Evaluation Report

HARMONIZED RESEARCH ETHICS REVIEW
MINIMAL RISK MODEL PILOT

March 2016
The BC Ethics Harmonization Initiative (BCEHI) is a collaborative effort between eight partner organizations representing BC’s provincial health authorities and major research universities. The BCEHI aims to create a coordinated provincial approach to ethics review that supports and encourages human health research, and makes BC an attractive environment for multi-jurisdictional health research.

BCEHI is funded by the Michael Smith Foundation for Health Research at $1 million over a five-year period until March 31, 2016.

BCEHI would like to acknowledge all the individuals who generously gave their time to participate in this evaluation. This report was prepared by the BCEHI project manager and project coordinator.

www.bcethics.ca

February, 2016
# Table of Contents

Executive Summary......................................................................................................................... 1

Background ......................................................................................................................................... 5

Stakeholders .......................................................................................................................................... 5

The Harmonized Ethics Review Minimal Risk Model........................................................................ 5

Evaluation Plan and Methods .............................................................................................................. 6

Limitations of the Pilot Evaluation...................................................................................................... 7

Evaluation Results ................................................................................................................................. 8

  Ease of the Process for Researchers ............................................................................................... 8
  REB Administrator Experience ......................................................................................................... 9
  Reviewer Experience .......................................................................................................................... 12

Duration of Harmonized Research Ethics Review............................................................................. 14

Conclusion ........................................................................................................................................... 16

Recommendations ............................................................................................................................... 16

Appendix A – Guidance Harmonized Ethics Reviews...................................................................... 18

Appendix B – Harmonized Minimal Risk Ethics Review Model – Initial and Continuing Review......... 26

Appendix C – Survey Questions ........................................................................................................ 27

Appendix D – Qualitative Interview Questions.................................................................................. 32

Appendix E – Glossary......................................................................................................................... 33

Appendix F – Application Data.......................................................................................................... 35
Executive Summary

The **BC Ethics Harmonization Initiative** (BCEHI) aims to create efficient, coordinated, and high-quality processes that support and encourage multi-jurisdictional human health research. The goal is to make BC a more attractive environment for research activity. The initiative, which began in 2010, is funded and facilitated by the Michael Smith Foundation for Health Research until March 31, 2016.

BCEHI is a collaborative effort of eight partners — four universities (Simon Fraser University, University of British Columbia, University of Northern BC, and University of Victoria) and four health authorities (Fraser, Interior, Island, Northern). Vancouver Coastal Health, Provincial Health Services Authority (Providence Health Care, Children’s and Women’s) and BC Cancer Agency are represented through their affiliations with UBC.

BCEHI is focused on achieving three objectives:

- Improve the timeliness and efficiency of the ethical review process
- 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

The BCEHI Advisory Committee was formed in May 2014 to guide the development and implementation of harmonized ethics review models. Committee members represent the main geographical areas of BC as well as areas of expertise and experience relevant to the ethical review of human research, and confer on behalf of the partner organizations. Decision making for BCEHI is the responsibility of senior leaders in the partner organizations.

The BCEHI partner organizations are currently supporting the pilot implementation and evaluation of harmonized ethics review models. A pilot implementation of a review model for minimal risk studies launched in December 2014 and extended eight months to July 31, 2015. This report presents the evaluation findings of the Minimal Risk Model pilot over that time.

Evaluation Plan and Methods

The evaluation plan was developed in consultation with Engage Associates Consulting Group\(^1\) in October 2014. A survey tool measured the process from initiation of an ethics application to approval, with five role-based surveys being issued for each study reviewed during the pilot. To supplement the quantitative data gathered through the survey, interviews were conducted with 11 Research Ethics Board (REB) members and administrators.

\(^1\) Engage Associates Consulting Group is a Vancouver-based firm that addresses diverse issues and questions within the health research ethics arena.
Limitations of the Evaluation of the Pilot

The main limitation of the evaluation is the lack of reliable data that would allow comparison with previously approved, multi-jurisdiction applications reviewed either collaboratively or as part of a non-harmonized process. Partner organizations collect data differently, which makes reporting on multi-jurisdictional studies problematic.

The Minimal Risk Model was developed with studies involving three or more REBs in mind. However, since dyads (studies involving two REBs) are more common, BCEHI partner organizations were asked to use and report on the harmonized process for dyads as well. Not all partner institutions agreed to use the harmonized process for these dyads, which limited the overall number of studies that could be evaluated. However, where the model process was used in a dyad review, the survey data was collected for the evaluation.

The Harmonized Ethics Review Minimal Risk Model

The Minimal Risk Model was developed collaboratively by the BCEHI Advisory Committee in consultation with their institutional colleagues. The model reflects the ethics review requirements and practices in health authorities and academic institutions and is designed to serve both organization contexts.

A key element of the model is the determination of the Board of Record for each ethics application. The Board of Record is determined by agreement between the REBs under whose auspices the harmonized review is being conducted. This REB then serves as the primary authority and coordinating REB for the harmonized ethics review. Specific criteria for determining the Board of Record are included in the model.

Evaluation Results

Twenty-six studies were reviewed using the harmonized ethics review Minimal Risk Model. Participation in the evaluation survey was high. For 26 pilot studies, 138 surveys were delivered, and 121 were received, representing a response rate of 87.7 percent.

