BC Ethics Harmonization Initiative

Final Evaluation Report

November 2016

Acknowledgments

The evaluation team at Reichert & Associates would like to acknowledge the many researchers, research staff, REB reviewers, REB administrators, and Senior Leaders for their willingness to participate in the evaluation.

We would also like to thank the BCEHI project team for their insight and guidance throughout the evaluation process.

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Acronyms and Abbreviations

AC	Advisory Committee
BCCA	BC Cancer Agency
BCEHI	BC Ethics Harmonization Initiative
CWHC	Children's and Women's Health Centre
FH	Fraser Health
IH	Interior Health
MSFHR	Michael Smith Foundation for Health Research
NH	Northern Health
PHC	Providence Health Care
REB	Research Ethics Board
RFP	Request for Proposal
SL	Senior Leaders
SC	Steering Committee
SFU	Simon Fraser University
UBC	University of British Columbia
UNBC	University of Northern BC
UVic	University of Victoria
VIHA	Island Health
WG	Working Group

Executive Summary

This is a summative evaluation that examines the governance, operation, and outcomes of Phase II of the BC Ethics Harmonization Initiative (BCEHI) (2011 to 2016).

The Michael Smith Foundation for Health Research (MSFHR) provided funding and project management support for the BCEHI until March 31, 2016 and this evaluation was conducted on their behalf. At the time of this report, MSFHR has agreed to provide two awards to support the initiative's ongoing management, growth, and sustainability.

About the Evaluation

The purpose of the evaluation was to document and assess the BCEHI's operation and identify strengths, challenges, and lessons learned. The evaluation also examined the extent to which the initiative achieved its intended outcomes and comments on its future sustainability.

The evaluation used a mixed methods research design, which included an online survey (n=220), a review of project documents (n=90), and in-depth interviews with key stakeholders (n=27). The following questions guided the evaluation:

1. How has the initiative been operated and implemented?
2. How successful has the initiative been in engaging appropriate stakeholders?
3. To what extent has the initiative achieved its intended outcomes?
4. To what extent are the outcomes of the project sustainable?

About the BC Ethics Harmonization Initiative (BCEHI)

The BCEHI is a collaboration between eight partner organizations, including: Fraser Health, Interior Health, Island Health, Northern Health, Simon Fraser University, University of British Columbia[1], University of Northern British Columbia, and University of Victoria.

The overarching goal of BCEHI is to make BC a more attractive environment for research activity through the creation of coordinated and efficient processes that facilitate multi-jurisdictional human health research. The initiative's key objectives are to:

- Improve the timeliness and efficiency of the ethics review processes
- Improve the system effectiveness for health research ethics review
- Facilitate maximal reciprocity between BC institutions for the ethical review of health research conducted within BC

[1] In the context of the BCEHI, the University of British Columbia represents the affiliated UBC Behavioural and Clinical Research Ethics Boards as well as Providence Health Care, BC Cancer Agency, Children's and Women's Health Centre of BC.

Background

Initial Planning and Consultation

Health research stakeholders across BC identified the need for an effective, coordinated, provincial approach to the ethical review of studies involving human subjects.

In 2007, with the endorsement of the Ministry of Health and Ministry of Advanced Education, MSFHR agreed to facilitate a process to explore options for harmonizing review processes across British Columbia's disparate research ethics boards. A task force was established to determine the focus and scope of the ethics harmonization initiative, and its recommendations were released in February 2008.

BCEHI - Phase I

In 2010, a consortium of three BC universities (Simon Fraser University, the University of British Columbia, and the University of Victoria) submitted a proposal to develop a provincial collaborative approach to ethical review of human research. A report on Phase I activities was submitted in April 2011, and included recommendations for moving forward with developing a harmonized approach for ethics review in BC.

BCEHI - Phase II

In 2011, MSFHR provided funding for Phase II of the BCEHI and the initiative expanded to include eight partner institutions: Fraser Health, Interior Health, Island Health, Northern Health, Simon Fraser University, University of British Columbia, University of Northern British Columbia, and University of Victoria. A Steering Committee was created to govern the initiative and a director was hired to lead operations. Phase II centered on three key components:

- Strengthening the initiative through networking and leadership
- Developing effective and sustainable collaborative review models and resources
- Building capacity and education to implement and sustain the initiative

Evaluation Findings

How was the initiative operated and implemented?

Effectiveness of initial BCEHI operations (2011-2014)

During the first two years of operation, the initiative experienced delays in terms of meeting its deliverables. Stakeholders who participated in the evaluation process identified that varied levels of decision-making capacity of the Steering Committee members and a lack of clear direction and leadership at the Steering Committee level contributed to this slow progress. With agreement of the partner organizations, the BCEHI was restructured in April 2014 in an effort to improve progress:

- MSFHR assumed project management responsibility for the BCEHI.
- The Steering Committee was dissolved.
- Decision-making authority became the responsibility of a **Senior Leaders** group composed of Vice Presidents of Research (or their designates) from each partner institution.

- An **Advisory Committee** was formed in May 2014 to guide the development and operationalization of two harmonized review models (Minimal Risk Model and Above Minimal Risk Model).

Effectiveness of BCEHI operations following the initiative's re-structuring (2014-2016)

Stakeholders reported that the restructuring in 2014 was effective and resulted in a positive change for the initiative. A strength of the Advisory Committee is that it is composed of members who are deeply ingrained in the ethics review process and have practical insight into how a model can be implemented on the ground. Advisory Committee members also noted that the BCEHI project team (consisting of the MSFHR Manager and BCEHI Project Coordinator) provided a strong backbone of support for the initiative.

BCEHI Key Accomplishments to date

Based on a review of key project documents and an analysis of qualitative data from in-depth interviews and open-ended survey responses, the following key accomplishments of the BCEHI were highlighted:

- ✓ **Developed a harmonized approach to ethics, including two working harmonized review models.** The initiative successfully developed a harmonized approach to ethics, which included key components such as the BC Research Ethics Review Reciprocity Agreement that was signed in April 2013 by all partner institutions, a Harmonized Minimal Risk Ethics Review Model, and a Harmonized Above Minimal Risk Ethics Review Model.
- ✓ **Piloted the Harmonized Minimal Risk and Above Minimal Risk Ethics Review Models.** The Minimal Risk Model was piloted between December 2014 and July 2015; 26 studies were included in the pilot. The Above Minimal Risk Ethics Review Model was piloted in June 2015 but very few studies have met the criteria for review. As a result, the partners agreed to use and monitor the effectiveness of the model.
- ✓ **Evaluated the pilot implementation of the Harmonized Minimal Risk Model.** The evaluation, which was finalized in January 2016, provided a review of the effectiveness of the Minimal Risk model during its eight-month pilot implementation. The evaluation revealed that researchers found the harmonized model easy to use while reviewers found the model saved them time by allowing them to share feedback with other REBs. The evaluation recommended adoption of the model and the partner organizations approved the model's operationalization.
- ✓ **Created a platform for widespread stakeholder communication (BCEHI website).** With the support of the BCEHI project team, MSFHR contributed their communications staff to develop the BCEHI website, providing the initiative with a platform to communicate pertinent information to key stakeholders.
- ✓ **Increased collaboration and trust between institutions.** Significant progress was made in terms of relationship-building between institutional REBs. Evaluation data revealed that all committee and working group members agreed that the BCEHI improved relationship-building between partner institutions. The majority of Senior Leaders, REB administrators, REB reviewers, and research staff were also satisfied with the progress made towards increasing mutual trust among the BCEHI partner institutions.

How successful was the initiative in engaging appropriate stakeholders?

Overall, the BCEHI was able to effectively engage stakeholders throughout the multi-year initiative, although this differed to some extent across stakeholder groups.

Survey data indicates that a large majority of stakeholders are aware of the BCEHI. Of the 220 participants who began the final evaluation survey, **88% were familiar with the BCEHI.**

However, a need to increase the research community's awareness of the BCEHI also surfaced in written survey responses and in-depth interviews.

The website is intended to be the BCEHI's public face. Yet, survey responses revealed that only 32% of researchers and research staff had visited the BCEHI website. 85% of those who had visited the website found it be effective.

To what extent did the initiative achieve its intended outcomes?

The overarching goal of the BCEHI is to make BC a more attractive environment for research activity through the creation of coordinated and efficient processes that facilitate multi-jurisdictional human health research. **Three-quarters of survey respondents expressed a belief that the BCEHI was having a positive effect on making BC a more attractive research environment.**

The initiative also made progress towards its three primary objectives:

Objective 1: Improve the timeliness and efficiency of the ethics review processes

Evaluation findings indicate that the initiative had a positive impact on the timeliness and efficiency of the ethics review process.

Researchers expressed appreciation for receiving a single set of provisos, with many stating this ensures they do not receive "*multiple comments based on multiple reviewers*" or "*contradictory feedback*" from different REBs. Survey data revealed that the majority of researchers who submitted an application for harmonized ethics review had an overall positive experience with the harmonized ethics review process.

However, approximately one quarter of respondents did not rate the harmonization process favourably. Open-ended responses from these stakeholders indicated that more information and education about the process was needed.

Objective 2: Improve the system effectiveness for health research ethics review

Stakeholders reported that progress has been made in terms of system effectiveness for health research ethics review. When asked to rate the progress the BCEHI has made in terms of improving system effectiveness, the mean rating was 3.4 out of 5; comparatively, this indicator's rating in 2013 was 1.96 out of 5.

Specific system improvements identified by stakeholders ranged from improved communication and collaboration between institutions to a reduction in the duplication of efforts, particularly for researchers. REB reviewers and administrators also noted that REBs communicate and collaborate with one another more effectively as a result of the BCEHI.

Objective 3: Facilitate maximal reciprocity between BC institutions for the ethical review of health research conducted within BC

Stakeholders noted that signing the BC Ethics Review Reciprocity Agreement in 2013 was a key milestone towards facilitating maximal reciprocity.[2] However, in practice many stakeholders observed that minimal risk harmonized reviews tend to be "*more collaborative than reciprocal.*"

To what extent is the BCEHI sustainable?

Evaluation data suggests that the majority of stakeholders believe that sustaining the BCEHI is both desirable and possible: 85% of survey respondents believed it was very desirable that the BC ethics review harmonization be sustained. Further, 93% of participants believed that ongoing institutional participation was sustainable and 90% of survey participants believed the harmonized models are at least somewhat sustainable in their current form.

Discussion

Strengths of the Initiative

The initiative was able to change course when necessary. The ability to change course when it became evident that the initiative was not progressing as intended was vital to the initiative's ability to move forward.

The BCEHI built support from the ground up. The BCEHI was a grassroots effort involving those who were most affected by the change to harmonized processes. Building the initiative from the ground up provided stakeholders with an avenue to shape change in a way that made the most sense for the diverse stakeholders involved and promoted acceptance of new processes.

The Advisory Committee was committed to moving the initiative forward. The Advisory Committee is composed of a highly committed group of stakeholders who worked intently and collaboratively on developing and implementing the harmonized models. Interviewees highlighted the Advisory Committee's commitment and ability to collaborate effectively as key enablers of the initiative's progress.

The initiative had a strong backbone of support from the BCEHI team. Finally, several Advisory Committee members and Senior Leaders acknowledged the major support provided by the BCEHI project team. Stakeholders agreed that project management support helped keep the initiative on track and on task, and focused on making progress towards the BCEHI goals.

Challenges Faced and Lessons Learned

A) Challenge: The initial governance structure was not an effective model. Stakeholders acknowledged that there was a substantial lack of authoritative leadership during the early phases to push the initiative forward.

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[2] According to the BC Ethics Review Reciprocity Agreement (2013), maximal reciprocity is defined as "*the highest level of reciprocity acceptable to a Party for its ethical review requirements for a Multi-Jurisdictional Study, based upon the relationship of the relevant Parties to each other, the perceived risks of the study, the relevant Parties' institutional policies, and any other considerations and judgments that a Party may deem, in its sole discretion, to be relevant.*"

Lesson learned: The project needed external facilitation. Many interviewees believed that if an external organization had facilitated the project from its initiation, some of the challenges the Steering Committee encountered may have been mitigated.

B) Challenge: REBs have different lenses and considerations when conducting ethics reviews. Many REB members and Senior Leaders observed that there is a fundamental difference between health authorities and academic institutions: while health authorities "*exist to deliver service to patients*," academic institutions "*exist to do research*." The different lenses that academic institutions and health authorities bring to ethical reviews was seen to impede progress towards achieving higher levels of reciprocity in harmonized reviews.

Lesson learned: Achieving higher levels of reciprocity in ethics harmonization takes time and requires ongoing trust and relationship-building between partner institutions.

C) Challenge: Information about harmonization was not widely disseminated to the research community. Many researchers reported not knowing about ethics harmonization until their REB administrators informed them about the opportunity for harmonization. Additionally, many researchers and research staff were not aware that ethics harmonization does not include institutional approval, and that this requires an additional application once the ethics review is complete.

Lessons learned: The initiative would have benefitted from a communications plan to ensure that the research community was well-informed and educated about the ethics harmonization process.

D) Challenge: Stakeholders reported the lack of a shared technology platform was a barrier to achieving timely and efficient harmonized ethics review.

Lesson learned: Technological infrastructure was needed early in the process to support the development and implementation of harmonization of research ethics review.

Opportunities for Development

A synthesis of evaluation data helped identify the following recommendations:

- **Recommendation: Sustain the Advisory Committee and continue to hold in-person meetings with initiative stakeholders.** It is suggested that the Advisory Committee holds at least one in-person meeting per year to help maintain relationships between institutional partners and retain institutional knowledge around ethics harmonization.

- **Recommendation: Implement a data collection/evaluation plan for harmonized studies.** This will help partner institutions evaluate the effectiveness of the harmonized ethics review process and support quality improvement efforts to determine if/when changes to the models need to be made.

- **Recommendation: Continue to support the development and implementation of a common technology platform.** At the time of writing, MSFHR has agreed to provide funding to develop a shared workspace on the UBC RISe system for the conduct of harmonized ethics review. It is recommended that this effort continues and is supported by all partner institutions moving forward.

- **Recommendation: Develop and implement a communications plan.** Given the communication challenges that were identified in the evaluation data, key stakeholders may consider developing a communications plan to increase awareness of the harmonization initiative throughout the research community.

- **Recommendation: Develop and implement an education/knowledge translation plan**. In addition to a communication plan, several stakeholders suggested that an education plan be developed to provide all stakeholder groups with consistent information about the criteria for harmonized reviews, the harmonized application and review process, and how harmonization may impact their work.

