



RESEARCH ETHICS BOARDS TERMS OF REFERENCE

1. GENERAL

The Vancouver Island Health Authority (VIHA) is committed to providing an effective foundation for clinical teaching and research to ensure that the quality of care provided for patients is evidence-based.

The VIHA maintains two Research Ethics Boards (REBs) to provide oversight of all human research conducted in VIHA: the Clinical Research Ethics Board (CREB) and the Health Research Ethics Board (HREB).

2. RESEARCH ETHICS REQUIREMENTS

All human research that is conducted by VIHA staff or that involves VIHA facilities, patients, residents, clients, staff or resources requires VIHA ethical approval prior to commencement. Research involving human participants, remains, cadavers, tissues, biological fluids, embryos, fetuses and other biological materials including human DNA, RNA or DNA and RNA fragments is subject to VIHA ethical review and approval.

At a minimum, all human research conducted in Canada must comply with the principles set out in the:

[Tri-council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS\)](#) (1998, and updates [May 2000](#), [September 2002](#), and [October 2005](#)).

Clinical trial research must comply with the following international ethical and scientific quality standards:

[International Conference on Harmonisation; Good Clinical Practice \(ICH GCP\): Consolidated Guideline \(CPMP/ICH/135/95 July 2002\)](#).

Both the TCPS and the ICH GCP are founded on the ethical principles developed in the [Declaration of Helsinki](#) (1964).

Canadian Research Ethics Boards that conduct ethical reviews of clinical trials using drugs, radiopharmaceuticals, natural health products and medical devices are also regulated by the following Health Canada legislation and must fulfill specific obligations under these Acts:

[Food and Drug Act regulations for clinical trials for drugs and radiopharmaceuticals](#)

[Food and Drug Act regulations for medical devices](#)

[Natural Health Products Act](#)

Research that is funded by sources in the United States is regulated by the following:

[Code of Federal Regulations, Title 21, Volume 5, Revised April 1, 2006](#)

[Code of Federal Regulations, Title 45, Part 46, Volume 5, Revised November 17, 2005](#)

3. TERMS OF REFERENCE

3.1 MANDATE

The mandate of the two REBs is to ensure that:

- Research involving human subjects meets scientific and ethical standards;
- Research is conducted as outlined in the approved protocol and that the rights, safety and well-being of human subjects are protected; and
- Any proposed modifications to approved human research studies meets the above standards.
- All operational issues are addressed before the research is begun;

The REBs are responsible for reviewing, approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research, using the principles set out in the relevant regulations and guidelines.

3.2 MEMBERSHIP

Each of the Research Ethics Boards has at least five members, including both men and women, a majority of whom are Canadian citizens or permanent residents under the *Immigration Act*. The composition of each REB is made up of at least:

- i. Two members whose primary experience and expertise is in a scientific discipline, one of whom is from a medical discipline, and both of whom have broad experience in the methods and areas of research to be approved;
- ii. One member who is knowledgeable in ethics,
- iii. One member who is knowledgeable in Canadian laws relevant to the biomedical research to be approved,
- iv. One member who is from the community served by VIHA and who is not affiliated with the sponsor or the institution where the research is to be conducted.

The majority of REB members have both the training and expertise to make sound judgements on the science and ethics of research proposals involving human subjects. Lists of REB members' qualifications are maintained in a separate document available on the Research Ethics website.

Each REB has a Chair appointed by the Director of Research and Academic Development for a term of two years with the possibility of reappointment for one or more additional term of two years. The Chair presides over the regular meetings, provides oversight of the minutes of these meetings and signs the written communication to researchers conveying REB decisions made at the meetings. The Chair may be called upon to provide advice on administrative matters pertaining to research ethics.

The Director of Research and Academic Development, in consultation with the REB Chairs, appoints members to the REBs. The term of appointment is three years, with the possibility of one or more additional term of three years. REB members are selected to ensure broad representation of medical expertise, programs and services in VIHA. Membership changeover occurs in a way that ensures a core group of experienced members is always present.

In the event that an REB receives a research ethics application for a research proposal that requires particular expertise not available from its regular members, the REB Chair nominates appropriate ad hoc members for the duration of the review. If this occurs regularly in a specific field, the membership of the REB is reviewed and modifications are considered.