Of the 26 studies, a health authority acted as the Board of Record on 13 applications and a university on the other 13 applications. Twenty of the studies involved at least one health authority. Six studies included only academic institutions.

The findings of the evaluation reveal both the benefits and challenges associated with the adoption of harmonization and highlight areas for improvement. Some progress was made toward achieving the BCEHI priority objectives: improved timeliness and efficiency, improved system effectiveness, and maximal reciprocity. However, evaluation findings show that more work needs to be done to achieve the overall aims of the initiative.

Ease of Process for Researchers

The ability for researchers to submit one application, regardless of the number of jurisdictions involved in a study, and to receive one set of provisos was seen as a benefit. However, evaluation data revealed that many researchers did not feel the harmonized review was more efficient. Likely, researchers require more experience and familiarity with harmonized processes to realize efficiencies. For
researchers, the perceived efficiency of receiving full approval for a study is affected by other factors, such as the requirement to apply for institutional approvals, particularly for studies that involve health authorities. BCEHI partner organizations decided early that institutional approval was beyond the scope of the initiative.

**Research Ethics Board Administrator Effort**

REB administrators experienced varied levels of efficiency with the harmonized ethics review process. It was anticipated that Board of Record administrators’ workload would increase, since they act as the central coordinating person for harmonized reviews. Yet, the findings show that they are not spending a disproportionate amount of time coordinating the review. When they were asked to estimate the time they would have spent administering the same ethics application if it had been single jurisdiction, 50 percent did not feel the harmonized applications took additional time; the other 50 percent felt it would have taken less time.

A distinct benefit of harmonization and a contributing factor to system effectiveness is the high degree of trust that has developed amongst the REB administrators. This is due to the collaborative effort required to effectively coordinate ethics reviews. While there have been challenges with applying the model consistently, administrators acknowledge the model is new and is becoming easier to implement with more experience. It is expected that efficiency will improve as the process becomes embedded into organizational practice.

**Reviewer Experience**

This evaluation revealed that reviewers’ experience participating in harmonized reviews led to some positive findings. The Minimal Risk Model requires that the Board of Record shares their provisos with other REBs involved in the harmonized review of a study. This was seen to be helpful and reduced the time other REBs spent on their reviews. Non-Board of Record reviewers were largely in agreement with the review from the Board of Record. The duplication of provisos was low, and the provisos being added to the Board of Record review were perceived by both reviewers and REB administrators as enhancing the quality of review.

The aim of the BCEHI is to achieve maximal reciprocity in ethics review and this was achieved as defined in the BC Ethics Harmonization Reciprocity Agreement. However, reciprocity was rarely extended to the point of accepting the Board of Record review without some additional oversight by other REBs involved in a study. For the 26 studies surveyed, there were 42 opportunities for a REB to choose full reciprocity. This option was chosen only four times. This is mainly due to the requirement of most partner organization REBs to conduct, at minimum, a proportionate review. Comments received through the survey and interviews indicate that the requirement to conduct a site-specific review, which was perceived in some cases to be disproportionate to the level of risk, presents a challenge to achieving higher levels of reciprocity, particularly for minimal risk studies.

Interview comments point to the need for more clarity in the model around REB expertise as a deciding factor in choosing the Board of Record. Comments from reviewers and administrators show that the tendency of strict adherence to the model’s criteria resulted in situations where the Board of Record may not have had the necessary expertise to perform the review. This is a valuable finding, and will help ensure more effective implementation of this model in the future.
The role of technology in this pilot implementation of the Minimal Risk Model was not included in the evaluation. However, comments received through the survey and interviews suggest that a key barrier to both improved efficiency and system effectiveness is the lack of a common technology platform. When REB members and administrators were asked about the one thing they would change in the harmonization process, the majority stated the need for a technology platform.

**Recommendations**

Overall, the evaluation of the harmonized ethics review Minimal Risk Model demonstrates that it is workable. It is expected that implementation of the model will become better coordinated and more efficient with time, experience and some refinements suggested in this report.

Recommendations for improvements reflect the main challenges encountered with implementing the harmonized ethics review Minimal Risk Model during the eight-month pilot period.

The BCEHI Advisory Committee recommends that the harmonized ethics review Minimal Risk Model be adopted by BCEHI partner organizations. The following recommendations are put forward for consideration.

1. In order to help researchers distinguish between ethics review and other administrative processes, provide more education/information to researchers, specifically on what is required when the research involves health authorities, including the need to separately apply for institutional approval. A self-directed learning module could be developed to facilitate this process.

2. Provide more training to REB administrators on the Minimal Risk Model guidelines to ensure consistent application of the model across BCEHI partner organizations. The BCEHI Advisory Committee is best equipped to facilitate further training.

3. Revise the criteria for determination of the Board of Record in the model, with consideration given to:
   - Location of participants and/or study team
   - Which institution is best placed to mitigate risk to participants/data
   - Expertise of the REBs
   - Proportion of study that is based in specific locations (e.g. hospital and community)

4. Evaluation of technology used in harmonized ethics review was not part of the evaluation. However, consider developing a common technology platform or similar mechanism (including appropriate support personnel) to enable more timely and efficient ethics review and approval.

5. To ensure the continuous improvement of the model, use the data generated through this evaluation to establish a baseline for ongoing assessment and analysis of harmonized processes.

