



## CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA

AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY

University of British Columbia – Children's & Women's Health Centre of BC  
Research Ethics Board  
(UBC C&W REB)

### UBC C & W Research Ethics Board

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## UNIVERSITY OF BRITISH COLUMBIA / CHILDREN'S AND WOMEN'S RESEARCH ETHICS BOARD

### TERMS OF REFERENCE

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#### 1. INTRODUCTION

The University of British Columbia / Children's & Women's Health Centre of BC Research Ethics Board (C&W REB) is a University of British Columbia Research Ethics Board (REB) located on the Oak Street campus to serve the site-associated PHSA agencies including BC Children's Hospital, Sunny Hill Health Centre for Children, BC Mental Health & Addictions Services, and BC Women's Hospital and Health Centre, and research institutes, including the BC Mental Health and Addictions Research Institute (MHARI), the Child & Family Research Institute (CFRI) and the Women's Health Research Institute (WHRI). The C&W REB also serves non-site associated PHSA agencies and services. The C&W-REB operates under the Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans" (TCPS) and [UBC Policy #89](#) "Research And Other Studies Involving Human Subjects". The UBC Vice-President (VP) Research who has delegated authority from the President of UBC is responsible for the general oversight of research ethics review processes and appointment of members to the UBC REBs. The UBC Office of Research Ethics (ORE) provides administrative support for the Behavioural and Clinical REBs. C&W REB membership is multidisciplinary and accords with the requirements of the TCPS.

#### 2. SCOPE AND JURISDICTION

The C&W REB is a fully authorized UBC affiliated Research Ethics Board, which may review any clinical or behavioural research study involving human participants that is conducted under the auspices of UBC in accordance with the provisions of [UBC Policy 89](#).

A. UBC faculty members are required to use a UBC Ethics Board when their research project involves studies with human subjects. This requirement includes research undertaken at other sites within Canada and/or other countries around the world. [ref. TCPS 8.4]

B. Faculty members of institutions other than UBC whose research project involves patients, records or resources of UBC/affiliated hospitals or agencies are required to use a UBC Research Ethics Board. They may also have to meet requirements of the research site for local administrative and resource utilization review.

C. UBC investigators who have an office on the Oak Street campus, but whose research project does not directly involve patients, records or resources of the Oak Street campus, have the option of having their study reviewed by another UBC-affiliated REB.

D. UBC affiliated Investigators whose project directly involves patients, records or resources of the Oak Street campus and no other UBC-affiliated site are required to use the C&W REB. Researchers from other institutions must appoint an individual who is employed by C&W/PHSA as site lead or co-investigator for the research.

E. UBC affiliated Investigators who hold primary appointments at UBC-affiliated sites other than the Oak Street campus, and who wish to conduct research at multiple UBC-affiliated sites, including the Oak Street campus have the option of having their study reviewed by another UBC affiliated REB. They must however, meet the local administrative and resource requirements for each UBC-affiliated site. When C&W is a site for such a study, the PI must appoint an individual who is employed by C&W/PHSA as site lead or co-investigator for the project.

F. All trainees submitting to the CW REB must appoint an individual who holds either C&W/PHSA employment or a UBC faculty appointment as the principal investigator (PI) for the research, unless the trainee is employed by C&W/PHSA or holds a UBC faculty appointment

### **3. REPORTING**

For matters related to ethics and scientific issues, the C&W REB reports via the REB Chair to the UBC Vice-President (VP) Research, who has delegated authority from the President of UBC. For matters related to patient safety and quality assurance of research, and administrative matters, the C&W REB reports via the REB Chair to the Chief Administrative Officer- Research, Provincial Health Services Authority or an authorized delegate.

### **4. PURPOSE**

The mandate of the C&W REB is to function as an independent research ethics board to review the ethical acceptability of research involving humans conducted within the jurisdiction of and under the auspices of site-associated PHSA agencies and research institutes, and to a limited degree, other PHSA agencies and services.

The Board shall review the ethical acceptability of research in accordance with national, international and institutional guidelines and policies, including but not limited to the Tri-Council Policy Statement, UBC Policy 89 and the ICH-GCP Guidelines.

The C&W REB has the authority to review the ethical acceptability of research on behalf of the University, including approving, rejecting, proposing modifications to or terminating any proposed or ongoing research involving human participants that is conducted within the jurisdiction of the Children's & Women's Health Centre of BC and under the defined scope set out in Section 2.

To ensure integrity and to safeguard public trust the C&W REB shall maintain an arms-length relationship with and act independently from UBC and PHSA.

The Hospitals and Agencies of the Health Authority retain full authority for all matters related to patient care.