A Joint UVic/VIHA Ethics Sub-committee oversees the research of UVic faculty, staff and students who wish to conduct research in VIHA. Only research that fits the TCPS definition of 'minimal risk'¹ is reviewed through the Joint Sub-committee. The Joint Sub-Committee is Co-chaired by one member of the VIHA Health Research Ethics Board and one member of the UVic Human Research Ethics Board.

3.3 ACCOUNTABILITY

The REBs are accountable to the VIHA CEO. The REBs make recommendations regarding approval of research protocols to the Director of Research and Academic Development. The Joint Sub-Committee is accountable to the two parent REBs, the VIHA Health Research Ethics Board and the UVic Research Ethics Board.

The Director of Research and Academic Development has administrative responsibility for:

¹ *"The standard of minimal risk is commonly defined as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk."* (p. 1.5)

- Conducting ethical reviews of research;
- Providing administrative support for the REBs;
- Offering training about research ethics for REB members, ethics staff and the VIHA research community; and
- Providing an ethical review appeal mechanism.

3.4 LIABILITY

Any employee of VIHA is automatically covered by VIHA's liability insurance. For non-employee's, VIHA's liability coverage is also extended to include:

- "members of medical and other advisory boards and committees, and medical staff and professional staff committees while acting in their capacity as committee members."
- "physicians, interns, residents, dentists, or midwives, but only in the performance of their administrative duties on behalf of (VIHA)."

3.5 MEETINGS AND ATTENDANCE

The REBs meet regularly, either monthly or bi-monthly and at the call of the Chair. (See the Schedule of REB Meetings on the Research Ethics website.)

A quorum is at least 50 percent of the voting members of the REB and meets the requirements set out in item 3.2 of this document.

REB members are expected to attend meetings regularly. Frequent unexplained absences will be construed as a notice of resignation.

Minutes of all REB meetings are prepared and maintained for a minimum of 25 years and include all decisions, dissents, and the reasons for them.

4. RESEARCH ETHICS APPLICATION REVIEW PROCESS

All researchers must submit a complete ethics application package for each research study following the VIHA REB Ethics Application Guidelines. Incomplete applications are returned to the applicant for resubmission.

Applications are prescreened by the Research Ethics Coordinator to ensure that they are complete and to determine the most appropriate route and method for review. Applications for clinical trial research and other research that require review by medical specialists will be routed to the CREB. Applications for social science, behavioural and other types of non-medically invasive, non-clinical trial research will be reviewed by the HREB.

A proportionate approach to ethical review is used based on the general principle that the more invasive the research, the greater the care in assessing the research. Each application is sent for review to at least two members of either the CREB or the HREB.

4.1 Clinical Research Ethics Board (CREB)

In the case of the CREB, the full application package (including the protocol, informed consent form, investigators brochure, monographs, amendments, hand-outs, etc.) is sent to one primary and one secondary reviewer. Informed consent forms are sent to two additional REB members for detailed review. Protocol synopses are sent to all members of the CREB prior to the meeting.

The CREB primary reviewer:

- Reviews the application package in detail to ensure that it meets scientific and ethical standards and that all operational issues are addressed;
- Discusses the application with the secondary reviewer if required;
- If needed, requests the ethics coordinator to contact the researcher to obtain additional information/clarification of any issues;
- Determines if the investigator should be invited to attend the meeting to discuss the application;
- Presents an overview of the research protocol and a summary of their review findings to the REB at the monthly meeting and respond to questions from other REB members; and
- Provides a written summary of their recommendations regarding approval or lack of approval and indicate all required revisions and recommended revisions to staff for inclusion in the meeting minutes and in the letter to the researcher.

The CREB secondary reviewer:

- Reviews the application package in detail to ensure that it meets scientific and ethical standards and that all operational issues are addressed;
- Discusses the application with the primary reviewer if required;
- Shares the results of their review of the application at the monthly meeting; and
- Provides a written summary of their recommendations regarding approval or lack of approval and indicate all required revisions and recommended revisions to staff for inclusion in the meeting minutes and in the REB response to the researcher.

The CREB members who review the informed consent form only:

- Reviews the informed consent form in detail to ensure that it is understandable and complete in providing all of the required information listed on the consent form checklist.
- Shares their review comments on the informed consent form at the monthly REB meeting.