6. Determine and implement, in each BCEHI partner organization, mechanisms to attain higher levels of reciprocity for minimal risk studies.
Background

The BC Ethics Harmonization Initiative (BCEHI) aims to create efficient, coordinated, and high-quality processes that support and encourage multi-jurisdictional human health research. The goal is to make BC a more attractive environment for research activity. The initiative, which began in 2010, is funded and facilitated by the Michael Smith Foundation for Health Research until March 31, 2016.

BCEHI is a collaborative effort of eight partners — four universities (Simon Fraser University, University of British Columbia, University of Northern BC, and University of Victoria) and four health authorities (Fraser, Interior, Island, Northern). Vancouver Coastal Health, Provincial Health Services Authority (Providence Health Care, Children’s and Women’s) and BC Cancer Agency are represented through their affiliations with UBC.

BCEHI is focused on achieving priority objectives:

- Improve the timeliness and efficiency of the ethical review process
- 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

The BCEHI Advisory Committee was formed in May 2014 to guide the development and implementation of harmonized ethics review models. Committee members represent the main geographical areas of BC as well as areas of expertise and experience relevant to the ethical review of human research, and confer on behalf of the partner organizations. Decision making for BCEHI is the responsibility of senior leaders in the partner organizations.

The BCEHI partner organizations are currently supporting the pilot implementation and evaluation of harmonized ethics review models. A pilot implementation of a review model for minimal risk studies was launched in December 2014 and extended for eight months, to July 31, 2015. This report presents the evaluation findings of the Minimal Risk Model pilot over that time.

Stakeholders

Evaluation findings will be of interest to senior leaders of BCEHI partner organizations, researchers, REB members and administrators, and to the broad research community. During the pilot period, researchers, REB members and administrators involved in pilot studies were invited to participate in the evaluation survey. Their feedback provides valuable information about the effectiveness of, and their experiences with, the harmonized ethics review Minimal Risk Model.

The Harmonized Ethics Review Minimal Risk Model

The Minimal Risk Model was developed collaboratively by the BCEHI Advisory Committee in consultation with their institutional colleagues. It built upon a draft harmonization process agreed to in principle by REB chairs and staff of the partner organizations during a January 2014 forum. The model reflects the ethics review requirements and practices in health authorities and academic institutions and is designed to serve both organizational contexts.
A key element of the model is the determination of the Board of Record for each ethics application. The Board of Record is determined by agreement between the REBs under whose auspices the harmonized review is being conducted. This REB then serves as the primary authority and coordinating REB for the harmonized ethics review model.

During the pilot, the following criteria were used to determine which REB would act as the Board of Record:

a. If the study involves only one health authority, the Board of Record will be the REB representing that health authority.

b. If there is more than one health authority involved, the Board of Record will be the primary location where research will take place or, if all sites are equally involved, the health authority where the principal investigator (PI) holds their primary appointment.

c. If no health authority is involved, the Board of Record 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 Board of Record may be the REB that represents the institution where the majority of research is to occur.

d. If Northern Health would be considered the Board of Record under these guidelines, UNBC will by default be the Board of Record, as agreed between Northern Health and UNBC.

These are guidelines only and participating REBs will use their best judgement to determine the Board of Record on a case-by-case basis and, where appropriate, in consultation with the PI.

Materials were developed to support the model implementation; the Guidance document clarifies roles and expectations for participating REBs, REB staff, members and researchers. See Appendix A for the Guidance for Harmonized Ethics Review of Multi-Jurisdictional Studies and Appendix B for the Minimal Risk Model workflow diagram. Both are also available at www.bcethics.ca/resources.

The Minimal Risk Model requires that the Board of Record share its provisos with other REBs involved in the harmonized review of a study. The other REBs can either accept the Board of Record review or choose to conduct their own proportionate review.

**Evaluation Plan and Methods**

The evaluation plan included a survey tool as well as qualitative interviews with REB members and administrators.²

The survey instrument measured the process from initiation of an ethics application to approval, with five role-based surveys being issued for each study reviewed during the pilot period. The surveys were

² Staff worked with Engage Associates Consulting Group, a Vancouver-based firm that addresses diverse issues and questions within the health research ethics arena.
delivered in REDCap (a secure online tool hosted by the Faculty of Medicine at UBC) using survey participant contact information provided by REB administrators. Each invitee was notified through REDCap, with a link to their survey. The survey questions for each role can be found in Appendix C.

A unique survey was created for each ethics review role:

- **Researcher team**: one member, preferably the person most involved in submitting the ethics application. This could be the PI or research coordinator, or another member of the team.
- **Board of Record Reviewer**: one reviewer submitted per application.
- **Board of Record Administrator**: person who coordinated receipt of the application; provisos and notifications, and acted as liaison between REBs.
- **Other REB Reviewer**: one reviewer from each involved REB.
- **Other REB Administrator**: person with primary responsibility for coordinating and communicating with the Board of Record REBA on behalf of their REB.

The survey questions were developed to assess the following factors:

- a. The ease of the process for the researcher, including their workload for submitting a single harmonized ethics review, compared to the multiple applications and reviews required of a non-harmonized, multi-jurisdictional application.
- b. The effort required by REB administrators to manage harmonized ethics reviews, compared to the administrative effort of individual REBs to manage the review of similar ethics applications.
- c. The experience of reviewers of the harmonized ethics review process.
- d. The acceptance of the Board of Record review by other involved REBs.
- e. The degree to which the Board of Record captures the “global” issues (data on the occurrence of “non-local” provisos being submitted by other reviewers).
- f. Insights into possible challenges/problems with the harmonized ethics review process.

