



University of British Columbia - BC Cancer Agency Research Ethics Board



BC Cancer Agency

CARE & RESEARCH

An agency of the Provincial Health Services Authority

UBC BCCA REB

UBC BCCA Research Ethics Board

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UNIVERSITY OF BRITISH COLUMBIA - BC CANCER AGENCY RESEARCH ETHICS BOARD

TERMS OF REFERENCE

1. INTRODUCTION

Research involving humans or biological material originating from humans conducted within the British Columbia Cancer Agency (BCCA) must be approved by a duly constituted Research Ethics Board (REB). The University of British Columbia Vice-President Research, in accordance with [UBC Policy 89](#), has authorized the University of British Columbia-BC Cancer Agency Research Ethics Board (UBC BCCA REB) to function as the Research Ethics Board for the British Columbia Cancer Agency.

The UBC BCCA REB will comply fully with the requirements of the Tri-Council Policy statement, the requirements of Health Canada and the requirements of both the Office of Human Research Protection and the Food and Drug Administration of the United States. The UBC BCCA REB will also conform to the guidelines described in the most current International Committee on Harmonization Good Clinical Practices standards

2. SCOPE

All clinical research conducted at BCCA by BCCA staff or personnel must be approved by the UBC BCCA REB as required by the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. This includes but is not limited to:

1. Research on new medications and surgical techniques
2. Therapeutic interventions
3. Diagnostic procedures or tests
4. Screening or treatment techniques
5. DNA/tissue banking
6. Any other research involving humans or biological material originating from humans
7. Research involving the secondary use of identifiable personal data for research purposes.

Behavioural research at BCCA may be submitted to either the UBC BCCA REB or the UBC Behavioural REB (UBC BREB) as decided by the principal investigator. If behavioural research is reviewed by the UBC BCCA REB an expert in the area of behavioural research will be present for the discussion of that project or one will be invited to sit as an ad hoc member of the UBC BCCA REB for consideration of that project.

Non-BCCA researchers conducting research as described above to be carried out ONLY at a BCCA facility must designate a Principal Investigator who has a BCCA staff appointment and obtain ethics approval from the UBC BCCA REB. Examples of acceptable BCCA appointments include but are not limited to full or part time research scientist, physician, nursing, pharmacy, patient and family services, radiation therapy, dental or nutritional consulting staff; full time residents, fellows, graduate students or other trainees enrolled in programs supervised by BCCA staff. The principle is that the PI must have a sufficiently clear connection to BCCA that there is a reasonable assumption that the PI will feel bound by requirements placed on her or his performance of the research by BCCA.

UBC REBs "One Board of Record" Agreement: On April 2, 2007 the UBC affiliated REBs executed and forwarded to the UBC Vice President, Research a letter confirming their agreement to a one board of record process. This agreement ensures that formal review of the same research project by each of the UBC affiliated Boards is not required (Appendix 1).

3. REPORTING STRUCTURE

The UBC BCCA REB reports to the University of British Columbia Vice-President Research for all research ethics regulatory matters and administratively to the BC Cancer Agency Vice President Management & Operations and BC Cancer Agency President.

4. PURPOSE

1. To provide ethical review of adult oncology research involving humans, or material or information derived from humans, proposed and conducted at the BC Cancer Agency. Scientific review is part of the ethical process.
2. To ensure that the highest standards of scientific research and ethics apply to all adult oncology research involving humans, or material or information derived from humans, proposed and conducted at the BC Cancer Agency.
3. To perform other duties as delegated by the University of British Columbia Vice-President Research.

5. FUNCTIONS

1. To evaluate all proposed research involving humans for ethical standards including scientific quality.
2. To ensure that all studies have undergone appropriate internal and/or external review.
3. To recommend approval or disapproval after review.
4. To ensure effective liaison is maintained between this Board and other bodies. To assure these relevant bodies that, where applicable, studies submitted will be supplied for their information and comment.
5. To conduct an annual review of all ongoing UBC BCCA REB approved trials in accordance with Canadian and US guidelines in order to assess the progress of the investigations, and where necessary, recommend their modification or discontinuance.
6. To review protocol revisions, serious adverse event reports, and consent form changes to UBC BCCA REB approved studies.
7. To consider appeals against the decisions of the Board. Note that an appeal of the final decision of the UBC BCCA REB can be made to the parallel but separate UBC Clinical Research Ethics Board.
8. To respect the confidentiality of communications made to the Board and to assure investigators specifically that it will not distribute any of the protocols or privileged data outside of relevant bodies within the BCCA.
9. To ensure that conflicts of interest are disclosed that would interfere with, or appear to interfere, with the impartial judgment or actions of the REB members, investigators, sponsors and participants in studies.
10. To maintain a record of all clinical trial and research agreements for approved studies and to ensure that such agreements do not involve any conflict of interest that would interfere with the impartial judgment or actions of the investigators, sponsors and participants in studies.
11. To provide an annual report of the REB activities to the UBC VP Office of Research Services, and BC Cancer Agency President and Vice President Management & Operations. The annual report will also be made publicly available on the BC Cancer Agency website.