- **Recommendation: Develop a plan to engage additional institutions across the province in a dialogue about participating in the BCEHI.** Several institutions are not yet involved in the initiative, including the First Nations Health Authority and several other academic institutions (e.g. Thompson Rivers University, University of the Fraser Valley, Trinity Western University, Kwantlen Polytechnic University, Selkirk College, BCIT, etc.). The Phase II Strategic Plan identified expanding participation in the BCEHI as a priority focus area for the second half of the initiative and many stakeholders confirmed that this is an important area for future development.

Conclusion

Evaluation findings suggest that the BCEHI has made considerable progress towards achieving its intended outcomes. While there are still areas that require further development, the BCEHI has accomplished much in recent years and stakeholder feedback suggests general satisfaction with the direction of the initiative.

Moving forward, MSFHR has funded a one-year BCEHI Project Coordination function to support the initiative's ongoing management, and is providing funding to support the development of a shared technology platform. Advisory Committee members have affirmed their commitment to ethics harmonization and indicated that they plan to meet indefinitely to maintain the momentum that has been achieved in the area of harmonized ethics review. Ongoing sustainability planning for the BCEHI will be an important consideration for senior leadership at the partner institutions. Leaders will need to develop a plan to ensure the achievements of the BCEHI can be sustained in the longer-term.

1. Introduction

This is a summative evaluation that examines the operation and outcomes of the second phase of the BCEHI (2011 to 2016). The evaluation used a mixed methods research design to identify key accomplishments, challenges, learnings, opportunities for development, and considerations for sustainability.

The BCEHI is a collaboration between eight partner organizations, including: Fraser Health, Interior Health, Island Health, Northern Health, Simon Fraser University, University of British Columbia[3], University of Northern British Columbia, and University of Victoria.

The overarching goal of BCEHI was **to make BC a more attractive environment for research activity through the creation of coordinated and efficient processes that facilitate multi-jurisdictional human health research**. The Michael Smith Foundation for Health Research (MSFHR) provided funding and project management support for the BCEHI until March 31, 2016[i]. At the time of this report, MSFHR has agreed to provide providing two awards to support the initiative's ongoing management, growth and sustainability.

This report is organized into four sections. The remainder of section one provides an overview of the evaluation approach, questions, and methodology. This is followed by an overview of the BCEHI, including the history, key objectives, and organization of the initiative. Section two presents the evaluation findings, which include information about the operation of the initiative, stakeholder engagement, and progress towards initiative objectives. Section three contains a discussion about the evaluation findings and identifies key strengths, challenges, lessons learned, and opportunities for development. The final section contains a brief conclusion.

1.1 About the Evaluation

Evaluation Purpose and Approach

The purpose of the evaluation was to document and assess the BCEHI's operation and identify key strengths, challenges, and lessons learned. The evaluation also examined the extent to which the initiative achieved its intended outcomes, and comments on its future sustainability. This is intended to be the third and final evaluation of the BCEHI project.

The evaluation was designed to provide the BCEHI stakeholders with information to help guide future work. The primary intended users of the evaluation findings include the BCEHI project team, the Michael Smith Foundation for Health Research, Senior Leaders, and BCEHI Advisory Committee members. Evaluation findings may also be of interest to other stakeholders impacted by ethics harmonization, including REB reviewers, REB administrators, and the larger research community.

Throughout the BC Ethics Harmonization Initiative, a variety of stakeholder groups were engaged and participated in the initiative including the development and implementation of harmonized

[3] In the context of the BCEHI, the University of British Columbia represents the affiliated UBC Behavioural and Clinical Research Ethics Boards as well as Providence Health Care, BC Cancer Agency, Children's and Women's Health Centre of BC.

models. The evaluation was therefore designed to include a wide range of stakeholder participation throughout the data collection process. Evaluation information was gathered from the following key stakeholder groups:

- Researchers
- Research administrators (research managers, research coordinators etc.)
- Research Ethics Board (REB) Members
- REB administrators
- Senior leaders of partner institutions (e.g. VP of Research)
- BCEHI staff
- BCEHI Steering Committee, Advisory Committee, and Working Group members

Key Evaluation Questions

Based on the initiative and evaluation objectives, the following questions guided the evaluation:

1. How has the initiative been operated and implemented?
2. How successful has the initiative been in engaging appropriate stakeholders?
3. To what extent has the initiative achieved its intended outcomes?
4. To what extent are the outcomes of the project sustainable?

Evaluation Methods

A mixed methods approach was used to evaluate the BCEHI's implementation, impact, and opportunities for development. Evaluation findings are based on an analysis of survey data, qualitative data from key informant interviews, and a review of project documents. Evaluation data collected through surveys and interviews were reviewed alongside supporting project documents. More detailed information about the evaluation methods is provided below.

Online Evaluation Survey

The evaluation team worked closely with the BCEHI project team to develop an online survey that was designed to measure stakeholder awareness of the initiative, perceptions of the ethical review process, experiences with the harmonized review models, key successes and challenges of the initiative, and satisfaction with the initiative. The survey also asked stakeholders to rate the degree of progress made towards the initiative's objectives, and asked them to indicate how desirable it was that the initiative continue. The evaluation team built logic and branching into the survey to ensure that questions were relevant for each stakeholder group (e.g. researchers did not receive the same questions as REB administrators). Consequently, not all stakeholder groups received all survey questions and as a result the total number of respondents for each question differs.

A list of stakeholders was developed by the BCEHI project team in conjunction with administrators from each partner institution.[4] This list was then provided to the evaluation team, who sent out survey invitations to all identified stakeholders (n=637). The evaluation team hosted the survey

[4] The sampling frame included researchers who had submitted an application for ethics review within the past three years (based on administrative data maintained by partner institutions), research administrative staff, REB members, REB administrative staff, senior leaders, past and current committee members, BCEHI staff, and other key stakeholders that were identified by the BCEHI project team, Advisory Committee members, and partner institutions.

questionnaire on the *Fluidsurveys* online survey platform, and configured the software's anonymity settings to ensure the survey was completely anonymous and all survey responses remained unidentifiable. This setting ensured email addresses were hidden and unable to be viewed once the survey invitation was sent, and also prevented the software from collecting information about respondents' IP addresses.

Prior to being launched, the survey was piloted with a sample of stakeholders (approximately 10% of each stakeholder group) in early May. The survey was then launched on May 30, and closed on July 2, 2016. In total, 220 respondents participated in the survey (see Table 1 below), for a response rate of 35%. Of those who began the survey, 198 participants (90%) completed the survey. Data from the responses of the 22 participants who partially completed the survey were included in the analysis where possible.

Table 1 – Evaluation survey participants

Stakeholder Group	Respondents in Sample	Survey Participants	Response Rate by Stakeholder Group
Researchers & research administrators	460	152	33%
REB members[5]	141	43	30%
REB administrators	28	19	68%
Senior leaders	8	6	75%
Total	637	220	35%

63% of survey respondents indicated they were affiliated with academic institutions, while 32% reported their primary institution as a health authority. The remaining 5% selected 'other.' See Appendix A for a more detailed breakdown of institutional affiliation.

Key Informant Interviews

The evaluation team, in collaboration with the BCEHI project team, identified key informants to include in the in-depth interview process. In addition, participants who completed the online survey were re-directed to a separate page and invited to participate in the interview process; those who were interested were able to opt-in and provide their contact information. The evaluation team sent interview requests to all stakeholders who were identified by the BCEHI project team or who opted-in through the online survey (n=43).

27 interviews were conducted via telephone between June and July 2016 with:

- 12 researchers/ research staff
- 5 Advisory Committee members[6]
- 4 REB members

[5] The evaluation notes that REB members may also be actively engaged in research activities; survey respondents were therefore asked to complete the survey based on the role that is *most relevant* to their experience in the context of research ethics.
[6] Two Advisory Committee members were also members of the Steering Committee.

- 3 Senior Leaders[7]
- 3 REB staff (non-committee members)

The interviews were semi-structured and included open-ended questions relating to the initiative's development, operation, challenges, significant changes, and key accomplishments. A separate interview guide was tailored for each stakeholder group to ensure that interview questions were relevant to stakeholders' positions. An interview guide was forwarded to interviewees in advance of their interview. Interviews ranged between 20 minutes to 1 hour. Verbatim notes were taken during the telephone interviews to ensure in-depth qualitative data was available to supplement the survey data.

In this report, interviewees' roles have been left intentionally broad in order to protect the confidentiality and anonymity of the respondent.

Document Review

The evaluation reviewed approximately 90 project documents. The review included key project planning documents (e.g. work plans, activities forecasts), briefing notes, committee and working group meeting agendas, meeting minutes, previous evaluation reports, communications materials, and project material (e.g. harmonized model documentation, guidance, etc.).

Evaluation Limitations

While efforts were made to increase the response rate of the evaluation survey and qualitative interviews, the voluntary nature of the survey and interview participation mean that non-response bias may limit the generalizability of the findings reported here. Especially for web-based surveys that typically boast lower response rates than 'traditional' modes of survey administration, it is possible that the experiences of those who participated in the evaluation are systematically different than those who did not.[ii] In particular, the relatively small sample frame for certain institutions – including Northern Health, University of Northern British Columbia, Children and Women's Health Centre, and Fraser Health – pose issues for both statistical as well as qualitative comparisons of the experiences of different institutions. However, multiple streams of participant input and the robust overall response rate of both the evaluation survey as well as the qualitative interviews lessen the possibility of this kind of bias.[iii]

Additionally, as participant input is based on personal experience, the length of time between aspects of the initiative (i.e. transition from Steering Committee to Advisory Committee) and evaluation participation can pose challenges for the evaluation findings. The potential for recall bias increases as the time between the events of interest and evaluation participation also increases.[iv] Likewise, when conducting in-depth interviews there is a potential for response bias (i.e. social desirability bias) as many key stakeholders are closely involved with the project. This can make it difficult to be objective when providing information. Qualitative interview data was therefore reviewed alongside survey data, previous evaluation data, and project documents to minimize the impact of potential response bias.

Finally, a wording change in the 2014 evaluation survey regarding the initiative's progress towards meeting its goals means that a direct comparison cannot be made between all three evaluations.

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[7] One Senior Leader was also a member of the Steering Committee.

The present evaluation followed the original phrasing of the questions from the 2013 evaluation in order to maximize the time between evaluative comparisons.

1.2 About the BC Ethics Harmonization Initiative

The BCEHI is a collaboration between eight partner organizations, including: Fraser Health, Interior Health, Island Health, Northern Health, Simon Fraser University, University of British Columbia, University of Northern British Columbia, and University of Victoria. These major research institutions and provincial health authorities conduct more than 80% of BC's human subject ethics reviews.

The BCEHI aimed to encourage multi-jurisdictional human health research through the creation of efficient, coordinated, and high-quality processes. Specifically, the initiative prioritized the following objectives:

- Improve the timeliness and efficiency of the ethics review processes
- Improve the system effectiveness for health research ethics review
- Facilitate maximal reciprocity[8] between BC institutions for the ethical review of health research conducted within BC

Background

Initial Planning and Consultation Phase

In January 2007, a BC Ethics Harmonization Task Force was created to explore a coordinated provincial approach to ethical approval and provide guidance in developing a provincial approach to ethics review.[v] Later that year, MSFHR conducted an environmental scan of Research Ethics Boards (REBs) in British Columbia at the request of health research stakeholders and with the support of the Ministry of Health and the Ministry of Advanced Education. The Task Force was responsible for reviewing and making recommendations about the deliverables for the environmental scan, workshop, and subsequent report. The 14 members of the Task Force represented health authorities, universities, research institutes and teaching hospitals, and community research.[9]

In October 2007, a report containing the results from the environmental scan was published.[vi] The scan revealed that REBs approach multi-site studies differently and are variously challenged by a lack of human and financial resources, diverse representation from communities and disciplines, and effective technological platforms. Importantly, the environmental scan identified a perception that the quality of the review process varies across institutions. Consequently, it found that this has a negative impact on collaboration and reciprocity between organizations. Overall, the scan found

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[8] The BC Ethics Review Reciprocity Agreement (2013) clarified the terms for institutions to establish a coordinated approach to the review of multi-jurisdictional studies. This document defines maximal reciprocity as, "*the highest level of reciprocity acceptable to a Party for its ethical review requirements for a Multi-Jurisdictional Study, based upon the relationship of the relevant Parties to each other, the perceived risks of the study, the relevant Parties' institutional policies, and any other considerations and judgments that a Party may deem, in its sole discretion, to be relevant.*"

[9] Organizations represented included: Interior Health Authority, Vancouver Coastal Health, BC Cancer Agency, BC Medical Services Foundation (Vancouver Foundation), Ministry of Advanced Education, University of British Columbia, Genome BC, Ministry of Health, University of Victoria, Simon Fraser University, Providence Health Care.

that stakeholders felt there was value in working to develop a provincial approach to ethical reviews, but there was no consensus as to how this would be best achieved.

The following month, the MSFHR hosted an introductory workshop with researchers, Vice Presidents and Directors of Research, and Chairs and Managers of REBs from key research institutions across British Columbia. The results from the environmental scan were presented and attendees had the opportunity to discuss how to move forward with harmonization.

BCEHI - Phase I

In 2010, a consortium from Simon Fraser University, the University of British Columbia, and the University of Victoria submitted a proposal to the Michael Smith Foundation to develop a coordinated approach to ethical review of human research. The proposal was approved and funding was provided. A *Health Research Reciprocity Pilot Project* working group was formed and a Project Manager was hired. Based on this proposal, three pilot projects involving three or more research ethics boards were completed that utilized different approaches to collaborative review. Following submission of a report in April 2011, the consortium expanded to eight partners.

BCEHI - Phase II

Phase II of the BCEHI was approved for funding in the fall of 2011 and the initiative expanded to eight partners (Fraser Health, Interior Health, Island Health, Northern Health, Simon Fraser University, University of British Columbia, University of Northern British Columbia, and University of Victoria). This phase centered on three key components[vii]:

- Strengthening the initiative through networking and leadership
- Developing effective and sustainable collaborative review models and resources
- Building capacity and education to implement and sustain the initiative

Original organization of the initiative (2011-2014)

At the beginning of the second phase, project infrastructure was put in place. The initiative was governed by a Steering Committee composed of senior leaders from the partner organizations. A Director reported to the Steering Committee[10] and was responsible for the operation of the BCEHI. Two working groups, the Education and Best Practices Working Group and the Minimal Risk Criteria Working Group, were also formed (Appendix B contains an organizational chart of the original structure of the initiative).