- Provides a written summary of their questions and concerns regarding the informed consent form to staff for inclusion in the meeting minutes and in the REB response to the researcher.

4.2 Health Research Ethics Board (HREB)

For the Health REB (HREB), all application packages are sent to two reviewers.

In the case of above-minimal risk research, the HREB reviewers:

- Review the application package in detail to ensure that it meets scientific and ethical standards and that all operational issues are addressed;
- Discuss the application with the other reviewer if required;
- If needed, request the ethics coordinator to contact the researcher to obtain additional information/clarification of any issues;
- Determine if the investigator should be invited to attend the meeting to discuss the protocol;
- Present an overview of the research study and a summary of their review findings to the REB at the regular meeting and respond to questions from other REB members; and
- Provide a written summary of their recommendations regarding approval or lack of approval and indicate all required revisions and recommended revisions to staff for inclusion in the meeting minutes and in the REB response to the researcher.

In the case of minimal risk research, the HREB reviewers:

- Review the application package in detail to ensure that it meets scientific and ethical standards and that all operational issues are addressed;
- Discuss the application with the other reviewer if required;
- If needed, request the ethics coordinator to contact the researcher to obtain additional information/clarification of any issues;
- Provide a written summary of their recommendations regarding approval or lack of approval and indicate all required revisions and recommended revisions to staff for inclusion in the REB response to the researcher.

4.3 Joint UVic/VIHA Research Ethics Sub-committee

In the case of Joint UVic/VIHA minimal risk research ethics applications, one VIHA member and one UVic member of the Joint Sub-Committee:

- Review the application package in detail to ensure that it meets scientific and ethical standards and that all operational issues are addressed;
- Discuss the application with the other reviewer if required;
- If needed, request the ethics coordinator to contact the researcher to obtain additional information/clarification of any issues;
- Provide a written summary of their recommendations regarding approval or lack of approval and indicate all required revisions and recommended revisions to staff for inclusion in the REB response to the researcher.

5. RESEARCH ETHICS APPEAL BOARD

The VIHA has a reciprocal agreement with the Fraser Health Authority to provide research ethics applicants at each of the health authorities with an appeal mechanism for decisions of its respective REB, in compliance with the TCPS requirements. (See The Appeal Board Process on the Research Ethics website.)

6. RESEARCH ETHICS STAFF

Two VIHA staff, a Research Ethics Assistant and a Research Ethics Coordinator, are dedicated to providing clerical and administrative support to the two REBs and the Joint Sub-Committee.

The Research Ethics Assistant maintains a system for receiving, tracking and processing research ethics applications and all correspondence sent to and received from researchers and REB members. The REBs have delegated the following responsibilities to the Research Ethics Assistant:

- Organize and maintain REB meeting schedules;
- Prepare and distribute REB meeting agenda packages;
- Maintain logs and databases of all research ethics applications;
- Maintain records of REB members and REB meeting minutes, including deliberations and decisions (for 25 years);
- Provide written acknowledgement of receipt of correspondence from researchers, including Study Closure Reports and Investigator Brochures;
- Sign Research Ethics Board Attestation forms for approved protocols and approved protocol amendments;
- Issue Certificates of Approval for approved protocols.

The Research Ethics Coordinator facilitates the REBs in their oversight role. The REBs have delegated the following responsibilities to the Research Ethics Coordinator:

- Pre-screen all ethics applications for completeness and contact researchers to request any missing required documents prior to REB review;
- Determine which REB members are most appropriate to review applications and assign applications to these members;
- Act as a reviewer when required.
- Review researchers' responses to REB written communication and determine if all issues and concerns have been satisfactorily met, and approve completed applications;
- Follow up with researchers for clarification and obtain additional information
- Approve Annual Request for Renewal;
- Approve miscellaneous information items (e.g., handouts, wallet cards)

- Sign Research Ethics Board Attestation forms for approved protocols and approved protocol amendments;
- Monitor and compile Serious Adverse Event reports and present summaries to the CREB at the monthly meeting, for their approval;
- Review requests for amendments to approved protocols and present these to the REB at the monthly meeting, for their approval.

For more information, please visit the Research Ethics Website:

http://www.viha.ca/rnd/research_ethics.htm