To supplement the quantitative data gathered through the survey, qualitative interviews were conducted by the BCEHI manager and project coordinator; 11 REB members and staff were interviewed. The interview questions are in Appendix D.

The data provide a picture of how well the harmonization process is working and how it may be improved and sustained across the partner organizations.

**Limitations of the Pilot Evaluation**

The main limitation of the evaluation is the lack of reliable data that would allow comparison with previously approved, multi-jurisdiction applications reviewed either collaboratively or as part of a non-harmonized process. Partner organizations collect data differently, which makes reporting on multi-jurisdictional studies problematic. This pilot evaluation has the potential to establish a baseline for
future assessment and analysis, and BCEHI partners may wish to use it as a starting point for ongoing measurement.

The Minimal Risk Model was developed with studies involving three or more REBs in mind. However, since dyads (studies involving two REBs) are more common, BCEHI partner organizations were asked to use and report on the harmonized process for dyads as well. Not all partner institutions agreed to use the harmonized process for these dyads, which limited the overall number of studies that could be evaluated. However, where the model process was used in a dyad review, the survey data was collected for the evaluation.

**Evaluation Results**

Participation in the survey was high. For 26 pilot studies, 138 people were invited to complete the survey, and 121 responses were received, representing a response rate of 87.7 percent.

<table>
<thead>
<tr>
<th>Role</th>
<th>Actual responses</th>
<th>Possible responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Board of Record REBAs</td>
<td>24</td>
<td>26</td>
<td>92.30</td>
</tr>
<tr>
<td>Other REBAs</td>
<td>42</td>
<td>43</td>
<td>97.67</td>
</tr>
<tr>
<td>Reviewers</td>
<td>36</td>
<td>43</td>
<td>83.72</td>
</tr>
<tr>
<td>Research team</td>
<td>19</td>
<td>26</td>
<td>73.07</td>
</tr>
<tr>
<td>Total</td>
<td>121</td>
<td>138</td>
<td>87.68</td>
</tr>
</tbody>
</table>

Of the 26 studies, a health authority acted as the Board of Record on 13 applications and a university on the other 13 applications. Twenty of the studies involved at least one health authority. Six studies included only academic institutions. (See Appendix F, Table i.)

Five studies were approved by a REB outside BC prior to admission to a BCEHI partner organization. Of these, three were from western Canadian universities, one from an eastern Canadian university, and one from a university in the United Kingdom.

Fifty-four percent of respondents to the survey initiated their ethics application using the UBC RISe system and 17 percent submitted their application using another online platform. Respondents were not asked to indicate which other online platform was used. Twenty-nine percent were submitted by other means (via email or hard copy for example). Three of the applications reviewed and approved in RISe were overseen by a non-UBC Board of Record. In order to facilitate the use of RISe, a UBC staff member performed some of the BOR administrator’s tasks. (See Appendix F, Table ii.)

**Ease of the Process for Researchers**

Overall, of the 26 research team members who received a survey, 19 (73 percent) responded. Some researchers reported that the ability to submit one application and receive consolidated feedback was a good experience. Seven (27 percent) reported that the harmonization process was more efficient than submitting multiple applications; 3 (11 percent) reported the process was “about the same.” Three responded that it was less efficient and six responded that they did not know. Of the latter, some commented that they had never submitted an ethics application or had not done so recently. As a
result, they could not compare how efficient the harmonized review was to multiple REB applications. (See Appendix F, Table iii.)

RE: 'More efficient’— I haven’t submitted to REB for several years so I cannot say for sure that the process was ‘more efficient’. I would say it was ‘optimally efficient’. – researcher

This was much more efficient than multi-jurisdictional ethics review processes that I have followed in the past. The ethics process itself was very efficient. There was more inconsistency across health authorities with respect to the institutional approvals, but it was still, overall, more efficient. – researcher

For researchers, the perceived efficiency of receiving full approval for a study is affected by additional factors, including the requirement for institutional approvals, particularly for studies that involve health authorities. BCEHI partner organizations decided early that institutional approval was beyond the scope of the initiative. Of the 19 surveys completed, 15 included a health authority REB and required institutional approval. When research team members were asked if they had sought institutional approval before submitting their ethics application, eight (53 percent) of the 15 answered no; seven (47 percent) answered yes. (See Appendix F, Table iv.) Some researchers believed institutional approval would (or should) be included in the harmonized ethics review.

We had to apply for operational approval in VCHA, FHA, Island Health and Providence Health Care after getting UBC approval3 — This delayed the study process for 4 up to 6 weeks (depending on the HA). – researcher

A second factor that was expected to contribute to the ease of the process for researchers was whether they had the required site leads confirmed before the ethics review commenced. All but three of the 19 teams had their site leads in place, suggesting that researchers have a high level of awareness about needing site leads for multi-site ethics applications. However, only 37 percent of the researchers who did have their team in place before applying found the harmonized process more efficient. An equal percentage found it “about the same” or “less efficient.”