In April 2014, the BCEHI Director position became vacant and the initiative was re-structured.

Organization of the initiative post-restructuring (2014-2016)

With approval of the BCEHI partners, MSFHR assumed project management responsibility for the BCEHI and the Steering Committee was dissolved. Decision-making authority became the

[10] The Steering Committee included one representative from each of the eight partner institutions, an alternate representative from each institution, the BCEHI Director (non-voting status), and a representative from MSFHR (observer status).

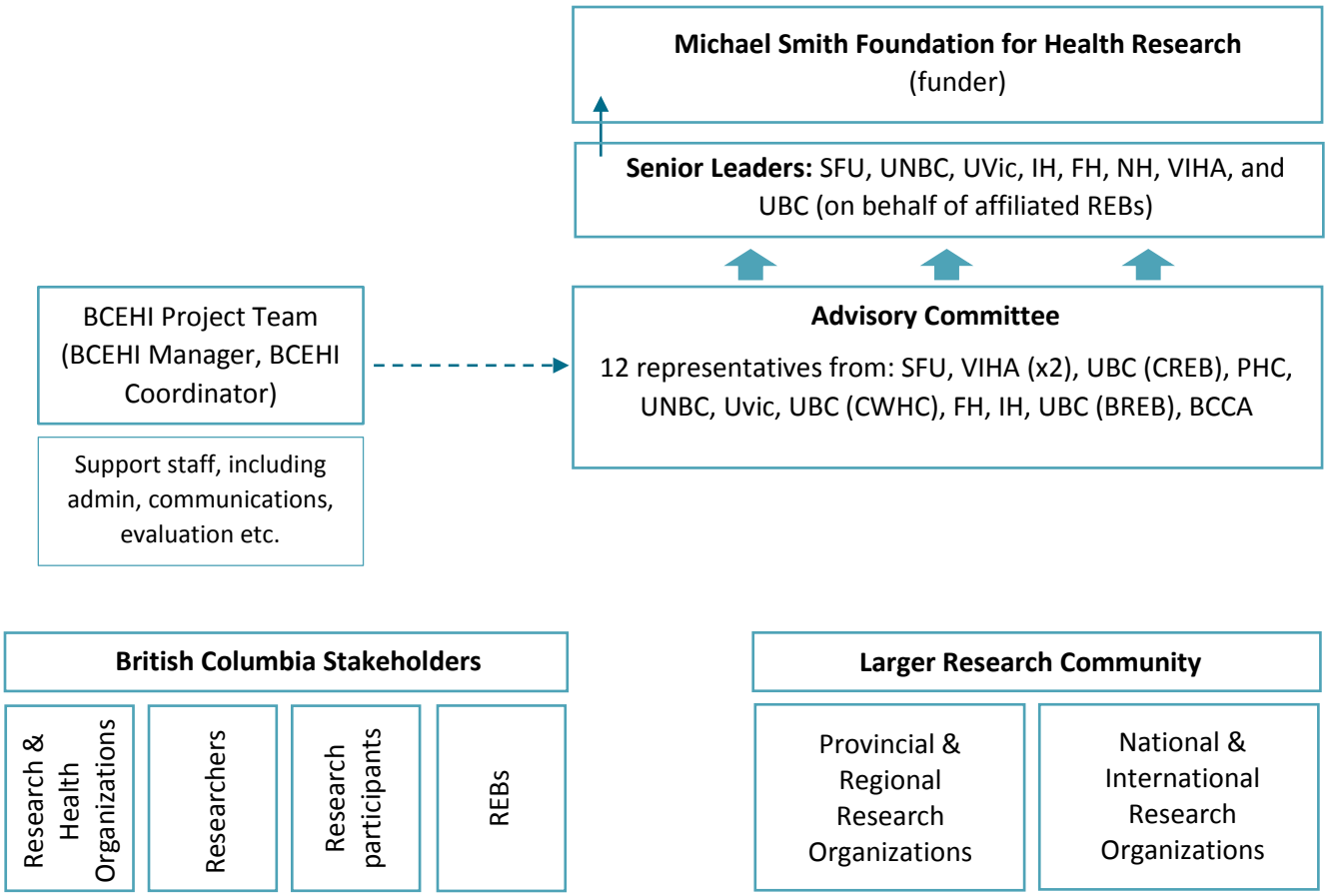
responsibility of a **Senior Leaders** group with representation from Vice Presidents of Research (or their designates) from each partner institution.

An **Advisory Committee** was formed in May 2014 to guide the development and operationalization of two harmonized review models (Minimal Risk Model and Above Minimal Risk Model). The Advisory Committee is composed of members who represent a variety of geographical areas across the province, as well as specific areas of expertise, experience, and institutional perspectives.[11] The Advisory Committee members provide subject matter expertise, advice, and recommendations to help support the BCEHI in achieving its intended outcomes. As the Advisory Committee did not have decision-making authority, the Committee made recommendations to the Senior Leaders group. In Phase II, the Advisory Committee focused on:

- Developing and implementing BC harmonized ethics review models
- Considering technology solutions to support centralized ethics application and review processes
- Increasing outreach and collaboration within partner organizations to build capacity and awareness about the model

[11] The 12 members of the Advisory Committee include representatives from BC Cancer Agency, Fraser Health, Island Health, Interior Health, Providence Health Care Research Institute, Simon Fraser University, University of British Columbia, University of Northern British Columbia, UBC Children's & Women's Research Ethics Board, and University of Victoria.

Fig. 1 – Organization of the BCEHI (2014-2016)[viii]



2. Evaluation Findings

2.1 How was the initiative operated and implemented?

Effectiveness of initial BCEHI operations (2011-2014)

The initiative experienced delays in terms of meeting its deliverables during the first two years of operation. While collaboration between institutions increased and movement towards reciprocity was achieved, the initiative struggled to maintain momentum. Stakeholders who participated in the evaluation process identified that challenges with the decision-making capacity of the Steering Committee members and a lack of clear direction at the Steering Committee level contributed to this slow progress.

Given that Committee members came from a wide range of leadership positions, some with substantial decision-making capacity and others with very little, interviewees noted the Committee struggled to reach consensus around key initiative deliverables and decision-making was often delayed.

Findings from the evaluation survey supported interview findings that the Steering Committee had room for improvement. When Steering Committee members were asked to rate the effectiveness of the committee, the average rating was 5.1 out of 10[12].

Although the Steering Committee struggled to make progress towards the initiative's goals, many stakeholders stated that the Committee was useful in strengthening relationships and trust between partner institutions. The Committee also helped improve partners' understanding of how each institutional REB operates. As one Steering Committee member reflected, "*I noticed how much we didn't know about each other. We were working in different spheres of expectations in our communities and institutions*."

> *"Time was needed to build trust amongst the health organizations and academic institutions. Sometimes it felt like process was interfering with progress. However, we first needed to understand where each member was coming from: i.e. the burden of risk when conducting research, the priority research has in each organization's operations, and the varying resources each organization has to put toward research."*
>
> *– Steering Committee member*

Despite these challenges, at a meeting in 2013 REB Chairs determined that a Made for BC centralized model was the preferred approach to harmonization of ethics. This direction was endorsed by the Steering Committee.

[12] Using a ten-point scale where 1 represented "very ineffective" and 10 represented "highly effective."

Effectiveness of BCEHI operations following the initiative's re-structuring (2014-2016)

As noted previously, MSFHR restructured the initiative with agreement from the partner institutions. The main elements of this restructuring were:

1) MSFHR assumed project management responsibility.
2) A 'Senior Leaders' group of Vice Presidents of Research (or their designates) was formed to establish decision-making authority.
3) The Steering Committee was dissolved and a new Advisory Committee was formed that included REB managers, coordinators, and REB chairs who were to act as a working group and guide the development and operationalization of two harmonized review models (Minimal Risk Model and Above Minimal Risk Model). In this new structure, the Advisory Committee made recommendations to the Senior Leaders who were responsible for decision-making authority.
4) The BCEHI administrative assistant transitioned to a project coordinator role, which expanded to include providing ongoing administrative support, as well as assistance with development of documents related to the models (diagrams, guidance documents, education materials) and the development of evaluation materials for the initiative as well as coordinating collaborative ethics reviews among REBs.

These changes were designed to help stakeholders achieve a common vision and foster more substantive progress towards BCEHI deliverables. According to key stakeholders, the transition was implemented effectively and the new Advisory Committee was initiated in April 2014.

To ensure the initiative had sufficient support, MSFHR appointed a staff member (Manager) to assume project management responsibilities for the BCEHI (in-kind), with support from the BCEHI Project Coordinator (funded as part of the BCEHI). The BCEHI project team provided coordination and facilitation support to the Advisory Committee, produced education and communications materials, and developed support materials for the models, among other tasks.

MSFHR convened with the Senior Leaders group to present items for approval. MSFHR also provided in-kind support to create and maintain the BCEHI website and develop communication materials for the initiative. Stakeholders reported that the project team provided a strong backbone of support for the initiative, which "*took time and load off us as individual Advisory Committee members…we were kind of kept on task in a positive way by [the MSFHR Manager] and [the BCEHI Project Coordinator].*"

> "It was a bit more grassroots, made up of the people who were going to have to implement it. That was the successful part and we were all strategic thinkers as well."
>
> "For the most part we were people who are working in the trenches everyday around ethics applications…everyone was coming from an equal place."
>
> "I was very satisfied with the model and what we were tasked to do."
>
> *- Advisory Committee members on the new organizational structure*

Overall, stakeholders reported the transition to the Advisory Committee in 2014 was a positive change. As one interviewee reflected, "o*nce we revamped into the Advisory Committee structure, the*

work seemed to be laid out more clearly… we were able to progress the work forward better than the Steering Committee, where the roles weren't so clear." One of the strengths of the Advisory Committee was that it was composed of members who were deeply ingrained in the ethics review process and therefore had extensive insight into how a model could be implemented on the ground. All Advisory Committee members who completed the final evaluation survey (n=7) agreed that they clearly understood the mandate of the committee, the right stakeholders were involved, and that the committee was focused in its work. When asked to rate the Advisory Committee's effectiveness in meeting its objectives, the average rating from participants was 8.6 out of 10.

Once the Advisory Committee was established, stakeholders reported more rapid advancement towards a harmonized approach to ethics review. "*Real progress was made towards developing models, piloting processes and providing constructive feedback,"* wrote one survey participant.

The relationship-building and institutional collaboration that started with the Steering Committee was further enhanced through the Advisory Committee, who were able to effectively move the initiative forward.

BCEHI Key Accomplishments

Based on a review of key project documents and an analysis of qualitative data from in-depth interviews and open-ended survey responses, the following key accomplishments were highlighted:

✓ Developed a harmonized approach to ethics, including two working harmonized review models.

The initiative successfully developed a harmonized approach to ethics review. Key components included the BC Research Ethics Review Reciprocity Agreement that was signed in April 2013 by all partner institutions, and the development of two harmonized ethics review models and associated guidance documents to facilitate the models' use for relevant stakeholders.

Where previous multi-jurisdictional studies required a separate ethics application be submitted to each institution, the harmonized models enable researchers to submit a single application for ethics review when there are multiple sites/jurisdictions involved in the study. For each study, a Board of Record is established and serves as the primary authority and coordinating REB for ethical oversight. The researcher receives one set of provisos and a single Certificate of Approval.

> *"By default, we are not creating just a harmonized ethics review—the whole process is harmonized and standardized."*
>
> *– REB administrator*

Together, the Reciprocity Agreement, the two harmonized models, and the supporting documents serve as foundational pieces in the effort to harmonize multi-jurisdictional human health research ethics in BC.

✓ Piloted the Harmonized Minimal Risk and Above Minimal Risk Ethics Review Models.

Two harmonized models (Minimal Risk and Above Minimal Risk) were developed and refined by the Advisory Committee, with input from institutional colleagues, over the course of several committee meetings. The Harmonized Minimal Risk Model (Appendix C) was piloted between December 2014 and July 2015; 26 studies were included in the pilot. The Above Minimal Risk

Ethics Review Model (Appendix D) was piloted in June 2015. The number of studies that meet the criteria is small and very few studies have been piloted to date.

The models were subsequently recommended for approval by the Senior Leaders and fully operationalized.

Interview data from REB administrators suggests that the majority of institutions have incorporated the Harmonized Minimal Risk Model into their routine processes. One REB administrator wrote that the harmonized model "*has become a normalized part of our workflow and what we do*" while another confirmed, "*I don't think we could go back to a time where the process wasn't harmonized. It's hard to think about it to be honest- we've just ingrained it in our work. It's a major part of how we manage studies*."

✓ Evaluated the pilot implementation of the Harmonized Minimal Risk Model.

The BCEHI project team implemented an evaluation plan that was developed in consultation with an external evaluation consultant. The evaluation, which was finalized in January 2016, provided a comprehensive review of the effectiveness of the Minimal Risk model during its eight-month pilot implementation. In total, there were 26 studies that were piloted using the Harmonized Minimal Risk Model.

Role-specific surveys were administered to each stakeholder group involved in the harmonization process. The survey questionnaires were designed to capture information about the harmonized process from initiation to approval. 121 surveys were completed. The team also conducted 11 in-depth interviews.

The evaluation report, *Harmonized Research Ethics Review Minimal Risk Model Pilot,* indicated that researchers found the harmonized model was easy to use and reviewers reported the model saved them time by being able to share comments and feedback with other REBs. The report also stated that participation in the harmonization process promoted increased trust among REB administrators. Evaluation findings revealed a need to increase training for researchers and administrators and a need for a common technology platform to facilitate harmonized reviews. Overall, the evaluation recommended that the Minimal Risk Model be adopted, with some minor revisions across all partner institutions.

The complete evaluation report is available on the BCEHI website.

✓ Created a platform for widespread stakeholder communication (BCEHI website).

With the support of the BCEHI team, MSFHR communications staff developed the BCEHI website to ensure the initiative has a platform to communicate pertinent information to key stakeholders. The website contains an overview of the initiative, information about partner organizations, the Advisory Committee, resources and the initiative's history. It also has a section with the latest BCEHI news, and stakeholders have an option to subscribe to receive updates about the BCEHI via email. There is also a resources section that contains guidance documents, resources, and contact information to support harmonized ethics reviews.