6. MEMBERSHIP APPOINTMENT

The UBC BCCA REB Chair in consultation with the Vice-Chair and appropriate Program Directors and/or Professional Practice Leaders, or BCCA President will make recommendations to the UBC VP Research who will formally appoint the members, Chair and Associate Chair(s) of the UBC BCCA REB. New members must attend at least one full board meeting as an observer before becoming a voting member. Members will complete the Tri-Council Policy Statement on-line tutorial (<http://www.pre.ethics.gc.ca/english/tutorial/>).

7. TERMS OF CHAIRMANSHIP AND MEMBERS

Chair: three (3) years renewable once

Vice-Chair(s): three (3) years renewable indefinitely

Members: three (3) years renewable indefinitely

The UBC BCCA REB chair will be a member of the UBC Research Ethics Policy Advisory Board.

8. DELEGATION OF AUTHORITY

The UBC BCCA REB Chair and Vice-Chair(s) have signing authority. The Chair is authorized to act on behalf of the full board for review of all minimal risk ethics submissions that meet the criteria for expedited review by the Chair only. The UBC BCCA REB Chair is authorized to delegate this authority temporarily to a senior member in the absence of all Chairs to act on their behalf. The UBC BCCA REB Administration (REBA) is authorized to issue approval or acknowledgment of expedited items as delegated by the REB Chair under the direction of the REB Manager

9. MEMBERSHIP GUIDELINES

Members will be provided with appropriate guideline material at the time that they join the research ethics board. This material includes the guidelines as published in;

- [UBC Policy #89: Research and Other Studies Involving Human Subjects](#)
- [UBC Policy #97: Conflict of Interest](#)
- [Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans](#)
- [Health Canada](#)
- [US Food and Drug Administration](#)
- [US Code of Federal Regulations, Part 46 Protection of Human Subjects \(45 CFR 46\)](#)
- [Office for Human Research Protections \(OHRP\) of the United States](#)
- [International Committee on the Harmonization of Research-Good Clinical Practice Guidelines \(ICHR-GCP\)](#)
- AAMC guidelines Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research" (<http://www.aamc.org/research/coi/>)

Membership will be comprised of at least five members of whom:

1. At least two members with broad expertise in the methods or areas of research being addressed in the project under consideration;
2. At least one member knowledgeable in the ethics of scientific research;
3. At least one member knowledgeable in law relevant to scientific research;
4. At least one member who has no affiliation with the institution.
5. At least one member with primary experience and expertise in a non-scientific discipline (this may be a member from group 2, 3, or 4)
6. In accordance with Health Canada - Natural Health Products Directorate, when a REB reviews a research proposal involving the use of a natural product that has been formulated for therapeutic purposes the REB must include a member knowledgeable in complementary or alternative health care.

In addition to meeting the requirements stated in 1-6 above the UBC BCCA REB will also conform to the following Health Canada requirements:

1. The majority of members must be Canadian citizens or permanent residents under the Immigration Act;
2. The board must be composed of both men and women.

Membership will normally include:

1. Representation from BCCA disciplines such as Systemic and Radiation Programs, Cancer Control Research, Pharmacy, Sociobehavioural, Nursing, and Biostatistics.
2. Representation from each treatment centre of BCCA
3. Members with prior experience with the ethical issues involved in scientific research.

10. CONFLICT OF INTEREST

All members will be required to disclose any financial interest, relationship, or other arrangement, that would interfere with their impartial judgment. In particular, equity holdings in potential sponsors, receipt of compensation for consulting or speaker's fees.

Members will be expected to adhere to the guidelines of the Association of American Medical Colleges (and any similar Canadian guidelines) as enunciated in the AAMC monograph "Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research" (<http://www.aamc.org/research/coi/>), and to the Conflict of Interest policy of UBC (Policy #97) (<http://www.universitycounsel.ubc.ca/policies/policy97.pdf>).

Members will not be present or participate in the review or vote of any item for which they have a potential conflict of interest. Members are expected to identify and inform the Board of any such potential conflict.

11. FREQUENCY OF MEETINGS

Meetings are held at the call of the UBC REB Chair.

