies covered by the HREB;
ii. at least one member is knowledgeable in research ethics;
iii. at least one member with no affiliation with the university is recruited from the community;
iv. at least one member is knowledgeable in the relevant law, but not the university's legal counsel or risk manager. (This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research); and

These five members represent quorum for the HREB.

b) As much as it is possible, each member shall be appointed to formally fulfill the requirements of only one of the above categories.

c) Other members who may serve on the HREB include:

i. one or two graduate student members, recruited through the Graduate Student's Society, will be appointed for a period of one year, with the possibility of one renewal of one year;
ii. ad hoc members appointed by the Vice-President Research and Innovation, in consultation with the HREB and the Chair for special purpose reviews;
iii. substitute members appointed by the Vice-President Research and Innovation to serve as replacements for regular members when they are unable to attend meetings; and
iv. staff administrators including the Human Research Ethics Coordinator, Human Research Ethics Facilitator and Human Research Ethics Assistant as non-voting members.

13.00 Prior to serving on the HREB, all members will attend an orientation session, organized by the Office of Research Services (ORS), and complete the TCPS tutorial, to ensure that they have an understanding of the principles and practices of human research ethics review.

14.00 Members are expected to fulfill the requirements of board members, as outlined in their letter of appointment.

HREB MEETINGS

15.00 Meetings will be held, at a minimum, bi-monthly (every second month from September through May). Other meetings may be called by the Chair or Vice-Chair as necessary. Meetings are held *in camera* during the full board review of ethics protocols.

PROCEDURES FOR HREB REVIEW OF NEW AND ONGOING RESEARCH

16.00 The Researcher shall submit their proposals for Research Involving Human Participants, including proposals for pilot studies, for review by the HREB prior to the start of recruitment of participants, access to data or collection of human biological materials. HREB review is not required for the initial exploratory phase, which may involve the establishment of research partnerships with individuals or communities.

17.00 The HREB will use a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research:

a) the lower the level of foreseeable risk to participants or their communities, the lower the level of scrutiny (delegated review); and
b) the higher the level of risk, the higher the level of scrutiny (full board review).

A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research.

There are three levels of review based on the level of risk: full board above minimal, board review and expedited review.

18.00 Full board above minimal reviews are used for research that poses above minimal risk. These reviews are normally conducted in a face to face meeting of the full HREB. Alternatively if the regular HREB meeting is not available, an *ad hoc* (face-to-face or conference call) quorum HREB meeting may be called at the decision of the Chair.

19.00 Board review is a delegated review used for research that is deemed to be of minimal risk to participants with one or more issues requiring additional expertise. Board review consists of review by two HREB members and the Chair or Vice-Chair, with input from the Coordinator or Facilitator.

20.00 Expedited review is a delegated review used for research that meets the criteria for very low foreseeable risk, considerable benefit and very few identified ethical implications. The review is conducted by the HREB Chair or Vice-Chair with input from the Human Research Ethics Coordinator and/or Facilitator.

21.00 The AVPRO, upon recommendation of the HREB chair, may establish committees for administrative and educational purposes.

22.00 Where committees have been established under section 21.00, a Chair will be appointed for each committee by the AVPRO. Normally, the Chair of the committee will also be a member of the HREB.

HREB ADMINISTRATIVE SUPPORT

23.00 The AVPRO will develop a reporting and administrative structure that ensures full compliance with the TCPS including requirements that the HREB will:

a) screen and review applications in the order that complete applications are received;
b) forward decisions to researchers as soon as possible after receiving input from all required reviewers;
c) submit an annual report of its activities to the AVPRO; and
d) review the ethical implications of the methods and design of the research including, where appropriate, relevant disciplinary scholarly standards.

HREB RECORDS

24.00 Minutes of all HREB meetings shall be prepared and maintained and include all attendance, decisions, and dissents, and the reasons for them.

25.00 The Office of Research Services (ORS) will maintain a file of all HREB approved applications for a period of seven years following the completion of an approved study. In the case of research governed by Health Canada (i.e. certain clinically or medically based research) ORS will maintain these HREB approved applications and records for a period of twenty-five years.