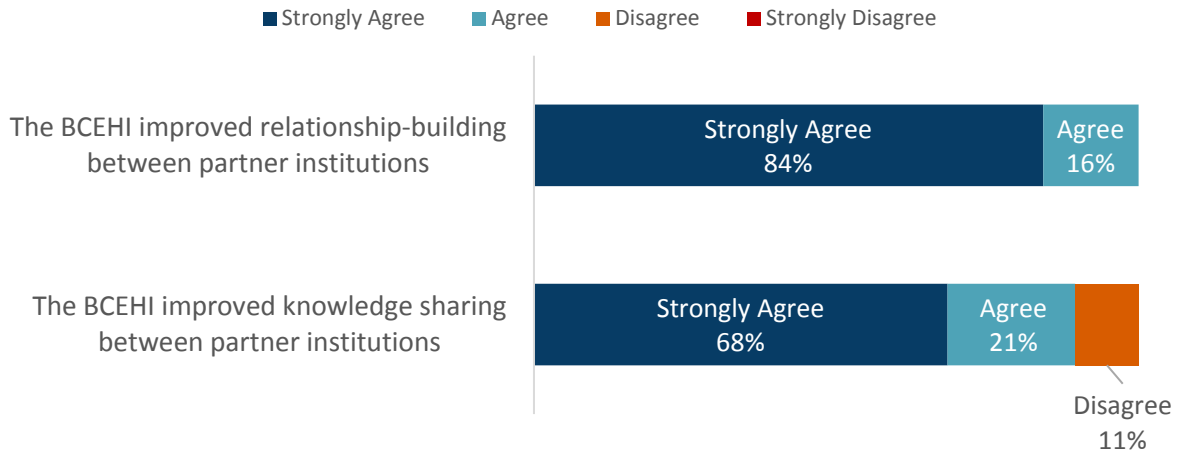
✓ Increased collaboration and trust between institutions.

Throughout the initiative significant progress was made in terms of relationship-building between institutional REBs. Many interviewees and survey participants attributed this shift to having representation from REB operational staff on the Advisory Committee, which fostered collaboration and trust between institutions. In fact, 80% of Senior Leaders, REB administrators, REB reviewers, and research staff (63 of 79) were either somewhat or very satisfied with the progress that has been made in terms of increasing mutual trust among the BCEHI partner institutions. As one REB administrator stated, "*certainly the collaboration between research institutions in the province is much better. And that's purely because people know each other and we know how each other works.*" Similarly, a Senior Leader reflected, *"The initiative has brought together the REB administrators from the main health research institutions and created a culture of trust and cooperation in ethical reviews. As time goes on, processes will become more accepted and faster as a result."*

> "Partner REB administration teams have gotten to know each other and learned how to work together very well in the last few years. This is a big accomplishment and probably does the most in terms of easing the multi-jurisdictional REB review process for the researcher." – REB staff member

As Fig. 2 shows, 100% of committee and working group members agreed that the BCEHI improved relationship-building between partner institutions, while 89% of committee members agreed that the initiative improved knowledge-sharing between institutions.

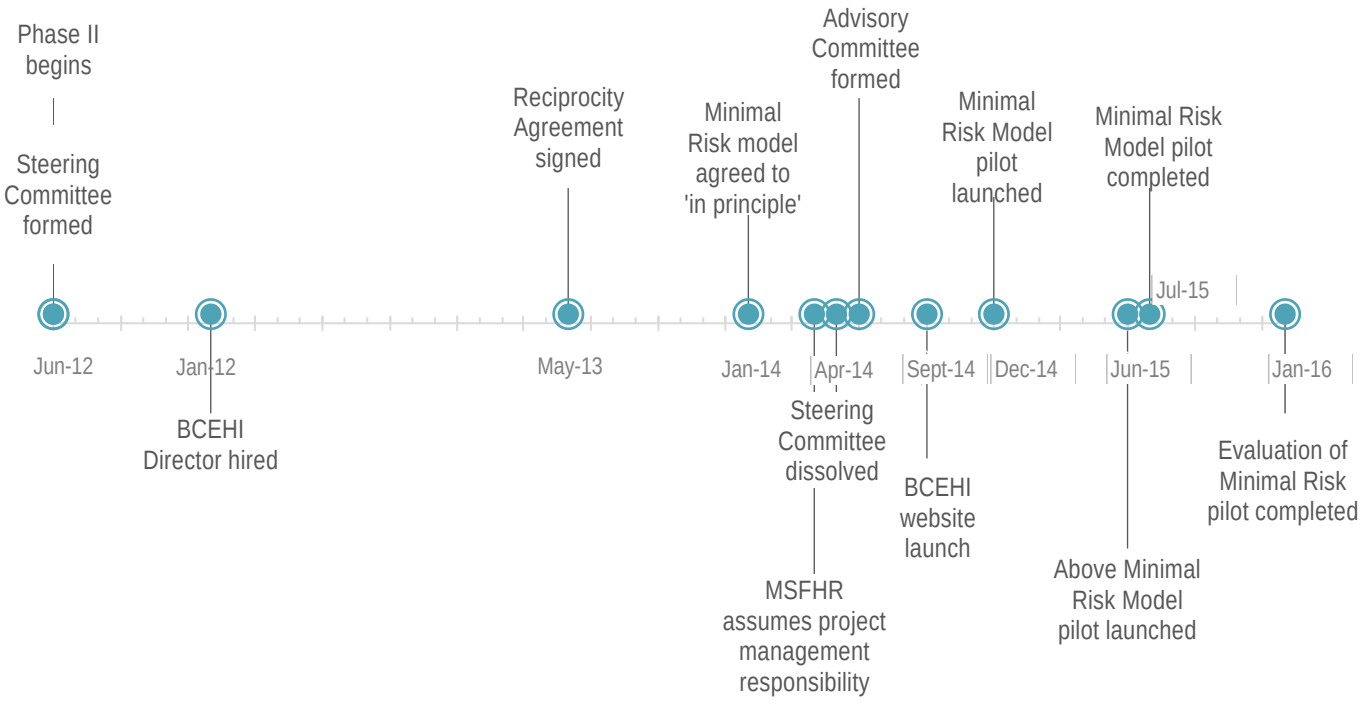
Fig. 2 - The majority of committee/working group members agree the BCEHI improved relationship-building and knowledge sharing (n=19)



According to key stakeholders, an informal "community of practice" has been created as a result of collaboration through the BCEHI. As one REB administrator commented, "*we can turn to each other and say 'we are looking to make a change— has anyone done this before?' We are all accepting change is difficult and we are working through it together.*"

Fig.3 below provides a visual timeline of the BCEHI operational milestones.

Fig.3 – Timeline of BCEHI Milestones



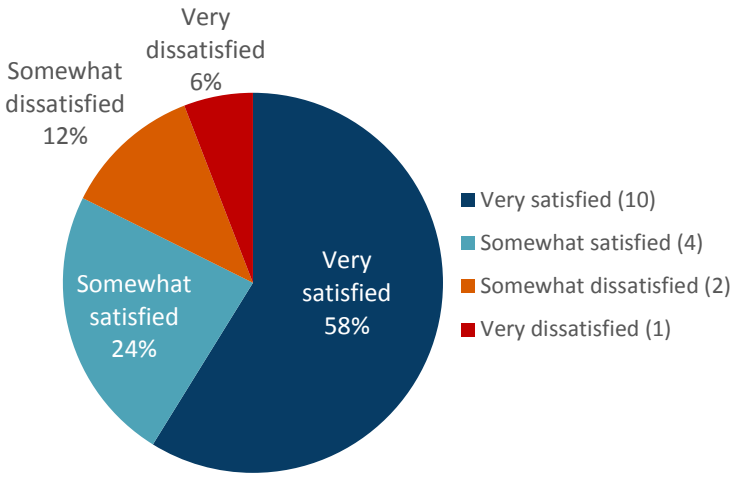
2.2 How successful was the initiative in engaging appropriate stakeholders?

Overall, the BCEHI effectively engaged stakeholders throughout the multi-year initiative, although this differed to some extent across stakeholder groups.

Committee members, particularly those on the Advisory Committee, were highly engaged and the majority reported high levels of satisfaction with their experience. 84% of Committee members agreed or strongly agreed that participating in the initiative was a valuable use of their time; the remaining 16% disagreed.

Further, as Fig.4 shows, the majority of Committee members (82%) were either somewhat or very satisfied with their

Fig. 4 - Overall, how satisfied are you with your participation in the BC Ethics Harmonization Initiative? (n=17)

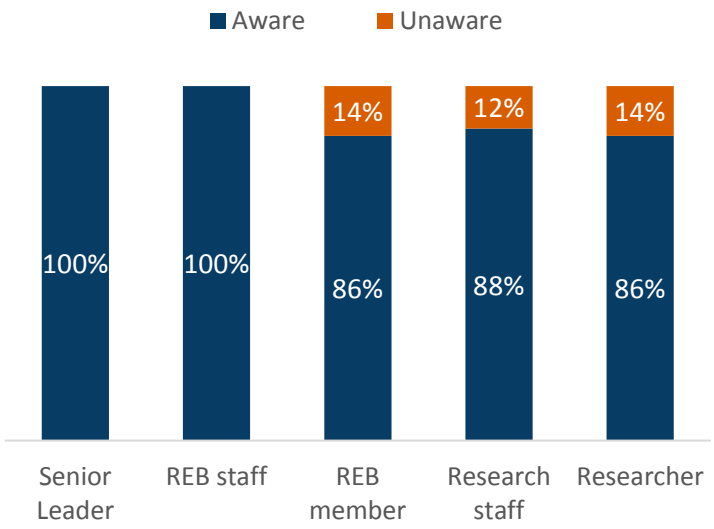


participation in the BCEHI, and the remaining 18% were dissatisfied. The participants who reported being dissatisfied with their involvement in the initiative were members of the Steering Committee.

Looking more broadly at all participants, survey data indicates that a large majority of stakeholders are aware of the BCEHI. Of the 220 participants who began the final evaluation survey, **88% were familiar with the BCEHI** while the remaining 12% were not.[13]

In terms of awareness by stakeholder groups, Fig.5 shows that all Senior Leaders and REB staff who began the survey were aware of the BCEHI. In contrast, between 12% and 14% of REB members, research staff, and researchers were *not* aware of the initiative.

Fig.5 - Stakeholder awareness of the BCEHI by stakeholder group (n=220)



An additional survey question asked all survey participants to rate the awareness of their institution's research community about ethics harmonization using a 10-point scale, where 1 represented very low awareness and 10 represented very high awareness. The average awareness rating, according to all survey respondents, was **5.75 out of 10**. Respondents from health authorities rated their institution's awareness at 6.1 out of 10, which is slightly higher than those at academic institutions who rated their institution's awareness at 5.6, although the difference between health authorities and academic institutions was not statistically significant.

A need to increase the research community's awareness of the BCEHI also surfaced in written survey responses and in-depth interviews. For example, several committee members noted that researchers were not involved in the initiative in a meaningful way; some respondents reflected that not having researchers represented on the Advisory Committee might have hampered the effectiveness of the Committee's communication efforts. Open-ended survey responses from many researchers also suggested a lack of in-depth knowledge about the initiative. As one researcher noted, "*I have not been aware of any progress, advancements or improvements that have been made apart from what we experience when we submit an ethics application.*" Similarly, one researcher stated that there has not been substantive discussion about the harmonization process, while another stated, "*we just don't know about it!*" A REB staff member summarized this sentiment, sharing:

> *"Communication with researchers is still not ideal. There are many misunderstandings across the board about what BCEHI means for the researcher. This communication*

[13] Note: those respondents who were not aware of the initiative only received general questions about ethics review practices and did not receive any specific questions about the BCEHI.

challenge with researchers is not unique to BCEHI and is something that each ethics board struggles with." – REB Staff Member

Additionally, survey responses revealed that only 32% of researchers and research staff had visited the BCEHI website. 85% of those who had visited the website were able to find what they were looking for. The majority were looking for general information and updates about harmonization, while many were looking for guidance, forms, and information about processes/procedures, and two respondents were looking for contact information.

2.3 To what extent did the initiative achieve its intended outcomes?

The overarching goal of the BCEHI was to make BC a more attractive environment for research activity through the creation of coordinated and efficient processes that facilitate multi-jurisdictional human health research.

There were many stakeholders who had positive experiences with harmonization and many who identified ongoing challenges with implementation and communication about the harmonized models. Overall, however, **the majority of stakeholders were satisfied with the BCEHI** (Fig.6) and open-ended comments expressed a desire for the initiative's work to continue.

Three-quarters of survey respondents expressed a belief that the BCEHI was having a positive effect on making BC a more attractive research environment (Fig.7), which suggests progress has been made towards the initiative's overarching goal.

Fig. 6 - Overall, how satisfied are you with the BC Ethics Harmonization Initiative? (n=164)

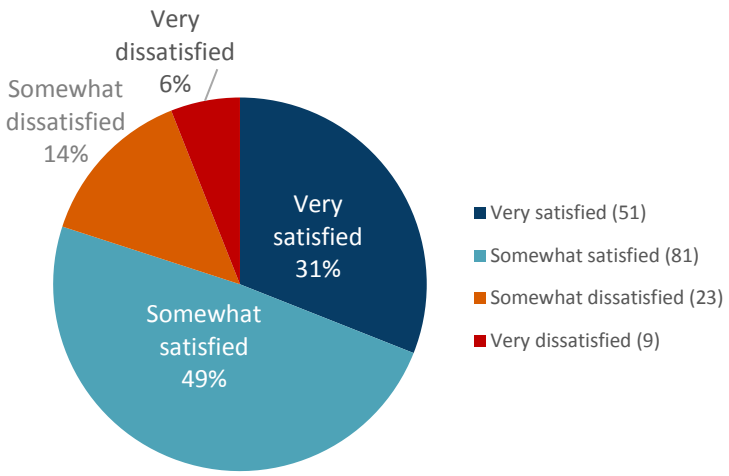
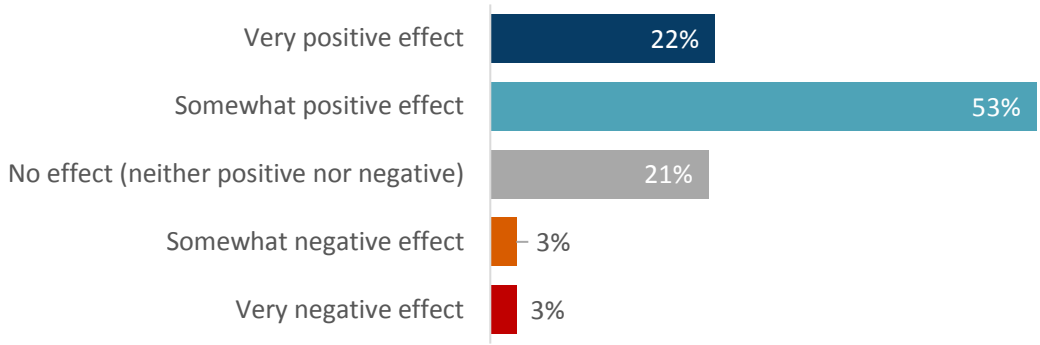


Fig.7 - In your opinion, what effect is the BC Ethics Harmonization Initiative having on making BC a more attractive research environment? (n=162)



"*Our involvement in reviews has skyrocketed,"* wrote one REB manager. *"I think the harmonized review has something to do with that. It opened up something for researchers."* 21% of the remaining respondents reported that the initiative has had no effect on making BC a more attractive research environment, and only 6% reported it has had a negative effect.

