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BC Ethics

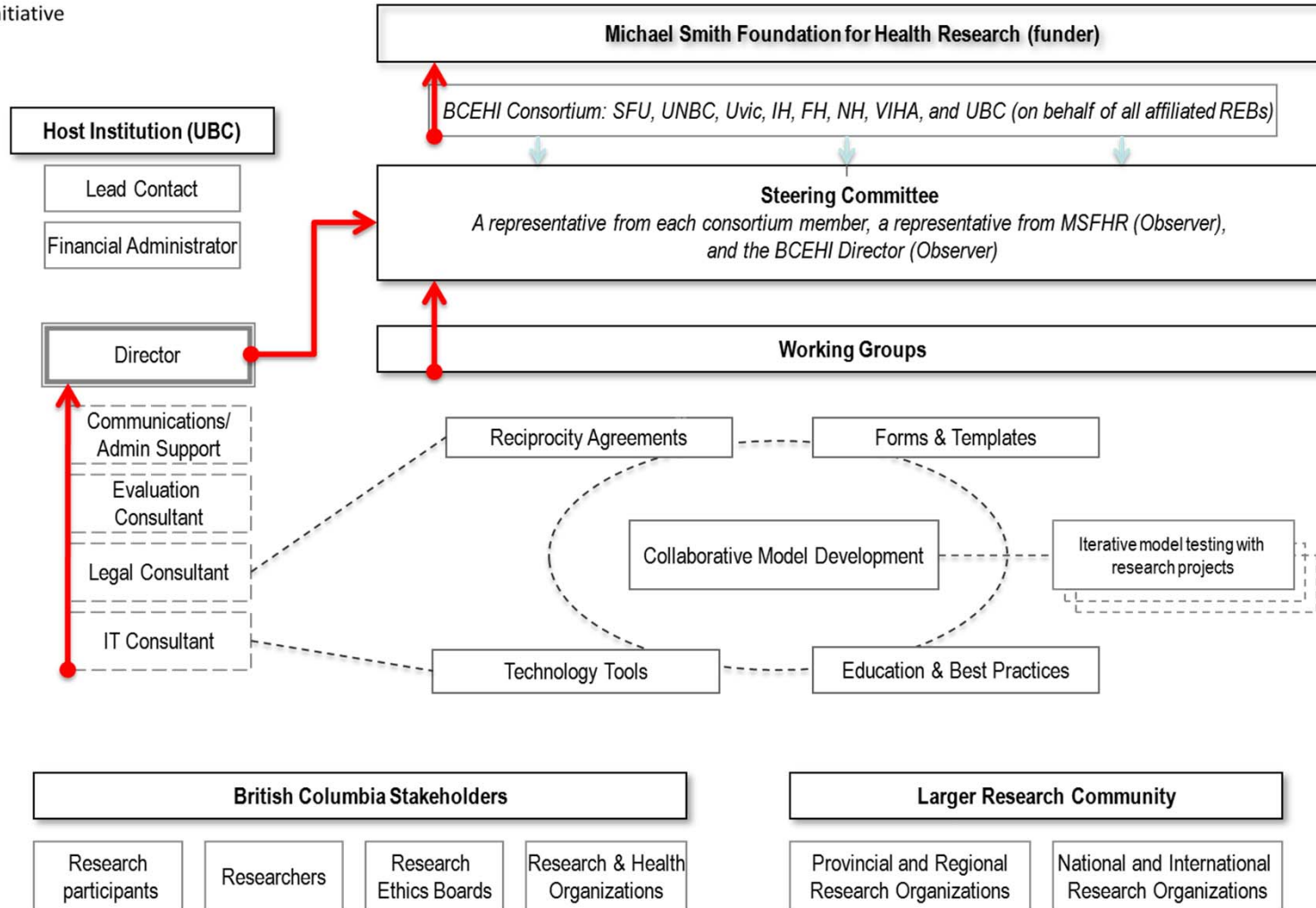
Harmonization Initiative



# The BC Ethics Harmonization Initiative

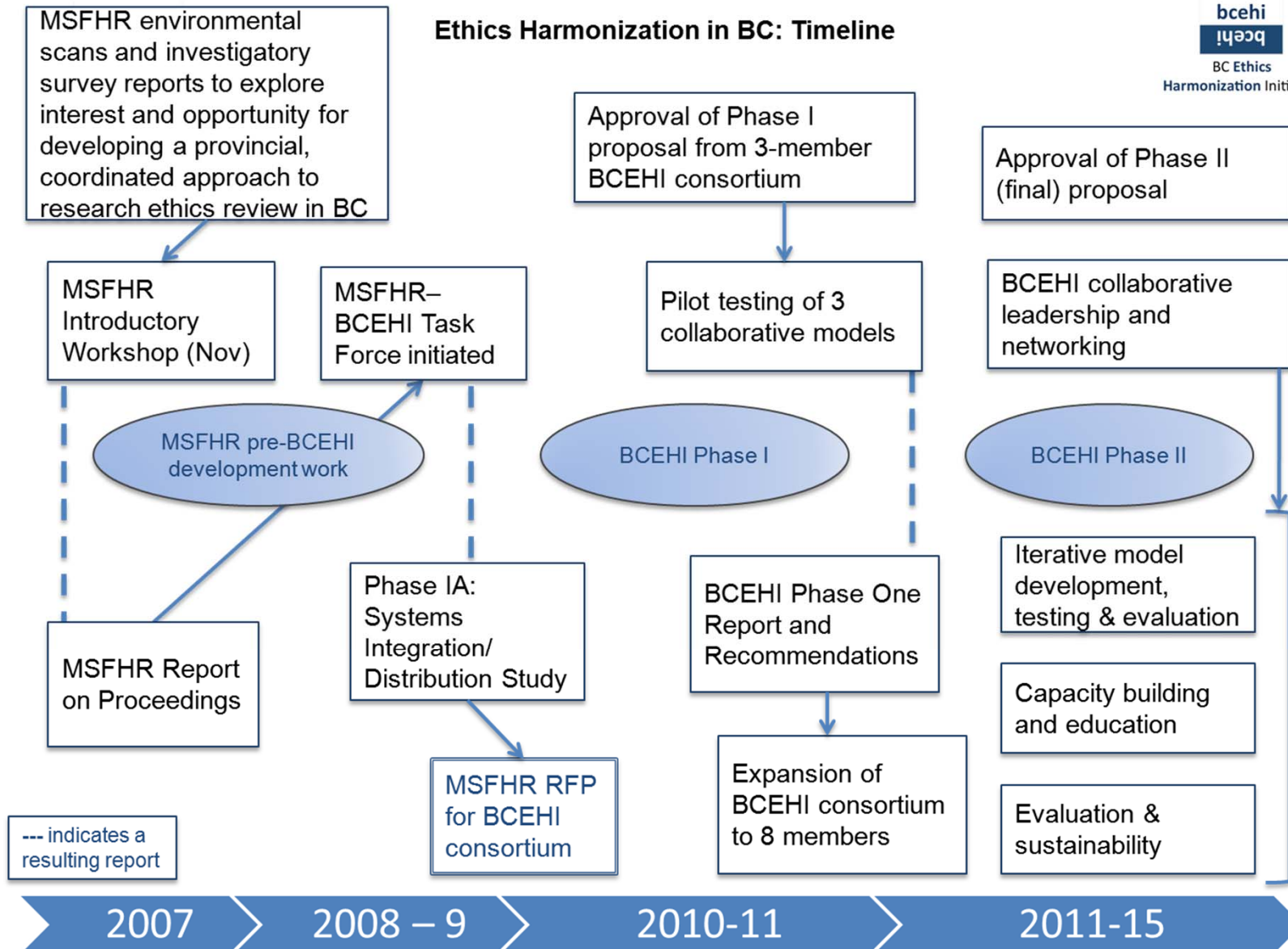
*A provincial collaboration working toward harmonizing ethical reviews  
for multi-jurisdictional research in BC*

# BCEHI Overview



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### Ethics Harmonization in BC: Timeline



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# BC Ethics Harmonization

Vision: To make BC an attractive environment in which to do health research that involves multiple sites, regions and populations.