HUMAN RESEARCH ETHICS CONTINUING REVIEW PROCESS

26.00 Approvals are issued for one year.

27.00 All projects are required to file an annual report or a final report at the end of the project.

28.00 The HREB may require more frequent reports, based on the risk or the project or the requirements of the funders.

29.00 In all cases, the Researcher will immediately notify the HREB of any modifications by filing a request for modification; the termination of a project by filing a completion report; or of any safety/ethical problems by filing an un-anticipated event report

30.00 All approved projects may be subject to audit.

INFORMED CONSENT

31.00 All prospective participants, or their authorized third party, have the right to be given the opportunity to voluntarily give free and informed consent both prior to, and during, their participation in the study as described in the TCPS.

RESEARCH EXEMPT FROM HREB REVIEW AND ACTIVITIES NOT REQUIRING HREB REVIEW

32.00 The TCPS policy allows exemptions from HREB review for research where protections are available by other means.

33.00 The TCPS policy defines activities outside the scope of research subject to HREB review as non-research activities, including quality assurance and quality improvement studies. Creative practice activities, in and of themselves, do not require HREB review.

34.00 Members or associated members of the university shall review the TCPS and the relevant university guidelines to determine whether their research is exempt or the activity is considered non-research.

HUMAN RESEARCH ETHICS APPROVAL FOR COURSE-BASED RESEARCH ASSIGNMENTS

35.00 Course projects and assignments involving Research Involving Human Participants must receive ethics approval from the HREB.

36.00 The HREB will establish administrative guidelines for the application and approval process for course based research assignments.

37.00 The course instructor has delegated responsibility for oversight of the Research Involving Human Participants. The course instructor is responsible for ensuring that the approval is in place before the research commences and that a report is filed on completion of the course.

HUMAN RESEARCH ETHICS ADVISORY COMMITTEE

38.00 The mandate of the Human Research Ethics Advisory Committee (HREAC) is to provide advice to the AVPRO on administrative and procedural matters related to human research ethics including, but not limited to:

a) the review and determination of resources and infrastructure required for HREB to conduct its business;
b) recruitment and training of HREB members; and
c) educational support for members and associated members of the University in in human ethics and application preparation (e.g. workshops, forums, educational materials, seminars, and administration of ethics process.

39.00 The Chair of HREAC is the AVPRO.

40.00 The Chair of HREB and the Chairs of any committee established under section 21.00 of these procedures are members of HREAC.

41.00 HRE staff and other members may be appointed to the HREAC on an *ad-hoc* basis at the discretion of the AVPRO.

42.00 HREAC will meet at least once per month or at the call of the Chair.

RECONSIDERATION OF HREB DECISIONS

43.00 Researchers have the right to request, and the HREB has the obligation to provide, reconsideration of decisions.

44.00 The HREB will reconsider its decision upon receipt of a written request from the Researcher, outlining the grounds on which the reconsideration is requested and to indicate any alleged breaches to the established process or any elements of the HREB decision not supported by the TCPS.

45.00 The HREB has an obligation to provide prompt reconsideration of the recommendations or decisions and to respond.

46.00 If the Researcher is not satisfied with the outcome of the reconsideration, the Researcher may file a written request for an appeal with the Vice-President Research and Innovation.

47.00 If the Vice-President Research and Innovation grants the request for an appeal, the Vice-President Research and Innovation will appoint the members (minimum of three) of the Human Research Ethics Appeal Tribunal to hear such appeal.

HUMAN RESEARCH ETHICS APPEAL TRIBUNAL

48.00 The mandate of the Human Research Ethics Tribunal (HREAT) is to provide a fair appeal mechanism for HREB decisions.

49.00 Members of the HREAT must have experience, expertise and knowledge comparable to what is expected of HREB.

50.00 Members of HREAT must be acceptable to both the Researcher and the Vice-President Research and Innovation and will include a minimum of 3 members with

a) one faculty member with past experience serving on HREB (not a current HREB member);
b) one community representative drawn from the Vancouver Island Health Authority HREB; and
c) one additional faculty member with or without previous HREB experience.

51.00 HREAT is empowered to:

a) seek a review of the research under appeal by another duly appointed ethics review board (e.g. from another institution);
b) hold face to face meetings with both the Researcher and the members of the HREB; and
c) seek other expert advice as required to rule on both substantive and procedural issues related to the ethics application under appeal.

52.00 Decisions of the HREAT are in writing, final and may include:

a) upholding the original decision of the HREB;
b) issuing additional requirements to those given by the HREB prior to approval;
c) removing any or all of the HREB requirements; or

d) approving or rejecting the ethics application.