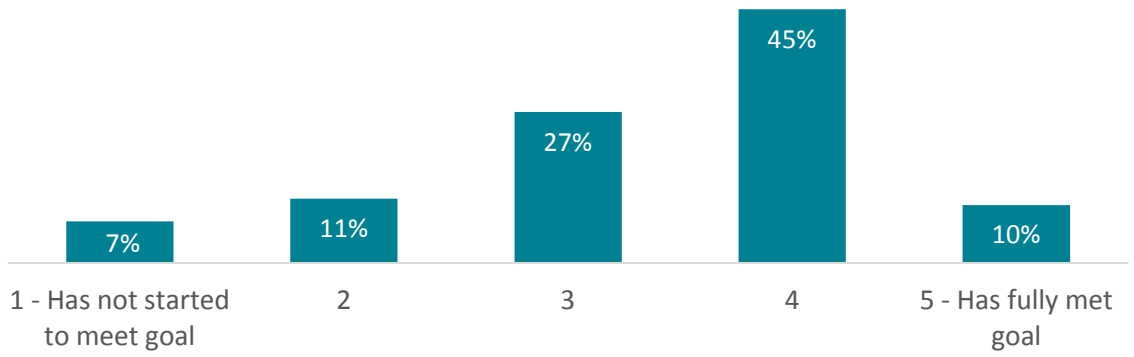
Progress towards each of the BCEHI's three primary objectives is assessed below.

Objective 1: Improve the timeliness and efficiency of the ethics review processes

Evaluation findings indicate that the initiative had a positive impact on the timeliness and efficiency of the ethics review process, in particular from the perspective of researchers who submitted ethics approval using the new process. Overall, survey participants (n=172) rated the progress towards this objective as 3.4/5, which is a significant improvement compared to 2013 survey results (1.8/5, n=25).[14]

Over half of the survey respondents rated progress towards this goal as either 4 or 5, which suggests that stakeholders perceive the initiative has made gains towards achieving this goal (Fig.8).

Fig. 8 - 2016 Rating of progress towards improving the timeliness and efficiency of ethical review processes (n=172)



Experiences of researchers & research staff

The final evaluation survey administered during Summer 2016 also included several questions for researchers and research staff (e.g. research coordinators, research managers) about their experience with harmonized ethics review to help measure progress towards improved timeliness and efficiency. Of the 120 researchers who completed the survey, 83% (n=100) had previously submitted an application for harmonized ethics review while the remaining 17% (n=20) had not.

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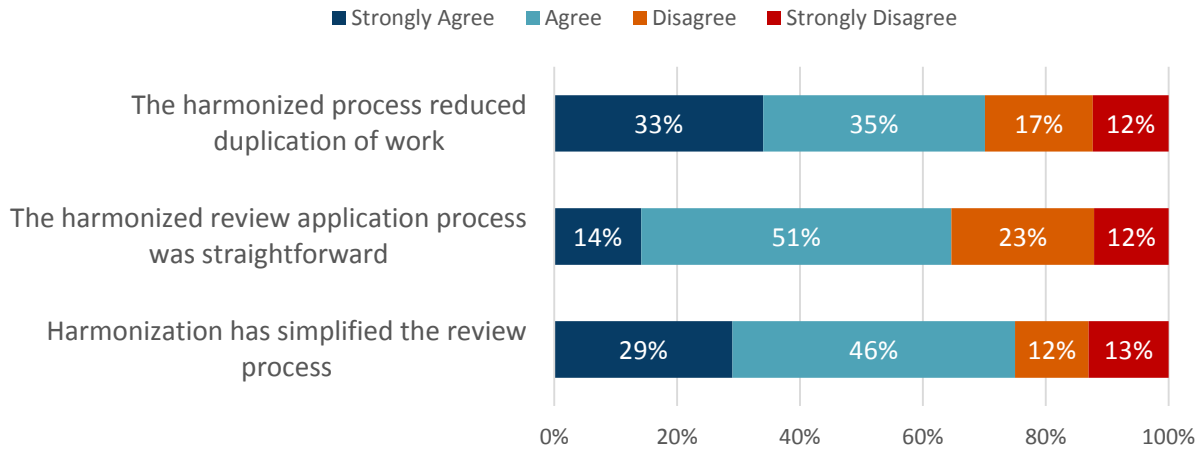
[14] All survey respondents who were familiar with the BCEHI were asked to rate the extent to which the initiative is meeting its objectives, using a 5-point scale where 1 represents the initiative "has not started to meet its goal" and 5 indicated the initiative "has fully met its goal". These same questions were asked in the 2013 evaluation.

There was a statistically significant difference ($p<0.001$) between the mean ratings in 2013 and 2016, which were tested using an unequal variances t-test (Welch's t-test).

When examining responses from the researchers/ research staff who had been through the harmonized ethics process, survey data suggests the majority of researchers had an overall positive experience with the harmonized ethics review process.

Fig. 9 - Researchers/research staff experiences with the harmonized review process (n=99)



Specifically, 65% of researchers agreed the harmonized review application process was straightforward while 68% reported the harmonized process reduced duplication of work. 75% agreed that harmonization has simplified the review process (Fig.9).

> "The opportunity for all REBs to discuss difficult issues seems to be bringing more clarity and uniformity."
>
> "I think that the process is excellent."
>
> "I have done three now and I love it!"
>
> - *Researchers*

Qualitative responses from researchers expressed appreciation for the BCEHI, which, in one researcher's words, is "*an excellent initiative and does improve the process.*" In general, respondents affirmed that the harmonized models reduced duplication and lessened the amount of work required of the research teams. One researcher stated the harmonized process "*reduces the "clunkiness" of dealing with multiple ethics boards with their different interpretations of the same guidelines, separately and repeatedly,*" while another researcher noted they "*appreciate not having to submit the same amendment multiple times."* This has resulted in efficiencies for the research team and reduced the administrative requirements for ethics applications. As one researcher commented, harmonization "*speeds up the process considerably*." Researchers expressed appreciation for receiving a single set of provisos, with many stating this ensures they do not receive "*multiple comments based on multiple reviewers*" or "*contradictory feedback*" from different REBs.

As Fig.9 illustrates, researchers and research staff members' experiences with the harmonized process were generally positive; however, approximately one quarter of respondents did not rate the harmonization process favourably. Open-ended responses from research staff members, in particular, expressed a degree of uncertainty with the process, with many noting the process itself was "confusing". Common responses indicated that more information and education about the process was needed, as several research administrators noted they struggled to locate consistent information about what the harmonized process entailed. As one research coordinator wrote, *"The ethics application I put in last year that underwent a harmonized ethics review was straightforward.*

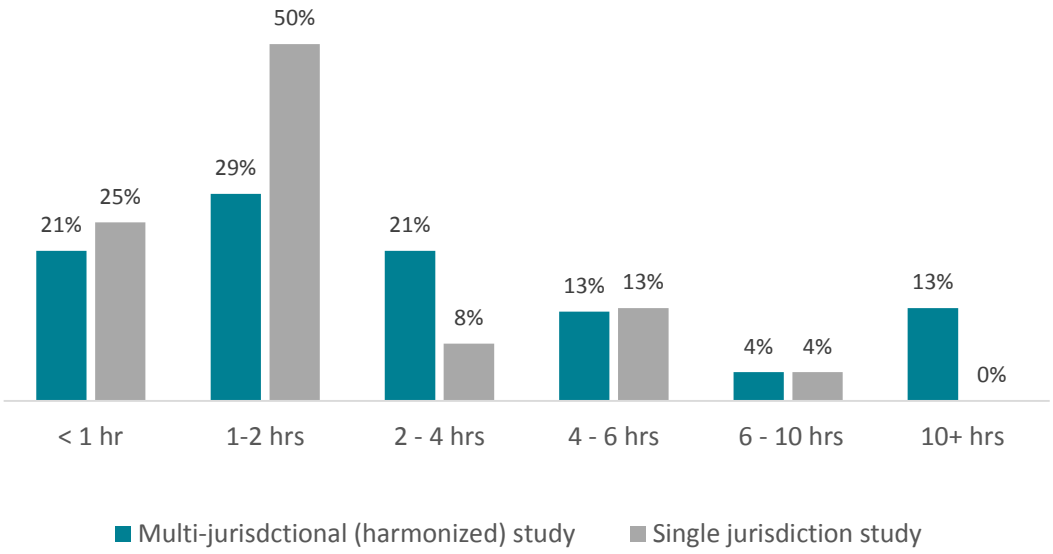
However, I felt that the steps were not clearly laid out and there was not one specific document or place that I could go to that told me what I would need to do... I had to write to the different ethics board to find out if they had any additional requirements."

In addition, several researchers reported experiencing long delays in their review time and expressed frustrations with the fact that the harmonized process is only as efficient as the least timely REB—a delay from one REB in providing comments to the Board of Record can have a substantial impact on the overall timeliness of ethics approval.

Experiences of REB administrators and reviewers

As Fig.10 shows, evaluation data collected by the BCEHI project team during the Minimal Risk Review pilot identified that Board of Record REB administrators spent more time coordinating harmonized multi-jurisdictional studies than they would have if the same applications were single jurisdiction studies, though the difference is not statistically significant at conventional levels ($p<0.05$). 50% of the 24 multi-jurisdictional studies were coordinated in 2 hours or less. Had it been a single jurisdiction study, REB administrators noted that 75% of the applications could have been done in 2 hours or less. Given that the Board of Record administrator coordinates the harmonized process and is the primary contact for stakeholders involved in the review (i.e. researcher, research team, other REB administrators, reviewers), this was not unexpected.

Fig.10 - Estimated Amount of Time that Board of Record REB Administrators Spend Coordinating Ethics Review and Approval (n=24)



Although acting as the Board of Record when coordinating a harmonized review appears to increase the workload of Board of Record staff to some extent, 84% of REB administrators (16/19) reported that overall the harmonized review process has streamlined the review of multi-jurisdictional studies. In addition, 83% were satisfied with the progress that has been made within their organization in terms of developing processes to facilitate harmonized reviews.

Finally, the Minimal Risk evaluation data revealed that 78% of reviewers (28/36) from receiving REBs indicated the provisos they received from the Board of Record REB helped reduce their review time. 14% said the provisos did not help reduce their review time, and 8% indicated 'not applicable', as they did not receive any provisos.

Objective 2: Improve the system effectiveness for health research ethics review

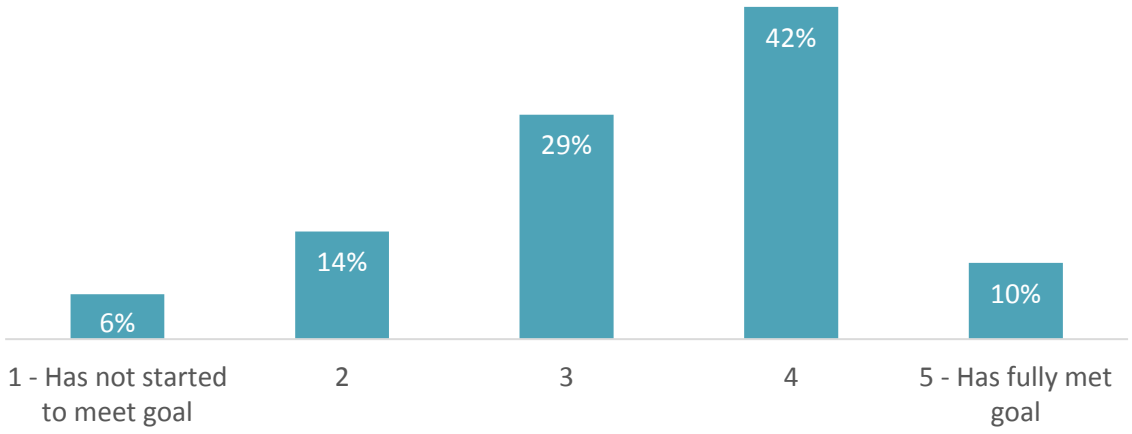
Survey respondents and key stakeholder interviewees reported that substantial progress has been made in terms of system effectiveness for health research ethics review, albeit more slowly than originally anticipated. There was consensus that the BCEHI acted as a catalyst for systemic improvements in the area of research ethics reviews. When asked to rate the progress the BCEHI has made in terms of improving system effectiveness, the mean rating was 3.37 out of 5, where 1 represents the initiative "has not started to meet its goal" and 5 indicated the initiative "has fully met its goal." Fig.11 shows the breakdown of survey participants' responses.

> "Ethics harmonization makes a lot of sense and the work done to date via the BCEHI has been invaluable in creating a research environment that is conducive to collaboration while maintaining the standards of TCPS2."
>
> – *Researcher*

Compared to this indicator's rating in 2013, which was 1.96 out of 5, there was a statistically significant change in stakeholders' perception of progress in the area of system effectiveness ($p<0.05$).

Specific systemic improvements identified by stakeholders ranged from improved communication and collaboration between institutions to a reduction in the duplication of efforts, particularly for researchers.

