UBC Research Ethics Boards

Guidance note on Harmonized Studies

Article 1: Background and Purpose

UBC's Policy 89 "Research Involving Human Participants" Article 5 permits the University to enter into Ethics Review Agreements with other research institutions or organizations. Such agreements allow for alternative models for ethics review with the express purpose of facilitating collaborative research projects involving researchers, data or participants from more than one institution, and in order to avoid a duplication of efforts with respect to research ethics reviews.

As of the date of this guidance, UBC has entered into written agreements with: Simon Fraser University, University of Alberta, University of Northern British Columbia, University of Saskatchewan, the University of Victoria, Fraser Health, Island Health, Interior Health and Northern Health.

Please note that Northern Health does not have a TCPS2 compliant REB. If Northern Health is involved in the study, please select University of Northern British Columbia/Northern Health.

The alternative review model and the review processes that will be used will vary depending upon the context of the study (minimal risk / above minimal risk, clinical / behavioural etc.) the number of other centers involved, and whether there has already been an ethical review conducted for the study.

UBC has agreed to collaborate on the ethical review of studies that involve UBC and one or more of the above-named Institutions. It has also adopted an abbreviated process for studies that are **both minimal risk and behavioural** which have previously been reviewed by another Canadian REB.

Researchers who have studies that qualify for harmonized review may choose to utilize this process or to simply apply for approval in accordance with normal submission requirements in which case they are required to complete the full application and to separately submit an application for approval at any other institution where ethical approval is required.

Applicability:

1. UBC's REBs reserve the discretion to determine the appropriate process to be applied to the review of any specific study.

2. The Ethics Review Agreements anticipate the implementation of a harmonized process for review and approval of post-approval activities, but for out-of-province studies there are some legislative restrictions. At this time, there is no harmonized post-approval process for studies that involve extra-Provincial institutions. (University of Alberta, University of Saskatchewan)

3. This Guidance and the harmonized process for ethical review do **not** apply to studies that are being conducted exclusively at **UBC** sites. In accordance with UBC's One Board of Record agreement, studies conducted by the same researcher at more than one University site, or the same study conducted by different researchers at more than one University site require only one UBC REB approval and the approving UBC Board is the Board of Record for all post-approval activities related to such studies. However, the harmonization process can apply to studies that involve more than one UBC site **and** another non-UBC partner site.

4. **Exclusions:** Please note that studies that are retrospective chart reviews, data registries or tissue banks are not eligible for harmonized review at this time. Please also note that after a study has been reviewed and approved as a non-harmonized study, you cannot change question 4.6 on the application during the post-approval amendment stage, to indicate that the study is now a multi-jurisdictional study. In some circumstances, depending upon inter-institutional determinations, you may be able to add a partner site to the UBC application so that the study will be treated as harmonized from the date of the amendment, but at the current time, you cannot change the answer to question 4.6 retroactively. In all of these instances, please answer "No" to question 4.6.

Article 2: Definitions

Ethics Review Agreement: means an agreement between UBC and another research institution or organization that authorizes an alternative model or models for ethics review of human participant research.

Ethics Review Information: means all documentation created in the course of an initial review of an ethics application by an Initial Review REB, including but not limited to the initial application form, **the correspondence between the REB and the researcher including all provisos and/or modifications required,** all informed consent/ assent forms, surveys, questionnaires, peer review documents and any documentation deemed relevant to the study and required to be reviewed by an Initial Review REB.

Multi-jurisdictional study: means a research study requiring review by more than one Institutional REB in accordance with the Institution's institutional policies, and including the requirements of the TCPS2.

Article 3: Process for Researchers

3.1:

(i) Researchers should submit the ethics application for the multi-jurisdictional study to their home institution's REB (i.e. the REB for the Institution with which the researcher has his or her **primary** affiliation).

(ii) In View 1.8 (project nickname) the Investigator should include "harmonized review project" in the first part of the study nickname.

(iii) In View 4.6 the Investigator should check "yes" to the question of whether or not the study is a multi-jurisdictional study. The RISe smart form will direct the Investigator to either View E or View F.