12. QUORUM

All actions requiring *full board approval* must have a majority (50% plus one), which must consist of five members from the following list present and voting in favor for approval;

1. At least two members with broad expertise in the methods or areas of research being addressed in the project under consideration;
2. At least one member knowledgeable in the ethics of scientific research;
3. At least one member knowledgeable in law relevant to scientific research;
4. At least one member who has no affiliation with the institution.
5. At least one member with primary experience and expertise in a non-scientific discipline (this may be a member from group 2, 3, or 4.)
6. In accordance with Health Canada - Natural Health Products Directorate. When a REB reviews a research proposal involving the use of a natural product that has been formulated for therapeutic purposes the REB must include a member knowledgeable in complementary or alternative health care. (*Consultation by this member is not required to be in person for post-approval activities.*)

A majority is defined as 50% plus one of the total REB membership (excluding alternate members and the member from group 6) voting in favour of approval. Any member who fulfills the required quorum designation from groups 2, 3, or 4 above will have veto power. When a member and their alternate both attend a meeting and participate in the discussion or review, only one vote may be counted, however either member will have veto power.

13. REVIEWER ASSIGNMENT (Full Board)

UBC BCCA REB members are expected to review all items on a full board agenda for which they are present and voting. The UBC BCCA REB will assign a primary reviewer (from the members scheduled to attend a meeting) to each agenda item as noted below. The assigned reviewer will have scientific expertise. The

assigned reviewer will be responsible for presenting a summary of the study and their recommendations to the full board for further discussion.

New Studies: A primary reviewer and (when available) a secondary reviewer will be assigned to each new study requiring full board review. If the primary reviewer is not present at the meeting, the secondary reviewer will assume the role of primary reviewer. In the absence of an assigned reviewer, a member of the Board with scientific expertise who is present may assume the role of primary reviewer if they are prepared to do so.

Post Approval Activities: In general, only one primary reviewer is assigned to post approval items.

14. CONCERNS OR APPEALS

Concerns about the function of the UBC BCCA REB may be brought to the attention of either of the following:

1. UBC BCCA REB Chair, Dr. George Browman by email to: gbrowman@bccancer.bc.ca
2. BC Cancer Agency Vice-President Cancer Care by calling: (604) 707-5973
3. UBC Vice-President Office of Research Services contact information by email to: vpr@exchange.ubc.ca

Concerns about the treatment or rights of a research subject should be directed to:

UBC BCCA Office of Research Services - Research Subject Information Line: (604) 822-8598 or by email to: RSIL@ors.ubc.ca

Concerns or request for appeal of an REB decision about a specific study should be directed to:

UBC BCCA REB Manager by email to: reb@bccancer.bc.ca

Additional contact information for the BCCA REB Administrative office is available at:

<http://www.bccancer.bc.ca/RES/REB/Contacts.htm>

Confidentiality will be respected in all matters.

Appendices:

Appendix 1 - Copy of UBC "One Board of Record" agreement.

John Hepburn, FRSC
Vice President, Research
University of British Columbia
Old Administration Building - Room 224
6328 Memorial Road
Vancouver, B.C. V6T 1Z2

April 2, 2007

Dear Dr. Hepburn,

Each research project reviewed by a University of British Columbia (UBC) Research Ethics Board (REB) should have a single REB of Record. The UBC REB that initially reviews a research project normally becomes the REB of Record for the Project but occasionally a project is referred to another of the boards. Once established as the Board of Record that REB should deal with all subsequent ethical supervision of that project. This means that the investigator is only required to submit all post approval submissions to one board, regardless of whether or not the research is being conducted at another institution under a UBC research ethics board's jurisdiction.

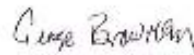
The purpose of implementing one board of record is to avoid the requirement for multiple formal reviews of the same research project. The need to identify one of several possible boards to be the Board of Record arises when the same principal investigator is conducting research at more than one institution under the UBC REB's jurisdiction.

Although there is one Board of Record, in order to ensure that institutional specific ethics requirements are being met, the Chair and Manager of each UBC REB for the institution involved in the research have the ability, through RISE, to view the application approved by the REB of Record. If, however, the REB Chair of any institution involved in the research has questions or concerns, these can be directed to the REB Chair of the REB of Record for resolution.

The Chairs of the following UBC Research Ethics Boards agree to this process.



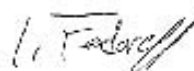
Dr. Gail Bellward, Chair
UBC - Clinical Research Ethics Board



Dr. George Browman, Chair
UBC - British Columbia Cancer Agency Research Ethics Board



Dr. Peter Suedfeld, Chair
UBC - Behavioral Research Ethics Board



Dr. Ingrid Fedoroff, Chair
UBC - Providence Health Care Research Ethics Board

Version 3: March 27, 2007 - One Board of Record.