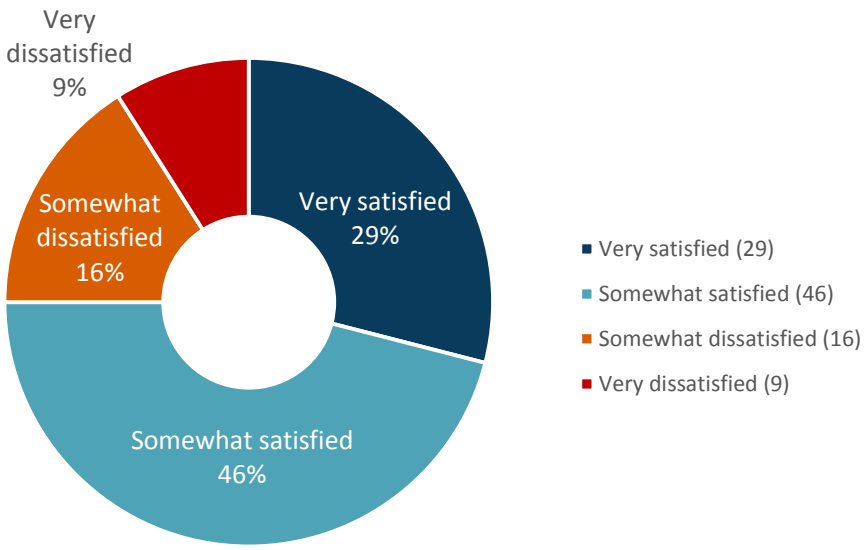
Fig. 11 - To what extent has the BCEHI improved the system effectiveness for health research ethics? (n=175)



In reflecting on system-wide changes, one REB administrator commented that, "*if [researchers] are getting tri-agency funding, they are not spending as much of their grant money preparing 6 ethics applications and going through 6 different reviews and satisfying all these requirements. They can move faster in the field and it is a better use of tax payers' money."* Similarly, an REB reviewer affirmed, *"It is a very important initiative that has made it significantly easier to get multi-jurisdictional REB approvals in BC."*

Survey data also confirmed that improvements in system effectiveness have been made. For example, **75% of researchers and research staff were satisfied with their experience of a harmonized ethics review,** while 25% were dissatisfied (Fig.12).

Fig. 12 - Overall, how satisfied are you with your experience of a harmonized review? (n=100)



Of note, researchers were significantly more satisfied with their experience of a harmonized ethics review in comparison with research staff ($p<0.05$). For the most part, those who experienced challenges with harmonization believed that implementation of the harmonized models would continue to improve as institutions became more familiar and experienced with the process. According to a Senior Leader, "*The more we move through the system the easier it will be to pick it up. Every time you have a conversation there are lessons learned that are shared."*

As a result of the BCEHI, REB reviewers and administrators also noted that REBs communicate and collaborate with one another more effectively. With this increase in inter-institutional trust, they report that improved system effectiveness has followed.

Implementing the harmonized Minimal Risk Model, for example, continues to become more streamlined and efficient according to many REB administrators. It has taken time to work out many of the challenges of operationalizing harmonized ethics reviews across the partner organizations, but the Advisory Committee has taken an iterative approach to refining the models as they continue to be used. According to one REB manager, "*the big parts of this [initiative] have been achieved, and as a*

result we have changes of procedures and also a change of culture – ethics boards [administrators] see each other as extensions of each other."

Evaluation data revealed several key challenges that impacted the system effectiveness of the harmonized ethics review processes. The most commonly identified challenge was the absence of a shared technology platform across institutions. Currently, each institution has a different approach to administering and managing ethics applications.[15] Reviewers report that this is challenging to manage: "*There are multiple renewals, amendments, provisos, responses. If we can't deal with that on one platform it becomes impossible."*

> "The biggest hindrance is lack of common software platform. Dealing with projects that have a huge amount of documentation attached, to keep track through email, working within rise system, and outside via email with other boards— it doesn't make anything streamlined."
>
> – REB reviewer

There were concerns that requiring all institutions to adopt the same system would be cost-prohibitive, so this was not pursued earlier in the initiative. However, Advisory Committee members submitted a funding proposal to MSFHR in conjunction with the University of British Columbia to create a shared workspace on the University of British Columbia's RISe platform for harmonized ethics review. As noted earlier, MSFHR has approved funding for the development of common technology platform for harmonized ethics review.

Many stakeholders also highlighted a challenge in terms of institutional approval. When conducting research at a health authority, investigators are required to obtain institutional approval from the health authority in addition to ethical approval. During the early stages of the initiative, partner organizations determined that institutional approval was out of scope for the BCEHI and was therefore not included in the harmonization process. Consequently, research teams must complete a separate application to request institutional approval, which caused some confusion for researchers and was identified as an additional barrier to the effectiveness of the harmonized process.

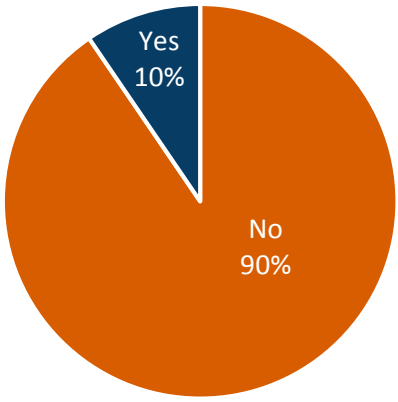
Objective 3: Facilitate maximal reciprocity between BC institutions for the ethical review of health research conducted within BC

Stakeholders noted that signing the BC Ethics Review Reciprocity Agreement in 2013 was a key milestone that facilitated maximal reciprocity. Indeed, survey respondents' mean rating of progress towards this objective was 3.2/5 in 2016 (n=174) compared to 2.3 in 2013 (n=27). However, in practice many stakeholders observed that minimal risk harmonized reviews tend to be "*more collaborative than reciprocal.*" Several researchers observed that their applications were reviewed by multiple REBs regardless of whether they submitted an application for harmonized review. "*In my experience, the different ethics boards still provided discrepant reviews of the same application, even though the application was harmonized."*

[15] Of note, when UBC was involved in a study, their electronic management system (RISe) could be used by reviewers from participating REBs.

A central component of the harmonized Minimal Risk Model is that the Board of Record shares the provisos from its initial review with the other REBs involved in the multi-jurisdictional study. These REBs can then accept the Board of Record's review unconditionally (which is considered full reciprocity), or conduct a proportionate review. Data from interviews, the BCEHI survey, and document data collected during the final evaluation indicated that the initiative has made minimal progress towards higher levels of reciprocity in the operationalization of minimal risk harmonized reviews.[16]

Fig. 13 - REBA: Did your institution opt to accept the BoR review unconditionally? (full reciprocity) (n=42)



In most cases, receiving REBs choose to conduct proportionate reviews for minimal risk studies rather than accept the Board of Record's review unconditionally. The 2016 Minimal Risk Pilot evaluation report indicated that there were 42 opportunities for a REB to choose full reciprocity but only 10% of receiving institution REBs accepted the Board of Record's review unconditionally (Fig.13).

Although many stakeholders confirmed that higher levels of reciprocity are desirable, they acknowledged that there are barriers to achieving reciprocity. One of the commonly cited barriers was that academic institutions and health authorities approach ethics reviews with different perspectives. Stakeholders noted that because health authorities oversee sensitive patient information, they are often less comfortable opting for straight reciprocity. There are also considerations of differing levels of expertise and experience; as one REB member noted, "*different boards have different needs. It would be easy if they all did the same thing, but they don't. All the different sciences are different businesses.*"

There was also a sense that some institutions were more risk-averse than others, which posed challenges to reciprocity. As one researcher noted, *"I believe that there continues to be work to be done to bring some of the lower volume hospitals in line with how the review process proceeds at other institutions. The level of caution and scrutiny expressed via some of the hospitals creates impediments without improving participant safety."* Several stakeholders who were familiar with the minimal risk pilot indicated that many proportionate reviews that were conducted seemed unnecessary given the study's low level of risk.

"One of the overarching goals was also to come to a place to provide reciprocity for the review done by another board. We didn't get to full maximum reciprocity."

– Senior Leader

"There could be greater reciprocity between institutions. We are getting there, and I believe that this will come with time."

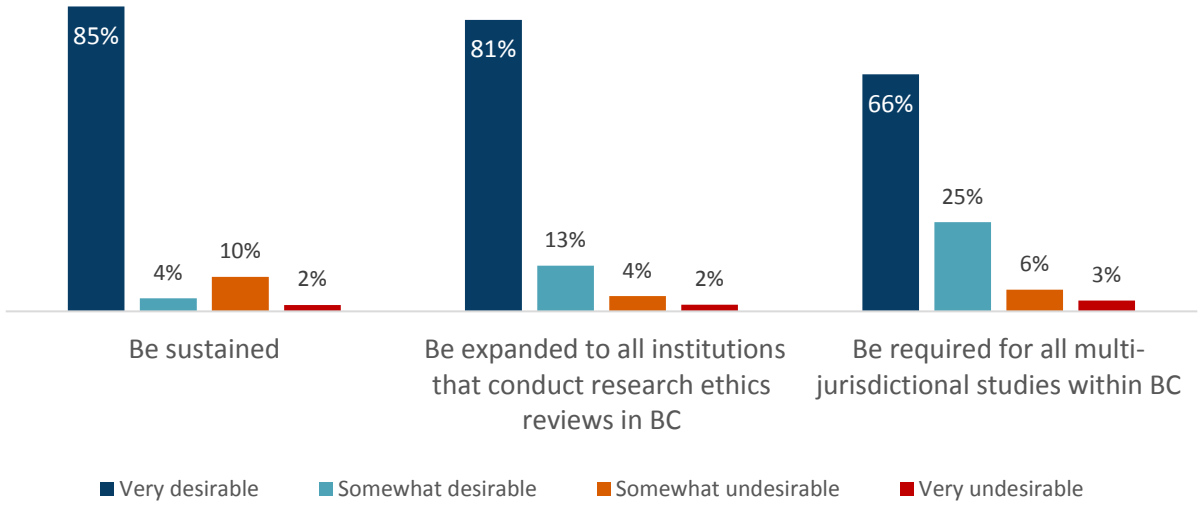
– Advisory Committee member

[16] There is currently insufficient data to assess reciprocity for above minimal risk reviews.

2.4 To what extent is the BCEHI sustainable?

Evaluation data suggests that the majority of stakeholders believe that sustaining the BCEHI is both desirable and possible.

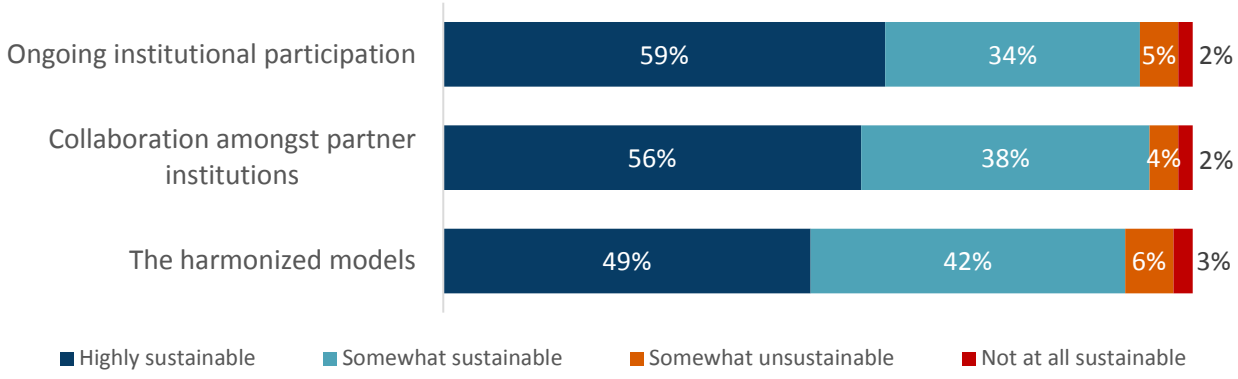
Fig. 14 - How desirable is it that ethics harmonization... (n=165)



As seen in Fig.14, 85% of survey respondents believed it was very desirable that the BC ethics review harmonization be sustained. 81% noted it was very desirable that the BCEHI be expanded to all institutions in BC that conduct research ethics reviews but a smaller proportion, just under two-thirds of survey participants (66%), responded that it was very desirable that ethics harmonization be *required* for all multi-jurisdictional studies within BC.

When asked to evaluate the actual sustainability of various aspects of the BCEHI initiative, respondents from the final evaluation survey generally rated the sustainability of each aspect favourably, with 3% or less indicating any aspect was "not at all sustainable" (Fig.15).

Fig.15 - To what extent are the following aspects of the BCEHI sustainable? (n=156)



Specifically, 93% of participants believed that ongoing institutional participation was either somewhat or highly sustainable, while 94% responded that the ongoing collaboration amongst partner institutions was sustainable. 90% of survey participants believed the harmonized models are at least somewhat sustainable in their current form. These responses suggest that respondents are optimistic about the sustainability of the BCEHI, but a degree of uncertainty does exist.

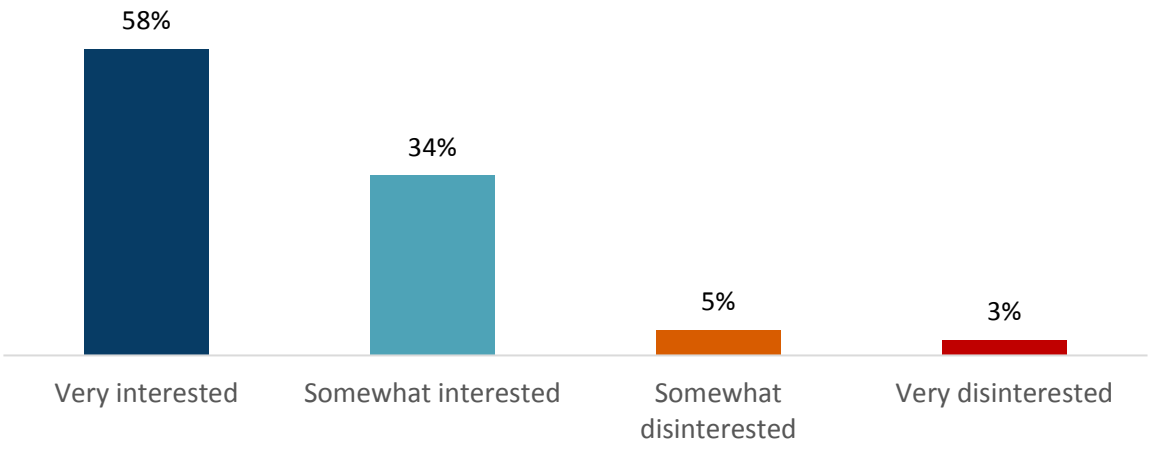
Finally, as Fig.16 shows, the majority (92%) are somewhat or very interested in supporting the BCEHI in the future.