Overall, researchers experienced varied levels of efficiency. The ability to submit one application and receive one set of provisos, regardless of the number of institutions involved in the review of a study was seen as a benefit. However, other factors such as the need to apply separately for institutional approval, which is not part of the model, may have affected researchers’ perception of the overall efficiency of their ethics application process. Likely, more experience with harmonized processes is required to realize efficiencies, as the number of studies included in the pilot was limited. It also appears that researchers need more education about this requirement. Ideally, institutional approval would be requested before or at the same time an investigator applies for ethics approval.4

REB Administrator Experience

The Board of Record administrator is the designated coordinator for the harmonized process and acts as the central contact for the research team and other REBs. Their role includes initiating and

---

3 Approval was from all the participating REBs, with UBC acting as the Board of Record and communicating with the research team.

4 An operational contacts list for the partner organizations is available at www.bcethics.ca.
distributing the Board of Record review comments, collating the provisos, and communicating with
the researcher team until the study is approved. Twenty-four out of a possible 26 Board of Record
administrators responded to the survey.

The other REB administrators also take on additional tasks with the harmonized model, which
include facilitating their REB reviewer’s response to Board of Record provisos, and communicating
collaboratively with other REBAs during review and approval. Forty-two out of a possible 43
administrator responses were received.

**Effort required for coordinating reviews**

It was anticipated that the expanded role of the Board of Record administrator would result in a
substantial increase in effort. The responses show that for the 24 applications surveyed, 71 percent
required four hours or less, regardless of how many REBs were involved in the review.

<table>
<thead>
<tr>
<th>Est. time</th>
<th>dyads</th>
<th>3+ REBs</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 - 4 hrs</td>
<td>12</td>
<td>5</td>
<td>17</td>
<td>70.83</td>
</tr>
<tr>
<td>4 - 10+ hrs</td>
<td>5</td>
<td>2</td>
<td>7</td>
<td>29.17</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>7</td>
<td>24</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Board of Record administrators were also asked to estimate the time they would have spent
administering the same ethics application if it had been single jurisdiction. It should be noted that 50
percent did not feel the harmonized applications took additional time; the other 50 percent felt the
review would have taken less time.

Overall, it does not appear that Board of Record administrators spent a disproportionate amount of time
as the central coordinating person during the pilot period. However, when the applications were not
submitted electronically, more time and effort was required.

*Paper-based, multi-jurisdictional reviews are the most time-consuming to coordinate. A lot of extra care and attention is needed when collating provisos, for example, vs when they are all posted on an electronic platform. Also, the paper-based email method means that the coordinator needs to check for duplicate provisos, vs the person posting them electronically being able to see if anyone has already posted the same comment. Having said that, the PI for this study was delighted with the fast turnaround time to receive REB approval from all of the REBs involved, so it certainly served its purpose. – Board of Record administrator*

Other REB administrators were also asked to estimate the time required to coordinate their REB’s
pilot reviews. Forty-two out of a possible 43 responses were received. As anticipated, other REB
administrators spent less time versus their Board of Record counterparts to administer the review:
88 percent required four hours or less; 67 percent reported spending two hours or less.
Other REB administrators

<table>
<thead>
<tr>
<th>Est. Time</th>
<th>2 dyads</th>
<th>3+ REBs</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 - 4 hrs</td>
<td>14</td>
<td>23</td>
<td>37</td>
<td>88.10</td>
</tr>
<tr>
<td>4 - 10+ hrs</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>11.90</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>16</strong></td>
<td><strong>26</strong></td>
<td><strong>42</strong></td>
<td><strong>100.00</strong></td>
</tr>
</tbody>
</table>

The data for either Board of Record or other administrators does not show a lessening of effort (based on time estimate) over the pilot period. This suggests that the process is new and more experience with the model is needed; unanticipated factors affecting how the model is applied continued to emerge throughout the pilot period. Comments received from administrators through the survey and interviews cited several instances where the model was not followed or where clearer communication amongst the REBs would have enhanced efficiency. One Board of Record administrator commented, “I also found I had to keep reminding the other boards to review the study.”

Comments from administrators indicate that the process gets easier with more experience and it is expected that efficiency will improve as the process becomes embedded into organizational practice.

Need more experience with the processes – as we become more familiar with the processes the reviews are improving – REB administrator

There is a bit more coordination involved for REBAs with respect to harmonized studies vs single-site studies, which is why they take more time. It is a necessary fact in order to meet the BCEHI goal of simplifying the process for the researcher, and it gets faster the more we do it, so should not be perceived as an impediment to our commitment to this process....Overall, I think the process gets better the more we use it. – REB administrator

I think the process worked efficiently considering we were not using a shared platform and this study existed outside of the UBC RISE platform. The Board of Record was very efficient and thorough in their ethics review and this expedited the review/approval process by our local REB. – REB administrator

A distinct benefit of harmonization is that it has enabled a high degree of trust due to the collaboration that takes place to coordinate ethics reviews effectively. Feedback from administrators revealed that the use of the model increased the trust and ease of communication amongst REB staff across the partner organizations.

[There is an] Increased comfort level working with other REBs, huge removal of silos between REBs....Remember when REB staff never spoke to one another – REB administrator

I was very grateful by how quickly the Board of Record responded to me and contacted me after they ‘caught’ that the study did involve my REB, and how quickly we worked together to create a harmonized process. The Board of Record administrators were really great. – REB administrator

REBAs had teleconferences in Sept & Oct to review the coversheet and determine how to proceed. Now (June 2015) this isn’t necessary because the process is clearer and decisions are made via email due to comfort and experience working with each other. – REB administrator
Reviewer Experience

Board of Record reviewers

Board of Record reviewers on minimal risk studies were the least affected by the harmonization model pilot during the initial review phase since they were performing the same level of review as on a single jurisdiction or non-harmonized multi-jurisdiction study. Survey results revealed that the initial review provisos shared with other involved REBs were accepted most of the time and there were few instances where other reviewers added non-local provisos.

