Research Ethics BC
British Columbia Academic Health Science Network

Guidance for Pediatric Multi-Jurisdictional Research in BC – Children's & Women's REB

BACKGROUND

1. BC Children's and Women's Hospitals are part of the Provincial Health Services Authority (PHSA), is a provincial government-funded treatment and research organization.
2. The BC Children's and Women's REB (C&W 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 C&W REB. The REB also complies with all relevant federal, provincial, and local laws (including applicable federal and provincial privacy laws).
3. The C&W REB is a specialized REB as per TCPS2 (2018) by virtue of its mandate as a child health REB responsible for the ethical review and oversight of child health research conducted by affiliated researchers for BC Children's and BC Women's Hospitals and/or under the auspices of BC Children's and BC Women's Hospitals.
4. The majority of clinical child health research in BC is led by affiliated researchers with BC Children's and BC Women's Hospitals and/or under the auspices of BC Children's and BC Women's Hospitals.
5. A Jurisdiction Working Group was formed by Research Ethics BC (REBC) and included REB representatives from various BC institutions with the goal of developing guidance to provide clarity and define the C&W REB as the provincial REB for review and approval of clinical child health research.
6. This guidance defines the scope and process of ethical review for multi-jurisdictional child health clinical research in BC.

SCOPE

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

a) Is clinical in nature;
   AND
b) Is being undertaken by affiliated researchers with BC Children's and BC Women's Hospitals;
   AND
c) Involves BC Children's and BC Women's Hospitals pediatric patients and/or their data or biological materials; or
d) Involves pediatric patients at health authorities in BC.

This is intended as a guidance document 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. “Clinical Research” means research that includes the administration or testing of drugs, medical devices, medical imaging or diagnostic techniques; and the taking of blood or other specimens. It also includes the analysis of laboratory, physiological, kinesiological or biological data obtained from physical interventions, medical records or clinical studies involving the linkage of data from existing databases.
3. "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.
4. “Direct Reciprocity” means that the partner REB(s) will accept the ethical review of the Board of Record without additional ethical review.
5. “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’.
6. "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.
7. "Multi-jurisdictional Research" means research involving multiple institutions and/or multiple research ethics boards (REBs).
8. "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.
9. “Pediatric/Child” is defined as patients under 19 years of age.
10. “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”.
11. “Proportionate and site-specific review” means the avoids duplication of provisos by the original BoR review and considers only the elements that may require ethical consideration due to differences in how the study may need to be conducted differently at their site.

INITIAL REVIEW PROCESS

1. For multijurisdictional Research, the C & W researcher/research team will complete the research ethics application in RISe/PREP.

2. In most cases, the algorithm within RISe/PREP will determine that the C&W REB will be the Board of Record (BoR). If it does not do so automatically, the REB Administrator(s) for the determined BoR will consult with C&W REB, and then make the change manually.
3. C&W REB will have responsibility for the ethical oversight of the project, including initial review and approval, and continuing research ethics reviews.
4. The C&W Research Ethics office 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 study involves only patients from BC Children's and BC Women's Hospitals, including those seen in 'outreach clinics' in other locations, and the only involvement by other institutions is due to affiliations of research team members, the C&W REB will review the study as direct reciprocity by the other affected institutions by default (essentially, not a 'harmonized' review).
    a. The C&W REB will click on the 'Harmonize' button in RISe/PREP to ensure the other Institutions identified are notified and facilitate any operational approvals required. Although notifications will not show up on the 'Inbox' of the REB Administrators for any action related to the application, the study will be listed in the RISe dashboard.
    b. If the C&W 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.
    c. The C&W REB comments and review decisions will be documented in RISe/PREP, as per standard procedure. Although notifications will not show up on the 'Inbox' of the REB Administrators for any action related to the application, the study will be listed in the RISe dashboard under Approved.
6. If the study involves patients or data from other health authorities, other than as described above, then the 'harmonized' ethical review process (as defined by the Research Ethics BC Guidance for Harmonized Ethics Review of Multi-Jurisdictional Research Studies) will proceed according to agreed models ensuring proportional review by the participating REBs.
7. In cases where there is a cross-appointment (affiliation) of a researcher between two institutions, if they are conducting any aspect of study-related activity under the auspices of an institution other than BC Children's and BC Women's Hospitals, the study will be considered as requiring 'harmonized' ethical review as in point 6 above.
8. If a study approved as per point 5 above is then amended to include patients from other health authorities, the added health authorities will have the opportunity for site specific ethical review. Once reviewed, an amended Certificate of Approval will be issued including the institutions that participated in the review, as well as their logos.
9. 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 (i.e. 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 C&W REB.
2. If reviewed in accordance with point 5 above, the relevant institutions (due to affiliations of study team members) will not be listed on the Certificate of Ethical Approval as having reviewed the study, but logos will still be applied to demonstrate that the study has received ethical approval for the sites indicated.
3. If reviewed in accordance with point 6 above, the institutions involved in the harmonized ethical review will be named on the Certificate of Ethical Approval and have their logos applied.