Focus of the key principles:

- ▶ Collaborative governance
- ▶ Importance of autonomy and independence
- ▶ Building on existing technology when possible
- ▶ Maintaining a high standard of ethical review
- ▶ Evolution and sustainability of REB harmonization

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# Priority objectives

- ▶ To improve timeliness and efficiency of ethical review processes
- ▶ To improve the system effectiveness for health research ethics
- ▶ To facilitate maximal reciprocity arrangements between BC institutions for the ethical review of health research conducted within BC

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# Lessons learned/Challenges

- ▶ Local input/review
  - review for local ethical considerations is important to most REBs, especially those within the health authorities
  - local investigators/support and funding/resources must be in place - speaks to feasibility
  - Health authority resource/impact review should be separate from a multi-centre REB review process
- ▶ Technology: any 'system' needs to be self-sustainable; ease of integration with existing systems must be considered
- ▶ There is support for harmonization across BCEHI partners; however different views on what this means and how to achieve it, is challenging for collaboration and consensus
- ▶ Sustainability must drive the go-forward process options as there is no confirmed funding after 2015

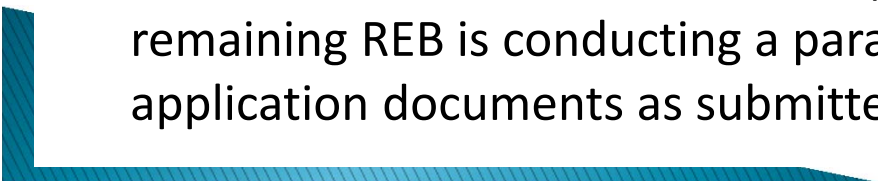
## Phase II: 2011-2015

BCEHI has received input and endorsement of many REB Chairs, members and administrators. Coordinated and collaborative reviews have been occurring between some organizations with/out formal agreements in place. In this phase we will be formalizing and building on some of these already established relationships.

- ▶ inter-institutional agreements put in place confirming support for the goal of achieving the highest degree of reciprocity in ethical reviews of multi-centre studies while respecting individual institutional autonomy
- ▶ continued development of a collaborative model incorporating reciprocal and collaborative review processes
- ▶ working groups formed to work on developing key areas such as education & best practices, common forms/templates, and technology tools

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# Collaborative reviews 2011/12

- ▶ BREB: a minimal risk, multi-centre project, the BCCRIN Clinical Trial Participation Survey - the RISE guest reviewer capacity was utilized to enable an REB Chair to participate in a collaborative review; the other REBs involved either accepted the UBC REB approval directly, and/or did not require REB review.
  - ▶ BREB/CREB: An interim agreement/process implemented between UBC, IH, VIHA, FH and NH to streamline and coordinate submissions from UBC Family Practice medical residents conducting research within a health authority's jurisdiction. Revisions to UBC Policy 89 approved in spring 2012 will enable UBC to accept other REB approvals directly. An agreement between the parties to this effect will now be developed.
  - ▶ CREB: A collaborative REB review process for a scientific evaluation of a program being implemented across the health authorities is now in process that involves REBs from 7 of the BCEHI partners. This process enabled the research team to submit ONE application to ONE REB for a full board review and then 5 other REBs will utilize those documents (application, review and approval). The remaining REB is conducting a parallel full board review, using the same application documents as submitted to the collaborative process.
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# Next steps: 2012-13

- ▶ Draft working model (see flowchart)
- ▶ Models created for minimal and above minimal risk studies (MR WG formed; AMR WG forming)
- ▶ Common application content vs 1 application (WG forming)
- ▶ Common ICF template expansion from UBC/FH to other BCEHI partners whose REBS review clinical studies (WG formed)
- ▶ Reciprocity agreements: enable the organizations to participate in collaborative and reciprocal review arrangements
  - 4 university agreement signed: UBC, UNBC, SFU, and Uvic
  - 8 partner agreement in development
- ▶ Education and Best Practices - WG to form in early 2013

Action: will be looking for REB members interested in participating on these various working groups (in addition to those already involved)

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