

Harmonized Ethics Review Update – Above Minimal Risk Model Pilot Launch

Introduction

The BC Ethics Harmonization Initiative (BCEHI) aims to create efficient, coordinated, and high-quality processes that support and encourage multi-jurisdictional human health research. The goal is to make BC a more attractive environment for research activity.

BCEHI is a collaborative effort among British Columbia's regional health authorities and four major universities (University of British Columbia, Simon Fraser University, University of Victoria, and University of Northern British Columbia), who collectively conduct more than 80 percent of the province's human subject ethics reviews.

The Michael Smith Foundation for Health Research is funding and facilitating the BCEHI until March 31, 2016. Senior Leaders of the partner organizations are responsible for making decisions related to the adoption and implementation of harmonized ethics review models, technology solutions and plans for sustainability.

The BCEHI Advisory Committee provides expert knowledge, advice and recommendations to support the achievement of the BCEHI priority objectives, with a primary focus on the development and implementation of harmonized ethics review models.

Model Development

The BCEHI Advisory Committee has developed two harmonized ethics review models for Minimal Risk and Above Minimal Risk studies.

The Minimal Risk Model pilot, which began in December 2014, has been extended to the end of July, 2015 and the results will be reported back to the research community in the fall. The Advisory Committee and Senior Leaders of the partner institutions have now endorsed an Above Minimal Risk Model which will begin piloting in June and continue through 2015.

Above Minimal Risk research requires full board ethics review. To meet this requirement and provide for efficient, high quality review, the Above Minimal Risk Model employs a Board of Record (BoR) + 1 model, whereby the BoR is joined by at least one voting member from each of the other involved Research Ethics Boards for review and approval of the harmonized study. A key advantage of this approach is that the harmonized review occurs within a regularly scheduled meeting of the BoR, and does not require that an additional REB meeting be called each time a harmonized study requires ethical review. The model also provides flexibility in how other REB members review the application and attend the full-board meeting, allowing them to submit their comments in advance to the BoR Chair, and to attend in-person, or via teleconference or videoconference.

At this time, retrospective chart reviews and sponsored clinical trials have not been included in the harmonized models, although they may be considered in the future.

Supporting Materials and Evaluation

During the model development and refinement phase, Advisory Committee members have been connecting with colleagues in their respective institutions to provide orientation and receive feedback on the Above Minimal Risk Model. They have also spear-headed the development of supporting materials for researchers and REB staff, including:

- Harmonized Ethics Review Model Diagrams (includes Minimal Risk and Above Minimal Risk study workflows)
- Guidance for Harmonized Ethics Review (includes Minimal Risk and Above Minimal Risk):
 - Describes procedures for conducting harmonized ethics reviews during the pilot period
 - Has been updated to incorporate feedback and questions from the REBs on the Above Minimal Risk Model
- Harmonized Ethics Review Cover Sheet (updated):
 - Initiates communication between the research team and the REB Administrators
 - Identifies the level of risk in a study, the sites for research, and the nature of research activity
 - Assists in determining which REB will act as the Board of Record
- Partner Operational Contacts
 - Provides direction to researchers on who to contact for operational/administrative approvals

In addition, a Joint Certificate of Approval template is now available for use by participating REBs.

As with the Minimal Risk Model, we will be seeking feedback from key stakeholders for each harmonized review through the collection of data (using pre-determined metrics) and a post review survey. Evaluation is an important component of the pilot implementation and its success will require the time and commitment of Research Ethics Board members and administrators and researchers.

Summary

The development and piloting of the Above Minimal Risk Model marks significant progress toward achieving harmonized ethics reviews in BC. Continued engagement and participation in this process is vital to the long term success of the BCEHI.

As harmonized ethics review models become integrated into the BCEHI partner institutions, the development of strategies to sustain harmonization in BC will be a key priority for the partners' senior leadership. Continued collaboration will be required in the months ahead to evolve and sustain the work achieved through the BCEHI.