
TERMS OF REFERENCE

FHREB RESEARCH ETHICS BOARD CHAIR

The Chair(s) of the FHREB is responsible for carrying out the following activities and functions, and operates under the authority of the FH Policy "The Ethical Conduct of Research and Other Studies Involving Human Subjects". The terms of reference for the FHREB co-Chairs, in addition, to those of the FHREB Members, are listed below.

1. Chair the full board meetings of the FHREB and ensure that the board meets Tri-Council Policy and Health Canada requirements for quorum at each meeting.
2. Review and edit as required the comments submitted by board members following a meeting and prior to distribution to the investigators as requests for modification or deferral memoranda.
3. Review all applications for initial review, amendments and renewals of previously approved research, that qualify for expedited review under the minimal risk criteria and:
 - a) approve if all FHREB requirements have been met satisfactorily, or;
 - b) request that the investigator modify the study and/or respond to questions concerning the study prior to approval, or;
 - c) refer to the FHREB for review and approval.
4. Review investigators' responses to requests for modifications that arise either from a full board meeting or from an initial expedited review of minimal risk studies, amendments and renewals and approve if all FHREB requirements have been met satisfactorily.
5. Develop guidance notes, policies and procedures for ethical review in collaboration with the board members and the Research Administration and Development Director.
6. Inform investigators of subject safety related issues that may arise during the course of a study and that require a response from the investigator. These may include, among others, following up serious adverse event reports, protocol violations and data safety monitoring board reports upon reviewing studies using interventions for which regulatory authorities (e.g. Health Canada, FDA) have issued safety alerts.
7. Review and respond to investigator's reports of serious adverse events and protocol deviations.
8. Acknowledge close-out notices from investigators.
9. Participate in Health Canada inspections or NCEHR site visits as required.
10. Participate in investigations related to breach of compliance with Tri-Council policy FH policy on "The Ethical Conduct of Research and other Studies Involving Human Subjects' and the "FH Research Policy".
11. Prepare the FHREB annual report in collaboration with the Director, Research Administration and Development.

12. Respond to investigator's inquiries as appropriate.
13. **Honoraria:** REB co-chairs are paid \$750.00 per meeting. This also includes the expedited review of minimal risk applications which is conducted on a weekly basis.
 - i. **Honoraria Paid to Non-FH Employees:** Cheques for the honoraria are sent directly to the REB members, who are physicians or non-FH employees by FH Finance, at the address of their choice. There are no restrictions on the use of the honoraria by REB members who are non-FH employees or who are physicians.
 - ii. **Honoraria Paid to FH Employees:** Honoraria for REB members who are FH employees may be claimed by that member with the submission of the following documentation to the Research Ethics Co-ordinator:
 - a. expense receipts,
 - b. as per FH "Travel and Business Expense" policy, the expense claim must be filled out on an "Employee Expense Report", and,
 - c. a written justification for that expense made to the Director of Research Administration and Development who will approve the request.

A cheque requisition form is sent to FH Finance for reimbursement of the approved funds to that REB member.

Honoraria to REB members who are FH employees may be used for the type of expenses that FH employees would normally be able to claim and that are related to the work of the Research Ethics Board. This would normally include expenses related to education, conferences, and other out-of-pocket expenses. Other expenses may be considered upon presentation of an adequate written justification.

Any purchase of equipment and supplies that is approved by the Director of Research Administration and Development must be made through FH Material Services as per the FH Research Policy Section 4.3c.

TERMS OF REFERENCE

FH RESEARCH ETHICS BOARD MEMBERS

The members of the FH Research Ethics Board [FHREB] are responsible for carrying out the following activities and functions and operates under the authority of FH Policy "The Ethical Conduct of Research and Other Studies Involving Human Subjects".

1. Complete the "Introductory Tutorial for the Tri-council Policy Statement: Ethical Conduct of Research Involving Human Subjects" at <http://www.pre.ethics.gc.ca/english/tutorial/>
2. Review all submissions that meet the criteria for full board review that are assigned for a full board meeting prior to the meeting date. These include applications for initial ethical review, applications for amendment and renewal of previously approved studies that meet specific criteria for full board review, and responses to studies that have been deferred from a previous board review.
3. Submit written comments to the FHREB office at the conclusion of the REB meeting for compilation into the modifications or deferral memoranda.
4. Ensure that the study complies with the applicable Canadian federal and provincial and U.S. regulations when applicable and that all research complies with the Tri-Council Policy for Ethical Conduct for Research Involving Humans and other non-regulatory requirements.
5. Make a decision about the outcome of the review for each study as follows:
 - a) approve if all FHREB requirements have been met satisfactorily, or
 - b) request that the investigator modify the study and/or respond to questions concerning the study prior to approval, or
 - c) refer to an external source for review, or
 - d) not approve.
6. Develop guidance notes, policies and procedures for ethical review in collaboration with the Director, Research Administration and Development.
7. Participate in educational activities, evaluations, audits or investigations related to the oversight of research ethics at FH.
8. Declare any conflict of interest pertaining to studies on the full board agenda before discussion begins.
9. Declare conflict of interest on an annual basis.
10. **Honoraria:** All REB members, excluding the co-Chairs, are paid \$350.00 per meeting attended.
 - i. **Honoraria Paid to Non-FH Employees:** Cheques for the honoraria are sent directly to the REB members, who are physicians or non-FH employees by FH Finance, at the address of their choice. There are no restrictions on the use of the honoraria by REB members who are non-FH employees or who are physicians.

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- a. expense receipts,
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