(iv)

View E (Clinical and Hospital Behavioural)

E.1. If you are directed to View E.1**.,** Indicate which of the REBs from the named institutions will also be required to review and approve the study in addition to the UBC REB(s) that you are submitting to. Please check all that apply based upon your information at the date of submission.

View F (Behavioural)

F.1. If you are directed to View F.1, indicate which of the REBs from the named Institution's REBs **if any** (there may be none) will be also required to review and approve the study in addition to the UBC REB(s) that you are submitting to. Please check all that apply based upon your information at the date of submission.

(v) After answering E.1. or F.1 you will be directed to E.2 or F.2.

View E (Clinical and Hospital Behavioural)

E.2. Indicate whether any of the REBs from the named institutions have **already (previous to your submission)** reviewed and approved the study. If you answer yes to E.2 after responding to E. 3 – E.5, your application should truncate to View 9 (Documents View). In View 9, you should attach **all** of the relevant documentation from the REB that has already approved the study. This includes the Certificate of Approval, the ethics application, the informed consent form, recruiting documents and all available correspondence between the other REB and yourself, including provisos and/or modifications required. The Board uses the correspondence to allow it to avoid asking you questions that the other board has already asked and you have answered. You should **also** attach local / UBC specific draft documentation.

If you answer no to E.2. you will be directed back to View 4.7 from View E, and be required to complete the rest of the Clinical / Hospital Behavioural REB application.

View F (Behavioural)

F.2. Indicate whether any of the REBs from the named institutions have **already (previous to your submission)** reviewed and approved the study. If you answer yes to F.2 you will be directed to F.3 – F.6 and then your application should truncate to View 9 (Documents View). In View 9, you should attach **all** of the relevant documentation from the other REB that has already approved the study. This includes the Certificate of Approval, the ethics application, the informed consent form, recruiting documents and all available correspondence between the other REB and yourself, including provisos and/or modifications required. The Board uses the correspondence to avoid asking you questions that the other board has already asked and you have answered. You should **also** attach all local / UBC specific draft documentation.

If you answer no to F.2. you will be directed to View F.3. In F.3. answer yes **only** if your study meets the criteria for behavioral minimal risk studies **and** it has been reviewed and approved by **any** Canadian REB (not just one of the partner institutions). If you answer yes to F.3. the application will truncate after F.6 and the guidance in F.2 above will apply. If you answer no to F.2 and no to F.3, you will be required to complete the rest of the Behavioural REB application.

Board Contact Information

You may wish to consult with REB administration either before or during the submission of an application for review of a multi-jurisdictional study. For your convenience, the current contacts are listed below.

BC Cancer Agency REB
Kristie Westerlaken, Manager
Phone: 604-877-5597 E-mail: reb@bccancer.bc.ca

Children & Women's REB
Jennie Prasad, C&W REB Manager
Phone: 604-875-2441 E-mail: cwreb@cfri.ubc.ca

Interior Health Authority REB
Dorothy Hebert, Research Coordinator
Phone: 250-870-4206 E-mail: Dorothy.herbert@interiorhealth.ca

Providence Healthcare REB
Julie Hadden, Manager
Phone: 604-682-2344 ext 63496 E-Mail: jhadden@providencehealth.bc.ca

UBC Behavioural REB
Shirley Thompson, Manager
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UBC Clinical REB
Pia Ganz, Manager
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Simon Fraser University
Sarah Bennett, Manager, Research Ethics
Phone: 778-782-3447 E-mail: sarah_bennett_2@sfu.ca

University of Alberta
Kim Kordov, Research Ethics Officer, Research Ethics
Phone: 780-492-2615 E-mail: kim.kordov@ualberta.ca

University of Northern British Columbia
Rheanna Robinson, REB Administrative Coordinator

Phone: 250-960-6736 E-mail: rheanna.robinson@unbc.ca

University of Saskatchewan
Beryl Radcliffe, Ethics Facilitator (Behavioural)
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University of Victoria
Eugenie Lam, Human Research Ethics Coordinator
Phone: 250-472-5202 E-mail: hrethics@uvic.ca

Vancouver Island Health Authority
Dawn Pollon, Research Ethics Coordinator
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