## **5. FUNCTIONS**

5.1 To review and monitor all proposed and on-going research involving humans for ethical acceptability including two essential components, which are:

- a) The selection and achievement of ethically acceptable ends;
- b) The ethically acceptable means to those ends

The REB shall consider the scientific merit of the proposed research in the course of its review process, as necessary to assess risks and benefits of the research as proposed.

5.2 To determine for the proposed or ongoing research whether to:

- a) approve it;
- b) require modifications to it;
- c) reject it; or
- d) suspend or terminate it.

5.3 To conduct continuing review of and maintain oversight over all on-going studies that have received C&W REB approval, including at a minimum, an annual review in accordance with the provisions of the TCPS

5.4 To re-consider its decisions upon request by affected researchers. Note that an appeal of the final decision of the UBC CW REB may be made to pursuant to the provisions of Policy 89.

5.5 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 typically on the Oak Street campus.

5.6 To ensure that conflicts of interest that would interfere with, or appear to interfere, with the impartial judgment or actions of the REB members, investigators, sponsors and participants in studies are disclosed and appropriately managed.

5.7 To provide an annual report of the REB activities to the Vice President Research, University of British Columbia.

At the discretion of the Chairs of the UBC affiliated research ethics boards, a submission may be re-directed to a more appropriate REB. When protocol design and personnel results in the overlapping of jurisdictions of more than one Board, the Board in whose area the research mostly falls and with the most real and substantial connection to the research and the researcher will be designated the Board of Record. The entire protocol will be made available to the members of each relevant Board.

Projects that do not require REB review are those involving:

- Quality of care/quality assurance projects that are for presentation within the hospital.
- Case reports, which will be reviewed by the Hospital Ethics Committee, according to their guidelines. When more than 2 case reports are involved, the REB will review the proposed project.

- Use of Records Management for chart review that is for “in-house” purposes only, such as rounds, continuous quality improvement, quality assurance, etc.
- Studies to establish normal values for clinical purposes
- Innovative interventions, which are the responsibility of Department Heads and the Medical Advisory Committee

## **6. MEMBERSHIP**

### **A. Appointment Process**

In consultation with the UBC C&W REB Chair, the Chief Administrative Officer – Research, Provincial Health Services Authority (or authorized delegate) will make recommendations to the UBC Vice President Research & International for the appointment of Members, Chair and Associate Chair(s). The University Vice President Research & International will formally appoint the Members, Chair and Associate Chair(s) of the UBC C&W REB, and retains the right to decline or to confirm an appointment.

### **B. Terms of Appointment**

The Chair of the C&W REB, will normally be appointed from amongst the membership of the C&W REB, for a three-year term, renewable for a further three years. The UBC C&W REB Chair will be a member of the UBC Research Ethics Board Chairs Committee.

Initial membership appointments are normally for three years. Renewal of appointments is by mutual agreement. Resignation of members must be in writing and addressed to the C&W REB Manager or to the UBC Vice President Research & International with a copy to the C&W REB Manager

### **C. Membership Guidelines**

#### **TCPS Requirements**

To conform to the requirements of the Tri-Council Policy on Research Ethics Boards, the C&W-REB will include members, as follows:

- a. at least one member knowledgeable in Ethics
- b. at least one member knowledgeable in law relevant to biomedical research; this is advisable but not mandatory for other areas of research. To avoid conflict of interest, this individual cannot have another relationship with the CW site.
- c. at least one member who has no affiliation with the Institution including the site associated PHSA agencies and Research Institutes, but is recruited from the community served by the institution.
- d. at least one member with primary experience and expertise in a non-scientific discipline
- e. 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.

## **Scientific membership**

The committee composition should include representation from program areas for populations served on the Oak Street campus (BC Children's Hospital, BC Women's Hospital Acute Perinatal Program and BC Women's Ambulatory Program's, Child Development and Rehabilitation, and Mental Health & Addictions). Efforts should be made to ensure representation from a variety of professional disciplines.

Committee members should be recommended by appropriate Department Heads, and Hospital and Research Institute program directors.

## **Health Canada Requirements**

The majority of members must be Canadian citizens or permanent residents under the Immigration Act

The Board must be composed of both men and women.

### D. Conditions of Appointment

The UBC C&W REB normally meets monthly, as scheduled by the C&W REB office and as called by the Chair. Members are expected to attend all meetings at which they are assigned protocols for review. At the discretion of the Chief Administrative Officer- Research, Provincial Health Services Authority (or authorized delegate), members may be appointed as a shared membership pair and attend alternate meetings. For members in a shared arrangement, it is expected that they try to cover for the other person's absence as far as possible.

Members must complete and abide by the C&W REB Confidentiality Declaration and the UBC Conflict of Interest Disclosure (Policy #97). Members are required to declare any conflict of interest pertaining to individual studies on the Full Board agenda before discussion begins.

Regular attendance by UBC C&W REB members is important, and repeated unexplained absences will be construed as a notice of resignation.

