



Michael Smith Foundation for
Health Research

Terms of Reference BC Ethics Harmonization Initiative Task Force

Background

Health research stakeholders across BC have identified the need for an effective, coordinated, value-add provincial approach to ethical approval – one that improves quality, access, consistency, efficiency and capacity for ethical review of research involving human subjects. Over the past year, a number of organizations have launched separate and, to date, uncoordinated initiatives in an attempt to address concerns at least with respect to their own institutional context.

While many agree that there is a clear need for such a provincial approach to ethics, it is not clear what potential approaches or solutions might be acceptable to stakeholders. Options vary widely from adoption of harmonized core guidelines and institutional review reciprocity to a coordinated, shared, provincial ethics review mechanism.

At the request of provincial health research stakeholders, and with the endorsement and support of the Ministry of Health and the Ministry of Advanced Education, the Michael Smith Foundation for Health Research has agreed to facilitate a process to explore options in greater depth. To support this project, MSFHR is striking a Task Force to provide advice relating to the initiative.

Purpose

1. The purpose of the Task Force is to provide advice and feedback, and make recommendations to MSFHR as requested, on topics relating to the BC Ethics Harmonization Initiative.
2. The scope of the Initiative is:
 - a. Environmental Scanning – description of mechanisms and structures for ethical review of research involving human subjects in the academic institutions, health authorities, health care facilities, government agencies, and communities of British Columbia, including identification of the issues and barriers related to ethical review that exist in the provincial health research environment (May to July, 2007)
 - b. Environmental Scanning – description of processes and structures adopted in other jurisdictions across Canada and selected other English speaking countries (May to July, 2007)
 - c. Workshop – gathering of key stakeholder representatives to receive the results of the environmental scans, hear from expert speakers, and discuss options for action (October 2007 – materials to be circulated in September 2007)
 - d. Workshop Report – produce and circulate a report that identifies issues and barriers to the creation of a streamlined approach to ethical approval in British Columbia, and options and recommendations for next steps to address these barriers (December 2007)

Duties

Based on professional knowledge and content expertise, the duties of The Task Force shall be to review and make recommendations to MSFHR on:

1. deliverables for the environmental scanning, workshop, next steps and report that comprise this initiative;
2. related plans and strategies, documents, activities, processes, personnel, and services;
3. and such other matters as may be brought forward for their consideration in relation to the initiative.

Membership

1. Membership in the Task Force shall be invitational, as identified by MSFHR in consultation with designated representatives of the Ministry of Advanced Education and the Ministry of Health.
2. A minimum of six and a maximum of eight members will be invited to join the Task Force.
3. Delegates are not permitted.
4. Membership of the Task Force will include at a minimum individuals with knowledge and understanding of processes for the ethical review of research involving human subjects, and one or more of the following areas of expertise or perspectives:
 - a) Health Authorities
 - b) Research Institutes & Teaching Hospitals
 - c) Universities
 - d) Community Research
5. Co-chairs will be selected from the Task Force membership by MSFHR in consultation with designated representatives of the Ministry of Advanced Education and the Ministry of Health.
6. Quorum for the Task Force will be 50% of members plus one.
7. The Task Force will be staffed by MSFHR.
8. Additional input may be sought by the Task Force from time to time, from individuals designated as Guests of the Task Force, when participation of Guests is required to provide specific knowledge or expertise via a more limited involvement than full membership.

Operational Protocol

1. The Task Force will conduct its business between May and December, 2007.
2. In-person meetings are targeted for the following dates and subject to change at the discretion of the Co-Chairs in consultation with MSFHR, the Ministry of Advanced Education and the Ministry of Health.
 - a) Tuesday May 1, 2007
 - b) Tuesday July 31, 2007
 - c) Tuesday November 13, 2007
3. MSFHR will minimize additional requirements for the Task Force to be available in the same place at the same time. Business may therefore be conducted in person, via teleconference, videoconference or web-conference, at the discretion of the Co-chairs and MSFHR in

consultation with designated representatives of the Ministry of Advanced Education and the Ministry of Health.

4. Except in the case of Members who are employees of the Government of British Columbia or its affiliated agencies, all Members and Guests of the Task Force will be reimbursed by MSFHR at cost for travel, long-distance and other authorized expenses incurred as a result of their participation in the Task Force, according to MSFHR's current Travel Policy.
5. No other financial remuneration or consideration will be provided by MSFHR to members of the Task Force.

Documentation Protocol

1. Minutes and all Panel documentation and discussions will be considered confidential by all members unless expressly indicated otherwise by the Co-Chairs.
2. All documentation relating to the Task Force's activities and discussions will be distributed electronically or in hard copy on paper, and panel members will ensure that all copies of such documents in their care and control (both paper and electronic) are stored and secured to restrict unauthorized access and maintain confidentiality.
3. Minutes and other supporting documents will be circulated to all Task Force members within 30 days following each meeting.
4. Minutes and related supporting documents will be circulated to designated representatives of the Ministry of Advanced Education and the Ministry of Health by MSFHR within 30 days following each meeting.