"It is imperative that ethics harmonization be sustained and supported in the Western Canadian research environment." – *REB member*

"Everything possible should be done to sustain and expand [the initiative]." – *REB member*

"Everyone is committed to the process. We said we will do it; we signed a collaboration agreement." – *Senior Leader*

Fig.16 - How interested are you in supporting the BC Ethics Harmonization Initiative in the future? (n=167)



3. Discussion

3.1 Strengths of the Initiative

When the BCEHI entered Phase II, key stakeholders did not yet have a clear and shared vision of what the harmonization of ethical reviews for multi-jurisdictional human health research would look like. By the end of the initiative, there were two workable harmonized models that were in operation. The following strengths of the initiative described below were identified by key stakeholders as being instrumental to this success.

> "Was this worthwhile? Yes. Was it smooth? No."
>
> – Senior Leader

The initiative was able to change course when necessary. As the BCEHI advanced, it became evident that the Steering Committee was not making progress as quickly as anticipated. Both MSFHR and the BCEHI Director identified that the initiative needed to be re-organized if it was going to achieve its goals. Consequently, MSFHR and the BCEHI Director worked together to design a plan to restructure the initiative. BCEHI partner institutions were supportive of the restructuring, which allowed MSFHR to execute the transition from the Steering Committee to the Advisory Committee, establish the Senior Leaders group, and take the lead in project management responsibilities. This flexibility and willingness to change course when necessary was vital to the initiative's ability to move forward.

The BCEHI built support from the ground up. Another key strength was that the BCEHI was a grassroots effort. Partner institutions and their Senior Leaders recognized that harmonization should be driven by those most impacted by the changes and consequently selected representatives for the BCEHI Advisory Committee who had an intimate understanding of the operations of ethics reviews. Building the initiative from the ground up rather than mandating change from the top down (e.g. mandated by the provincial government) may have been a slower process, but it provided stakeholders with an avenue to shape change in a way that made the most sense for the diverse stakeholders involved. As one Advisory Committee member observed, *"Though this brings challenges, it also creates a better chance for long term buy in and sustainability."* Evaluation data from REB administrators supports this; many interviewees and survey participants noted that there is wide acceptance of harmonization. In particular, using the harmonized minimal risk ethics review model has become part of their routine practice.

The Advisory Committee was committed to moving the initiative forward. As noted previously, the initiative appeared to have progressed slowly during the initial years but this period served as the foundation for relationship-building between partner institutions. The Advisory Committee was composed of a highly committed group of stakeholders who further enhanced inter-institutional collaboration and trust as they worked on developing and implementing the harmonized models. Interviewees highlighted that the Advisory Committee's commitment and ability to collaborate effectively were key enablers of the initiative's progress.

The initiative had a strong backbone of support from the BCEHI team. Finally, several Committee members and Senior Leaders acknowledged the major support provided by the BCEHI project team. Following the initiative's restructuring, the BCEHI project team played a large role in facilitating Advisory Committee meetings, providing project management support, and coordinating and developing BCEHI materials— among numerous other responsibilities. "*They provided us with a backbone and structure,"* stated an Advisory Committee member, who appreciated that this support allowed Committee members to reduce the amount of BCEHI work they had to do "*off the side of our desk*." Stakeholders agreed that it was highly effective to have had project management support; many believed this helped keep the initiative on track and on task, ensuring that Committee members moved the initiative forward and made progress towards the BCEHI goals.

3.2 Challenges Faced and Lessons Learned

A) Challenge: The initial governance structure was not an effective model.

The initial governance structure, whereby the Steering Committee governed the initiative, was not an effective model. As noted previously, there was a substantial lack of authoritative leadership during the early phases to push the initiative forward. The committee was composed of members who had diverse decision-making authority that ranged from junior administrative staff who did not have decision-making capacity to senior Vice Presidents of Research. "*It wasn't a good dynamic*," said one Steering Committee member. According to Steering Committee members who participated in in-depth interviews, the more senior members of the Committee tended to steer the conversation while the administrative staff, many of whom had useful experience and knowledge about the ethics processes, did not feel comfortable enough to participate in discussions. Further, senior leadership appointed alternates to attend Steering Committee meetings on their behalf, but since these delegates had minimal decision-making authority they were therefore were unable to make commitments on behalf of their institution. This also appeared to signal to some stakeholders that senior leadership was not committed to the initiative.

> "The work done in the early days informed the accomplishments that came at the end, but the process of getting there started out less smoothly than one would hope."
>
> – Advisory Committee member

Lesson learned: The project needed external facilitation. Once MSFHR assumed project management responsibility for the BCEHI and restructured the initiative, substantive and rapid progress was made towards the BCEHI objectives. Many interviewees believed that if an external organization had facilitated the project from its initiation some of the challenges the Steering Committee encountered may have been mitigated.

B) Challenge: REBs have different lenses and considerations when conducting ethics reviews.

Many REB members and Senior Leaders observed that there is a fundamental difference between health authorities and academic institutions: while health authorities *"exist to deliver service to patients*," academic institutions "*exist to do research*." The different lenses that academic institutions and health authorities bring to ethical reviews is believed to slow progress towards achieving full reciprocity in harmonized reviews.

One Senior Leader from a health authority articulated this divide: "*some conversations I've had with colleagues— they did not understand our concerns or perspectives. People who are purely research, they don't understand what it's like in a health authority*." Conversely, many researchers perceived health authorities to be overly risk-averse and believed they unnecessarily conducted proportionate reviews for low risk studies. From the health authority perspective, however, the need to review harmonized ethics applications with an eye for patient confidentiality and protection frequently requires a proportionate review. "*We don't have the same lenses when we are reviewing,"* noted a REB member from a health authority. These differences in perspective were identified by many stakeholders as a considerable barrier to higher levels of reciprocity in harmonized ethics reviews.

Lesson learned: Increased reciprocity in harmonized ethics review takes time and requires ongoing relationship-building between partner institutions. Many interviewees and survey participants commented that the process of harmonizing ethics reviews across numerous institutions—many of whom have vastly different operational contexts and considerations—takes time. They noted that moving towards increased reciprocity requires that trust between institutions is maintained and strengthened. Most Senior Leaders and Advisory Committee members were optimistic about the progress that has been made to date and were confident that continued collaboration on harmonization would result in improved relationships and reciprocity between institutions.

C) Challenge: Information about harmonization was not widely disseminated to the research community.

Survey data and interview responses from all stakeholder groups suggest that communication about the BCEHI and the use of the harmonized models was inconsistent, particularly to the research community. Many researchers reported not knowing about harmonization until their REB administrators informed them about the opportunity for harmonization. Additionally, many researchers and research staff were not aware that ethics harmonization did not include institutional approval, and that this requires an additional application once the ethics review is complete.

Lessons learned: The initiative needed communication and education plans to ensure consistent information about the BCEHI was disseminated to the research community. By not having a strategic communications plan, the BCEHI did not have a systematic approach to ensure that the research community was well-informed and educated about the ethics harmonization process. "*We didn't have any big events to promote to researchers. We communicated as and when they applied for ethics,"* a REB administrator confirmed. *"There wasn't a communication plan.*"

Researcher Awareness

"Better clarification of the process at the institutional level would be helpful." – Researcher

"A lot of researchers have stumbled across the fact that there is harmonization. You put in a proposal, and then there is the question about harmonization. I don't know that everybody was aware this was happening." – REB reviewer

"Please provide better information on the website about the process." – Research staff member

D) Challenge: Stakeholders reported the lack of a shared technology platform was a barrier to achieving timely and efficient harmonized ethics review.

As identified earlier, institutions have different systems for administering and managing ethics applications. Due to concerns about prohibitive costs, a shared technology platform was not pursued during the initiative's operation as was initially proposed in the BCEHI Phase II Strategic Plan. Not having a common technology platform to support harmonized reviews was identified by many reviewers, REB administrators, and researchers/research staff as being a primary obstacle to an efficient and streamlined process. Many stakeholders felt this had a negative impact on the implementation of ethics harmonization in BC, believing that "*integration [of harmonization] should be coordinated with the on-line applications systems to make the process as clear and seamless as possible*."

Lesson learned: Technological infrastructure was needed early in the process to support harmonization.

3.3 Opportunities for Development

Moving forward, stakeholders identified several opportunities for development that are described below. A synthesis of evaluation data helped identify more specific recommendations within each area.

Advisory Committee

- **Recommendation: Sustain the Advisory Committee and continue to hold in-person meetings with initiative stakeholders, at least once or twice per year.** It is recommended that the Advisory Committee is sustained in order to keep moving the work on ethics harmonization forward. At the time of publishing this report, MSFHR has agreed to fund a BCEHI Project Coordination function to provide the Advisory Committee with administrative support for a one-year period. Further, it is suggested that the Advisory Committee holds at least one in-person meeting per year to help maintain relationships between institutional partners and retain institutional knowledge around ethics harmonization.

- **Recommendation: Implement a data collection/evaluation plan for harmonized studies.** This will help partner institutions evaluate the effectiveness of the harmonized ethics review process and support quality improvement efforts to determine if/when changes to the models need to be made.

Technology

- **Recommendation: Continue to support the development and implementation of a common technology platform.** At the time of writing, MSFHR has agreed to provide funding to develop a shared workspace on the UBC RISe system for the conduct of harmonized ethics review. It is recommended that this effort continues and is supported by all partner institutions moving forward. After the funding has been used to integrate harmonized review capacity in the RISe system, partner institutions may consider formalizing a commitment to sustaining the resources needed to maintain this technology.

Stakeholder Communication

- **Recommendation: Develop and implement a communications plan.** Given the communication challenges that were identified in the evaluation data, key stakeholders may consider developing a communications plan to increase awareness of the harmonization initiative throughout the research community.

  Communication efforts could focus on directing stakeholders to the BCEHI website for comprehensive information and guidance materials regarding harmonization; however, it will be important that the BCEHI website is regularly maintained and contains pertinent updates for all stakeholder groups. It may also be useful to consult stakeholders during the development of the communication plan, to help ensure that communication materials will effectively reach their intended audience.

- **Recommendation: Develop and implement an education/knowledge translation plan**. In addition to a communication plan, several stakeholders suggested that an education plan be developed to provide all stakeholder groups with consistent information about the criteria for

harmonized reviews, the harmonized application and review process, and how harmonization may impact their work. This may be particularly relevant once a shared technology platform is operational.

BCEHI participation

- **Recommendation: Develop a plan to engage additional institutions across the province in a dialogue about participating in the BCEHI.** Several institutions are not yet involved in the initiative, including the First Nations Health Authority and several other academic institutions (e.g. Thompson Rivers University, University of the Fraser Valley, Trinity Western University, Kwantlen Polytechnic University, Selkirk College, BCIT, etc.). The Phase II Strategic Plan identified expanding participation in the BCEHI as a priority focus area for the second half of the initiative and many stakeholders confirmed that this an important area for future development.

> "It needs to be expanded. I imagine a future where all REB in Canada have the same application requirements, the same interpretations of the same guidelines, and single point of entry and monitoring for all projects."
>
> - Researcher

4. Conclusion

Evaluation findings suggest that the BCEHI has made considerable progress towards achieving its intended outcomes. While there are still areas that require further development, the BCEHI has accomplished much in recent years and stakeholder feedback suggests general satisfaction with the direction of the initiative.

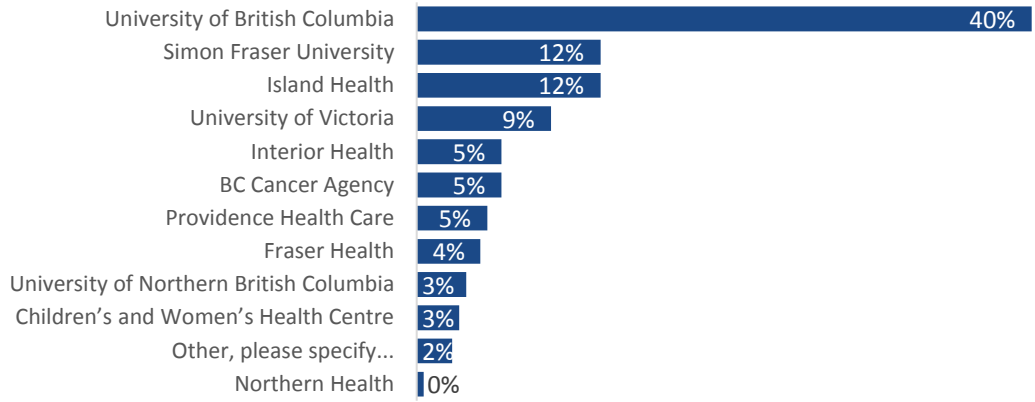
Overall, participants reported that the BCEHI has had a positive effect on the research environment in British Columbia. Further, the BCEHI has made substantial progress towards two of its three key objectives: improving the timeliness and efficiency of the ethics review processes, and improving the system effectiveness for health research ethics review. Less substantive progress has been made towards the third objective of facilitating higher levels of reciprocity between BC institutions for the ethical review of health research conducted within BC.

Moving forward, MSFHR has funded a one-year BCEHI Project Coordination function to support the initiative's ongoing management, and is providing funding to support the development of a shared technology platform. Advisory Committee members have affirmed their commitment to ethics harmonization and indicated that they plan to meet indefinitely to maintain the momentum that has been achieved in the area of harmonized ethics review. Ongoing sustainability planning for the BCEHI will be an important consideration for senior leadership at the partner institutions. Leaders will need to develop a plan to ensure the achievements of the BCEHI can be sustained in the longer-term.