Members must demonstrate due diligence when reviewing submissions and submitting comments.

Members may be requested by the Chair and/or Associate Chair(s) to provide input on submissions outside of the Full Board meetings.

Members are expected to be knowledgeable concerning the Tri-Council Policy for Ethical Conduct for Research Involving Humans and other regulatory and non-regulatory requirements related to research ethics, and to ensure that they are well-informed on other relevant standards for clinical research (such as privacy legislation and Health Canada requirements).

Members are required to take advantage of training and educational opportunities offered through the UBC C&W REB, the UBC Office of Research Ethics, and National and Provincial organizations, including workshops and conferences related to research ethics. The UBC C&W REB office will provide appropriate financial support to enable members to fulfill their ethical review duties.

Members may be asked to assist and collaborate with the C&W REB Chair, Associate Chairs, Manager and staff in the preparation of guidance notes, policies and procedures for ethical review and presentations on the ethical review process specific to the UBC C&W REB.

## **7. DELEGATION OF AUTHORITY**

The UBC C&W REB delegates authority to the Chair and Associate Chair to review ethics submissions that meet criteria for minimal risk review and to deal with other items, including but not limited to reports of serious adverse events, protocol deviations, annual renewals and any other REB correspondence that requires acknowledgement.

## **8. CONFLICT OF INTEREST**

All UBC-affiliated members are expected to complete the annual requirement for sign off of the UBC Conflict of Interest Policy (Policy#97) and all members are expected to execute the UBC-REB Member Declaration concerning Confidentiality and Conflict of Interest and the PHSA Research Conflict of Interest Policy declaration.

All members will be required to disclose any real, potential or perceived conflict of interest, including financial interests, relationships, and other arrangements, that may interfere with or appear to interfere with their impartial judgment.

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.

## **9. OPERATIONAL PROTOCOL**

Meetings are held at the call of the UBC C&W REB Chair.

### **Quorum**

All actions requiring full board approval must have a quorum present and a majority of those members present voting in favour of decisions. For all studies not subject to the United States' Office for Human Research Protections (OHRP) regulations or the US Food & Drug Administration regulations (FDA), a quorum will consist of at least five members from the list below, as mandated by the TCPS; for OHRP or FDA regulated studies, a quorum will consist of a majority of the full REB members (50% plus one) and will include at least five members from the following:

- At least two members with broad expertise in the methods or areas of research being addressed in the project under consideration;
- At least one member knowledgeable in ethics;
- at least one member knowledgeable in the relevant law; for biomedical research,

- At least one member who has no affiliation with the Institution, including the site-associated PHSA agencies and institutes, but is from the community served by the institution
- In accordance with the requirements of Health Canada, when an 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.

### **Decision Making**

For Board decisions a consensus must be reached or a majority of members participating in the meeting must support the decision (the Chair will cast a vote when necessary to establish a majority). When there is disagreement among committee members, effort shall be made to reach consensus. When this is not achieved at the meeting, the Chair will, if appropriate, defer the decision to a subsequent meeting, with the purpose of reaching a solution through communication with the investigator and dissenting REB members. In such cases a decision will be reached by consensus or a majority vote at a subsequent meeting. When a member and his/her alternate both participate in the discussion or review, only one vote will be counted.

Procedures regarding expedited review (soon to be termed delegated review) shall be established and communicated to investigators.

### **Full Board Reviewer Assignment**

UBC C&W REB members are expected to review all items on a full board agenda for which they are present and voting. The UBC C&W REB will assign a primary and secondary reviewer to each study to be reviewed. Generally primary reviewers will be responsible for presenting a summary of the study and both reviewers will present their assessments and recommendations to the full board for further discussion.

## **10. COMPLAINT/CONCERNS PROCEDURE**

**Concerns about the function of the UBC CW REB** may be brought to the attention of any of the following:

1. C&W REB Chair, Dr. Marc Levine by email to: [marc.levine@ubc.ca](mailto:marc.levine@ubc.ca)
2. Chief Administrative Officer- Research, Provincial Health Services Authority to: [echesney@phsa.ca](mailto:echesney@phsa.ca)
3. UBC Vice-President Research & International by email to: [vpr@exchange.ubc.ca](mailto:vpr@exchange.ubc.ca)

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

UBC C&W REB Manager by email to: [cwreb@cw.bc.ca](mailto:cwreb@cw.bc.ca)

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

UBC Office of Research Services – Research Participant Complaint Line: 604-822-8598  
(Toll Free: 1-877-822-8598) or by email to [rsil@ors.ubc.ca](mailto:rsil@ors.ubc.ca)

Additional contact information for the C&W REB Administrative office is available at:  
<http://cfri.ca/research-support/reb>

***Confidentiality will be respected in all matters.***