Board of Record reviewers responded to the survey for 24 out of the 26 studies. Of these, 14 (58 percent) reviewed the application in two hours or less, five (21 percent) were reviewed in two to four hours, with the remainder taking four hours or more. (See Appendix F, Table v.)

Other REB reviewers

Of a possible 42 other REB reviewers invited to participate in the survey, 35 responded (83 percent). Questions focused on: time spent in review, reviewers’ use of the Board of Record provisos, and level of agreement with the Board of Record review. Reviewers were also asked whether they found the Board of Record provisos helpful in forming their own response.

Sixty percent of other reviewers reported spending a maximum of two hours reviewing the applications and 20 percent reported spending less than one hour. (See Appendix F, Table vi.)

Acceptance of the Board of Record Review: Degree to which the Board of Record captures the “global” issues

The Minimal Risk Model, in keeping with TCPS2, is based on the principle of proportionate review and encourages reciprocity where possible and appropriate; the level of risk is a determining factor. As noted, the BCEHI Minimal Risk Model requires that all provisos resulting from the Board of Record’s initial review are shared with the participating REBs. The participating boards can respond either by accepting the Board of Record review unconditionally (full reciprocity), or by conducting a proportionate review, with a focus on site-specific issues.

For the 26 studies surveyed, there were 42 opportunities for a REB to choose full reciprocity. This option was chosen only four times. Various reasons were cited, but comments provided in the survey revealed that most partner organizations still require their REBs to conduct, at minimum, a proportionate review. This is an important finding, as it was anticipated that harmonized processes would lead to higher levels of reciprocity across the partner organizations.

---

5 According to the 2014 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), “The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review). A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research.”
...it was not clear how ethical issues specific to our health authority would be addressed — the original approved application did not need to address these issues (e.g. how existing data would be collected in health authorities? How would the recruiting strategy be adapted to fit the local environment? Who would be the local contact person for participants recruited outside of Vancouver? Etc.) – REB administrator

We always review for local considerations that have ethical implications. Fairly often we find that what is practical and ethical in an academic environment does not translate directly into a public health care setting and a PI based in a different institution would not necessarily know that. Sometimes we also find ethical considerations that are more universal, e.g. for this study we issued provisos relating to Privacy and Data Security. – REB administrator

We have not made the decision as an REB to opt for straight reciprocity. – REB administrator

We are in the process of establishing what a direct reciprocity situation would look like but in the meantime we do take a quick look at the studies. – REB administrator

One aim of harmonized ethics review is to streamline the effort required by reviewers. This is furthered if REB members have confidence in other REB’s processes, and perceive the benefits of receiving and reading the Board of Record provisos in advance of their own review. Of the 33 reviewers who read the Board of Record provisos, 16 (47 percent) did so before reading the application, 12 (36 percent) after reading the application, and five (15 percent) after formulating their own provisos. Only two studies out of 24 were identified where provisos from the Board of Record were duplicated by other reviewers (as reported by Board of Record administrators). When asked if the Board of Record provisos helped to reduce their own review time, 28 (78 percent) responded “yes,” five (14 percent) responded “no.”

This data reveals a good level of trust developing amongst the partner organizations’ REBS that can be built on going forward.

Reviewers were asked to rank their agreement with the Board of Record review. Of the 34 reviewers who responded, 82 percent placed themselves in the range of strongly agree to neutral. Eighteen percent placed themselves in the range of neutral to strongly disagree.

Level of agreement with the Board of Record provisos

<table>
<thead>
<tr>
<th>Score</th>
<th>Strongly Agree - Neutral</th>
<th>Neutral - Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td># Responses</td>
<td>0 - 25</td>
<td>26 - 50</td>
</tr>
<tr>
<td>19</td>
<td>9</td>
<td>4</td>
</tr>
</tbody>
</table>

Interviews with reviewers and administrators suggest that the harmonization process served to enhance the ethics review. Reviewers commented that they were motivated to do the best review possible with the recognition that other reviewers would be looking at their comments. As well, comments indicated that the provisos added to the Board of Record review improved the quality of the reviews.

The quality of reviews is going up; we are fine tuning and adding so the review is better, richer, with the different perspectives. – reviewer

Provisos I receive back from other reviewers are great and improve the review.
– REB administrator

Interviews with REB members and administrators revealed some challenges in the determination of the Board of Record. TCPS2 points out the requirement to include the necessary experience in an ethics
review. Because the criteria for determining the Board of Record in BCEHI review are guidelines only, it was expected that participating REBs would assess the study and demonstrate some flexibility when determining the Board of Record. However, the tendency of strict adherence to the model’s criteria resulted in situations where the Board of Record may not have had the necessary experience to perform the review. This is a valuable finding, and will help ensure more effective implementation of this model in the future.