Appendices

Appendix A – Institutional Affiliation of Survey Participants

Fig. 17 – Survey participants' institutional affiliation



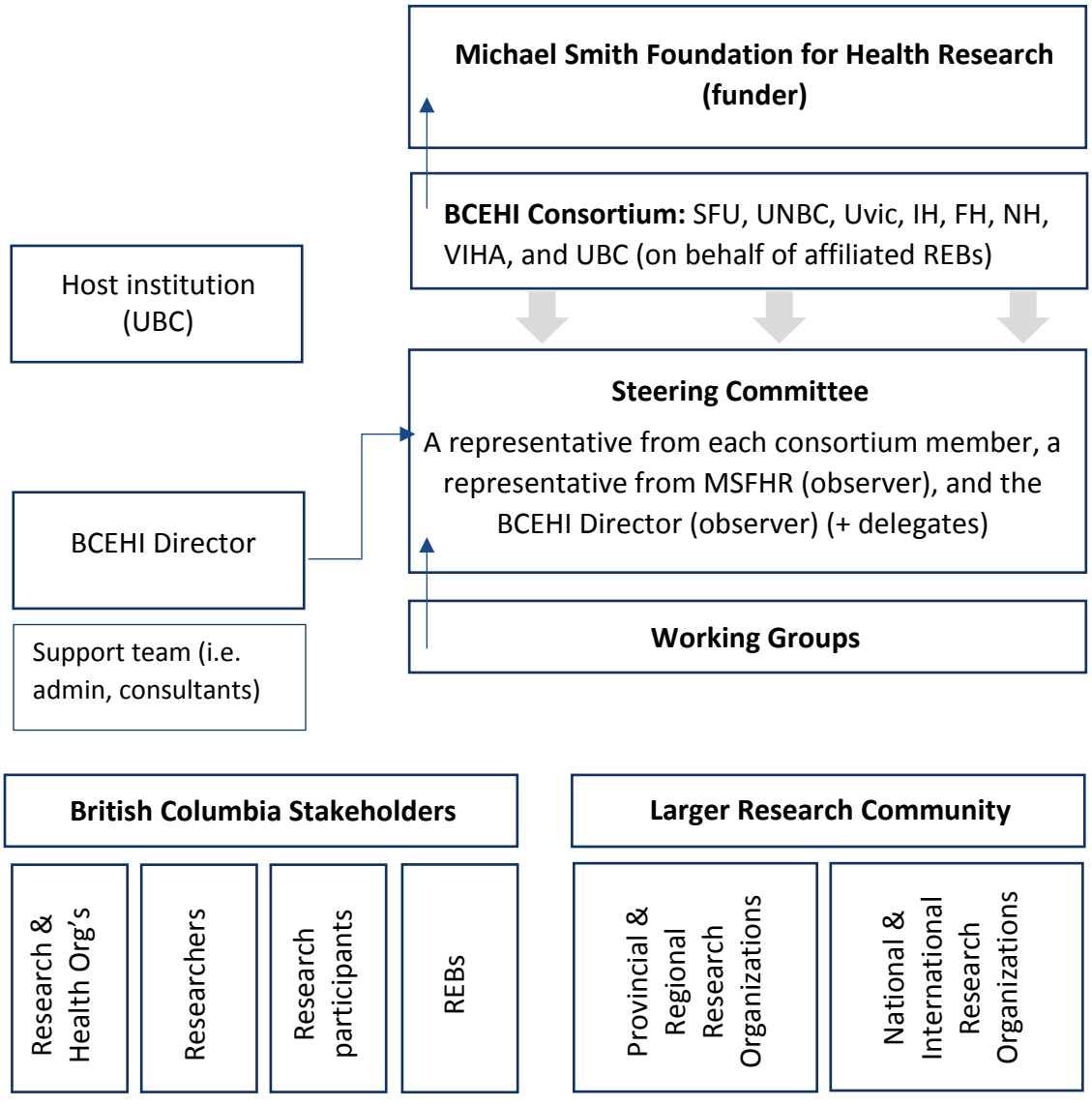
The table below provides an approximation of the primary institutional affiliation of stakeholders who received the BCEHI evaluation survey. Many respondents were affiliated with multiple institutions; however, the evaluation team eliminated all duplicate names. When attempting to determine the number of stakeholders according to their institutional affiliation, the evaluation team simply used the first listed institution. As a result, the numbers are an estimate only and may not be accurate. The following table should therefore be interpreted with caution, as respondents were able to select their primary institution when completing the survey and their response may not have aligned with the label they were assigned during the sampling process.

Table 2 – Estimated response rate by stakeholders' institutional affiliation

Institution	Sample size	Survey respondents	Response rate by institution
BC Cancer Agency	25	12	48%
Children's and Women's Health Centre	8	6	63%
Fraser Health	10	9	90%
Interior Health	15	12	80%
Island Health	122	26	21%
Northern Health	4	1	25%
Other, please specify...	0	5	
Providence Health Care	21	10	48%
Simon Fraser University	46	26	57%
University of British Columbia[17]	344	87	25%
University of Northern British Columbia	14	7	50%
University of Victoria	25	19	76%
Total	637	220	

[17] The University of British Columbia represents the affiliated UBC Behavioural and Clinical Research Ethics Boards. It also represents Providence Health Care, BC Cancer Agency, Children's and Women's Health Centre of BC. It is possible that stakeholders affiliated with these institutions may have selected UBC as their primary institution instead.

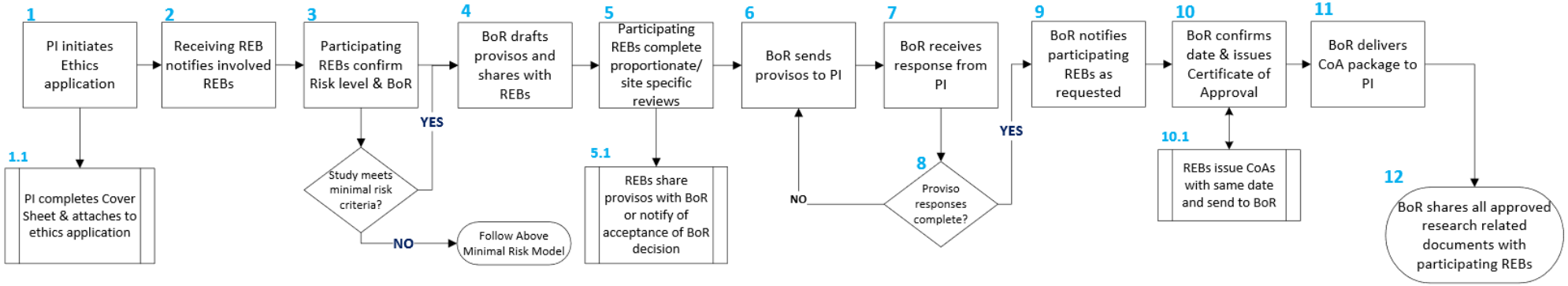
Appendix B – Original Organization of the BCEHI (2011-2014)



Appendix C – Minimal Risk Review Model

BC Ethics Harmonization Initiative

Harmonized Minimal Risk Ethics Review Model – Initial & Continuing Review

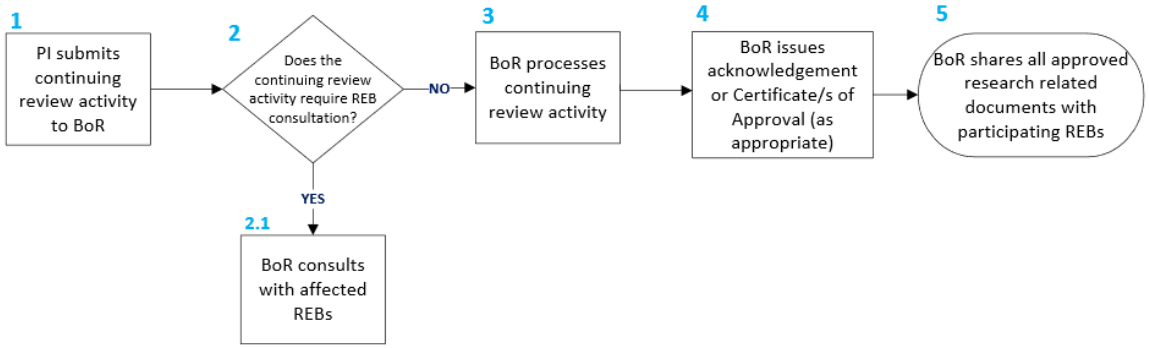


Board of Record (BoR) Decision Criteria

- If the study involves a Health Authority, the Board of Record will be the REB representing that Health Authority
- If there is more than one Health Authority involved, the BoR will be the primary location where the research will take place or, if all things are equal, the Health Authority where the PI holds their primary appointment
- If no Health Authority is involved, the BoR will be the REB representing the institution where the PI holds their primary appointment. In the event that the majority of research will take place in an institution other than that of the PI's primary appointment, the BoR may be the REB that represents the institution where the research will take place.
- If Northern Health would be considered the BoR under these guidelines, UNBC will by default be the BoR as agreed between Northern Health and UNBC.

Last updated May 14, 2015

Continuing Review



Appendix D – Above Minimal Risk Review Model

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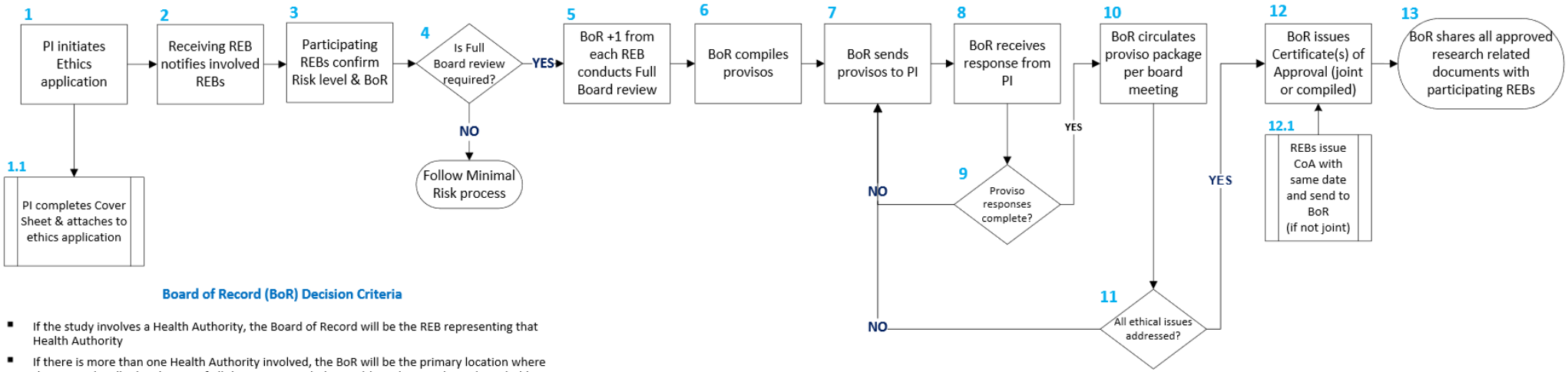
BC Ethics Harmonization Initiative

Harmonized Above Minimal Risk Ethics Review Model – Initial Review



Board of Record (BoR) Decision Criteria

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- If Northern Health would be considered the BoR under these guidelines, UNBC will by default be the BoR as agreed between Northern Health and UNBC.

Last updated May 14, 2015

Appendix F – CES Guidelines for Ethical Conduct

Competence
Evaluators are to be competent in their provision of service.

1. Evaluators should apply systematic methods of inquiry appropriate to the evaluation.
2. Evaluators should possess or provide content knowledge appropriate for the evaluation.
3. Evaluators should continuously strive to improve their methodological and practice skills.

Integrity
Evaluators are to act with integrity in their relationships with all stakeholders.

1. Evaluators should accurately represent their level of skills and knowledge.
2. Evaluators should declare any conflict of interest to clients before embarking on an evaluation project and at any point where such conflict occurs. This includes conflict of interest on the part of either evaluator or stakeholder.
3. Evaluators should be sensitive to the cultural and social environment of all stakeholders and conduct themselves in a manner appropriate to this environment.
4. Evaluators should confer with the client on contractual decisions such as: confidentiality; privacy; communication; and, ownership of findings and reports.

Accountability
Evaluators are to be accountable for their performance and their product.

1. Evaluators should be responsible for the provision of information to clients to facilitate their decision-making concerning the selection of appropriate evaluation strategies and methodologies. Such information should include the limitations of selected methodology.
2. Evaluators should be responsible for the clear, accurate, and fair, written and/or oral presentation of study findings and limitations, and recommendations.
3. Evaluators should be responsible in their fiscal decision-making so that expenditures are accounted for and clients receive good value for their dollars.
4. Evaluators should be responsible for the completion of the evaluation within a reasonable time as agreed to with the clients. Such agreements should acknowledge unprecedented delays resulting from factors beyond the evaluator's control.

(Canadian Evaluation Society, 2001-2010)

Endnotes

[i] BC Ethics Harmonization Initiative (2016). *About BCEHI.* Retrieved from: http://bcethics.ca/

[ii] Sax, Linda J., Shannon K. Gilmartin, and Alyssa N. Bryant. "Assessing response rates and nonresponse bias in web and paper surveys." *Research in higher education* 44.4 (2003): 409-432.

[iii] Groves, Robert M., and Emilia Peytcheva. "The impact of nonresponse rates on nonresponse bias: A meta-analysis." *Public opinion quarterly* 72.2 (2008): 167-189.

[iv] Coughlin, Steven S. "Recall bias in epidemiologic studies." *Journal of clinical epidemiology* 43.1 (1990): 87-91.

[v] The Michael Smith Foundation for Health Research (2007). *The Ethics Review Process in British Columbia. An Environmental Scan.* Vancouver: MSFHR. Retrieved from http://www.msfhr.org/sites/default/files/The%20Ethics%20Review%20Process%20in%20British%20Columbia%20%E2%80%93%20An%20Environmental%20Scan_0.pdf

[vi] The Michael Smith Foundation for Health Research (2007). *The Ethics Review Process in British Columbia. An Environmental Scan.* Vancouver: MSFHR. Retrieved from http://www.msfhr.org/sites/default/files/The%20Ethics%20Review%20Process%20in%20British%20Columbia%20%E2%80%93%20An%20Environmental%20Scan_0.pdf

[vii] Michael Smith Foundation for Health Research. (2012). *BCEHI Phase II Strategic Plan: 2011-2015.* Retrieved from: http://www.msfhr.org/sites/default/files/BCEHI_PhaseII_StrategicPlan.pdf

[viii] Source: Adapted from organization chart published in the BCEHI Phase II Strategic Plan report (MSFHR, 2012).

Michael Smith Foundation for Health Research. (2012). *BCEHI Phase II Strategic Plan: 2011-2015.* Retrieved from: http://www.msfhr.org/sites/default/files/BCEHI_PhaseII_StrategicPlan.pdf