

Guidance for Ethical Review of BC Cancer Multi-Jurisdictional Research

BACKGROUND

1. BC Cancer, part of the Provincial Health Services Authority (PHSA), is a provincial government-funded treatment and research organization.
2. BC Cancer's mandate covers the entire continuum of cancer care, from prevention, screening, diagnosis, treatment, supportive and palliative care, as well as research and education for British Columbia. Given the provincial mandate, research activities conducted by BC Cancer affiliated researchers and/or under the auspices of BC Cancer are routinely multi-jurisdictional research, i.e. involving multiple institutions and/or multiple research ethics boards (REBs).
3. The BC Cancer REB operates pursuant to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018), the International Conference on Harmonization Good Clinical Practice Guidelines (ICH-GCP) and the requirements of the US Department of Health and Human Services, as set out in the Federal Policy for the Protection of Human Subjects, 45 CFR Part 46. Federal wide Assurance (FWA) and Institutional Review Board (IRB) assurances with the Office for Human Research Protections (OHRP) and the Federal Drug Administration (FDA) have been obtained for both BC Cancer and the BC Cancer REB. BC Cancer and the BC Cancer REB also comply with all relevant federal, provincial, and local laws (including applicable federal and provincial privacy laws).
4. The BC Cancer REB is a specialized REB as per TCPS2 (2018) by virtue of its mandate as a disease specific REB responsible for the ethical review and oversight of adult oncology research conducted by BC Cancer affiliated researchers and/or under the auspices of BC Cancer
5. A Jurisdiction Working Group was formed by Research Ethics BC (REBC) and included representatives from various partner institutions of REBC with the goal of developing guidance on how multi-jurisdictional research conducted by BC Cancer affiliated researchers and/or under the auspices of BC Cancer will be ethically reviewed.

SCOPE

This Guidance applies to any multi-jurisdictional research involving human participants within British Columbia that:

- a) is being undertaken by BC Cancer affiliated researchers; and/or
- b) is under the auspices of BC Cancer; and/or
- c) involves BC Cancer patients; and/or their data or biological materials.

This is intended as a guidance and flexibility may be required in certain circumstances.

DEFINITIONS

Each of the following terms has the meaning ascribed to it in this Section, unless otherwise specifically provided or otherwise required by the context:

1. "Board of Record" means the REB that will serve as the primary authority for the ethical oversight of the research.
2. "Continuing Research Ethics Review" means any review of ongoing research conducted by a REB occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy.
3. "Human Participant" means an individual whose data, biological materials, or responses to interventions, stimuli, or questions by a researcher are relevant to answering the research question(s). Also referred to as a 'participant', 'subject' or 'research subject'.
4. "Maximal Reciprocity" means the highest level of reciprocity acceptable to a REB for its ethical review requirements for multi-jurisdictional research, based upon the relationship of the relevant REBs to each other, the perceived risks of the study, the relevant REBs' institutional policies, and any other considerations and judgments that a REB may deem, in its sole discretion, to be relevant.
5. "Multi-jurisdictional Research" means research involving multiple institutions and/or multiple research ethics boards (REBs).
6. "Research Ethics Board" or "REB" is a body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines, etc.) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.
7. "Provincial Research Ethics Platform" or "PREP" is an electronic module for the application, review, approval (initial and ongoing), and closure of multi-jurisdictional studies in BC. PREP is housed within the UBC's Research Information System or "RISe".

REVIEW PROCESS

1. The researcher will complete the research ethics application in RISe/PREP.
2. The BC Cancer REB will be the Board of Record (BoR) and will have responsibility for the ethical oversight of the project, including initial review and approval, and continuing research ethics reviews.
3. BC Cancer REB will 'harmonize' the study in RISe/PREP which notifies the other institutions of the study.
4. BC Cancer Research Ethics will review the application to ensure that there are adequate descriptions included of how the study affects other institution(s) and they are appropriately listed in section 4.2.C of the application form.
5. If the BC Cancer REB determines that a privacy review is necessary, it will refer the project to the PHSA Research Privacy Office to conduct a privacy review at the same time as the ethics review and the outcome of the review will be recorded in RISe/PREP. This privacy review address BC privacy law requirements and should not trigger any additional privacy reviews.
6. The BC Cancer REB comments and review decisions will be documented in RISe/PREP, as per standard procedure, and BC Cancer Research Ethics will notify any REBs affected by the multi-jurisdictional research within the RISe/PREP system upon completion of the review.
7. The notification will not trigger any duplicate research ethics review but is intended for information purposes only so relevant partner organizations and/or REBs can document the research.

8. Each institution is responsible for educating their institutional researchers that when undertaking multi-jurisdictional research, it is the researcher's responsibility to ensure:
 - a) their local REB is notified about the research;
 - b) any other required reviews and/or approvals are obtained prior to commencing the research (ie institutional or departmental approvals); and
 - c) they are aware of and will comply with all applicable and relevant institutional policies, procedures, and processes within those jurisdictions where the research is being conducted.

CERTIFICATE OF APPROVAL

1. The Certificate of Approval will be issued by the BC Cancer REB.
2. Relevant institutions/sites would be listed on the Certificate, but partner logos would not appear.

STUDENT RESEARCH

In relation to Student Research undertaken at BC Cancer, please refer to BC Cancer Research Ethics Board Guidance for Student Research, and accompanying flow chart:

- <http://www.bccancer.bc.ca/research-ethics-board-site/Documents/Research%20Ethics%20Board/BC%20Cancer%20REB%20Student%20Research%20Guidance.pdf>
- <http://www.bccancer.bc.ca/research-ethics-board-site/Documents/Research%20Ethics%20Board/BC%20Cancer%20REB%20Student%20Research%20Flow%20Chart.pdf>