... if the Board of Record does not have ample expertise in a certain area of research then another board may see comments that are not appropriate (Aboriginal studies) and so need to educate or carefully negotiate that the review be done by the board with expertise.” – reviewer

Expertise may need to be a criterion for determining Board of Record — if expertise is not there to review an application or even a part of an application then let the involved board with the expertise do the review. – reviewer

This evaluation revealed that reviewers’ experience participating in harmonized reviews led to some positive findings. The process of the Board of Record sharing provisos with other REBs was seen to be helpful and reduced the time other REBS spent on their reviews. Non-Board of Record reviewers were largely in agreement with the Board of Record review and the duplication of provisos was low. In addition, the harmonization process appears to be effective in maintaining the quality of ethics review, and comments from some reviewers suggest that provisos added through the review process seemed to enhance the overall ethics review.

The aim of the BCEHI is to achieve maximal reciprocity in ethics review and this was achieved as defined in the BC Ethics Harmonization Reciprocity Agreement. However, reciprocity was rarely extended to the point of accepting the Board of Record review without some additional oversight by other REBs. Comments received through the survey and interviews indicate that the requirement to conduct a site-specific review, which was perceived in some cases disproportionate to the level of risk, presents a challenge to achieving a higher level of reciprocity for minimal risk studies. The BCEHI partner organizations may want to examine how they can achieve higher levels of reciprocity, particularly as it relates to the review of minimal risk studies. Consideration should also be given to providing more clarity in the Minimal Risk Model around REB expertise as a deciding factor in choosing the Board of Record.

**Duration of Harmonized Research Ethics Review**

The main focus of this evaluation was to assess the overall harmonized ethics research review process of minimal risk studies as it was experienced by researchers and REB members and administrators, including the time spent by each of these groups on the ethics review. Some discrete data was collected on the time spent moving through the different steps of the harmonized model as documented in the Minimal Risk Model workflow diagram.

This data shows that 18 studies of a possible 23 moved through the first steps of the harmonized ethics review process in seven days, as noted in the table below. This suggests that reaching agreement on the Board of Record, to the review and turnaround by the Board of Record of their proviso to other involved REBS was achieved efficiently.
From date initial application received by Board of Record (1) to date assigned to reviewers (4)

From date initial application received by Board of Record (1) to date assigned to reviewers (4)

<table>
<thead>
<tr>
<th>Est. Time</th>
<th>dyads</th>
<th>3+ REBs</th>
<th>total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 1 days</td>
<td>7</td>
<td>3</td>
<td>10</td>
<td>43.48%</td>
</tr>
<tr>
<td>2 - 7 days</td>
<td>4</td>
<td>4</td>
<td>8</td>
<td>34.78%</td>
</tr>
<tr>
<td>8 - 14 days</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>13.04%</td>
</tr>
<tr>
<td>15 + days</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>8.70%</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>7</td>
<td>23</td>
<td>100.00%</td>
</tr>
</tbody>
</table>

One outlier study has been removed from data; data was unavailable for 2 studies.

After the Board of record provides their provisos, other participating REBs complete proportionate site specific reviews, share their provisos with the Board of Record or notify acceptance of Board of Record decision. Following this all provisos are sent to the research team. The guidance document which clarifies roles and expectations for participating REBs, REB staff, members and researchers states that other REBs should aim to deliver their provisos to the Board of Record within 10 business days of receiving the application and provisos from the Board of Record. While no data was collected on the average duration of these specific steps, data was collected on the duration of the ethics review from initiation of the application to provisos being sent to the research team, as noted in the table below. Of 23 studies, 10 moved through steps 1 to 6 of the model process in 14 days. When accounting for the time spent in the first steps of the review, the data suggests the 10 day target to complete steps 5 and 6 was met. However, 13 studies took between 15 to 29 or more days.

From date initial application received by BoR (1) to date first provisos submitted to PI (6) (calendar days)

<table>
<thead>
<tr>
<th>Est. Time</th>
<th>dyads</th>
<th>3+ REBs</th>
<th>total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 7 days</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>13.04%</td>
</tr>
<tr>
<td>8 - 14 days</td>
<td>6</td>
<td>1</td>
<td>7</td>
<td>30.43%</td>
</tr>
<tr>
<td>15 - 21 days</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>4.35%</td>
</tr>
<tr>
<td>22 - 28 days</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>26.09%</td>
</tr>
<tr>
<td>29 &gt; days</td>
<td>4</td>
<td>2</td>
<td>6</td>
<td>26.09%</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>7</td>
<td>23</td>
<td>100.00%</td>
</tr>
</tbody>
</table>
One outlier study has been removed from data; data was unavailable for 2 studies.

As stated earlier in this report, the level of agreement with the Board of Record review by other participating REBs in harmonized reviews was high, which suggests that there are other reasons for the additional time spent by participating REBs. Across the partner organizations, REBs experience different volumes of applications for research ethics review and have varied processes and protocols associated with how they conduct a proportionate review.

The final steps in the Minimal Risk Model include the calendar days it took the researcher/research team to respond to the Board of Record after receiving the provisos. For 11 of the 24 studies, it took researchers 14 days or less to respond to the Board of Record, and for 13 studies it took researchers 15 to 29 or more days. Why there is such wide variation in response time by researchers is not known.

**Conclusion**

The harmonized ethics review Minimal Risk Model was implemented over an eight-month period during which 26 multi-jurisdictional studies were reviewed. The experience of researchers, REB administrators and reviewers involved in the harmonized ethics review processes was evaluated using a survey tool supported by interviews with administrators and reviewers.

The findings of the evaluation reveal both the benefits and challenges associated with the adoption of harmonization and highlight areas for improvement. Some progress was made toward achieving the BCEHI priority objectives; improved timeliness and efficiency; improved system effectiveness and maximal reciprocity. However, more work needs to be done to achieve the overall aims of the initiative.

The role of technology in the pilot implementation of the Minimal Risk Model was not included in this evaluation. Nevertheless, comments from the survey suggest that a key barrier both to improved efficiency and system effectiveness is the lack of a common technology platform. Also, when REB members and administrators were asked about the one thing they would change in the harmonization process, the majority stated the need for a technology platform.

**Recommendations**

Overall, the evaluation of the harmonized ethics review Minimal Risk Model demonstrates that it is workable. It is expected that implementation of the model will become better coordinated and more efficient with time, experience and some refinements suggested in this report.

Recommendations for improvements reflect the main challenges encountered with implementing the harmonized ethics review Minimal Risk Model during the eight-month pilot period.

The BCEHI Advisory Committee recommends that the harmonized ethics review Minimal Risk Model be adopted by the BCEHI partner organizations. The following recommendations are put forward for consideration.

1. In order to help researchers in distinguishing between ethics review and other administrative processes, provide more education/information to researchers, specifically on what is required
when the research involves health authorities, including the need to separately apply for institutional approval. A self-directed learning module could be developed to facilitate this process.

2. Provide more training to REB administrators on the Minimal Risk Model guidelines to ensure consistent application of the model across the BCEHI partner organizations. The BCEHI Advisory Committee is best equipped to facilitate further training.

3. Revise the criteria for determination of the Board of Record in the model, with consideration given to:
   - Location of participants and/or study team
   - Which institution is best placed to mitigate risk to participants/data
   - Expertise of the REBs
   - Proportion of study that is based in specific locations (e.g. hospital and community)

4. Evaluation of technology used in harmonized ethics review was not part of the evaluation. However, based on comments received through the survey and interviews, consider developing a common technology platform or similar mechanism (including appropriate support personnel) to enable more timely and efficient ethics review and approval.

5. To ensure the continuous improvement of the model, use the data generated through this evaluation to establish a baseline for ongoing assessment and analysis of harmonized processes.

6. Determine and implement, in each BCEHI partner organization, mechanisms to attain higher levels of reciprocity for minimal risk studies.
Appendix A – Guidance Harmonized Ethics Reviews

1. PURPOSE
To provide guidance on how the proposed models for harmonized multi-jurisdictional research studies will be implemented during the pilot period.

2. SCOPE AND APPLICABILITY
2.1 This guidance is intended for use by Research Ethics Board\(^6\) (REB) administrators and members for harmonized multi-jurisdictional research studies where three or more\(^7\) partner institutions in the BC Ethics Harmonization Initiative (BCEHI) will be reviewing a research ethics application.

2.2 Research is considered either minimal risk or above minimal risk, in accordance with the Minimal Risk Criteria Guideline. The workflow diagrams for each model describe the process for determining risk level.

2.3 This guidance is not intended to address sponsored clinical trials or retrospective chart reviews.

2.4 This is guidance only and emphasis is on flexibility in the models, which may be required in certain circumstances.

2.5 Although the BoR will be responsible for providing the PI with contact information for operational approvals, this guidance does not address institution-specific approvals that may be required in addition to ethical approval.

2.6 Privacy review is considered an institutional approval. If a privacy review creates a requirement to change an ethics application, the REB involved will notify the BoR that an amendment will be required.

3. RESPONSE TIMES FOR ETHICS REVIEW
3.1 REBs will determine the Board of record and confirm Risk level within five business days of ethics application submission.

3.1.1 If an REB is unable to participate in a harmonized review, they will notify the participating REBs and the PI in writing as soon as possible, but within five business days of receiving the notification. It is recognized that in order to make this determination, the REBs may require additional information, such as the cover sheet and/or the application itself.

---

\(^6\) Throughout this document, “Research Ethics Board” and “REB” are intended to include the Northern Health Research Ethics Committee.

\(^7\) REBs engaged in dyad ethics reviews are welcome to follow the procedures outlined for harmonized multi-jurisdictional review.
3.2 Other REBs should deliver their provisos to the BoR within 10 business days of receiving the application and provisos from the BoR.

3.3 In accordance with section 9.3 below, if an REB requests to see the PI’s proviso responses, they will respond to the BoR within three business days of receiving the proviso response.

4. INITIATION OF ETHICS APPLICATION

4.1 The principal investigator (PI) will initiate the ethics application by contacting their primary REB office, by submitting a Cover Sheet, via their application, or by other means (e.g. phone, email or in person).

4.2 The ethics application will be submitted by whatever medium is particular to the institution receiving the initial application (electronic through RISE or other platform, email, or hard copy).

4.3 The Cover Sheet may be completed by the PI and submitted in advance or as part of their application, or it may be completed by the REB administration. Completion of a Cover Sheet is recommended to facilitate information exchange between REBs and the PI/research team.

4.4 The recipient REB will confirm which REBs are involved and will initiate communication among them to determine the Board of Record (BoR).

4.5 Participating REBs may opt in advance for full reciprocity with the BoR (choose to accept the BoR review and decision) and opt to receive a copy of the Certificate of Approval (CoA), once issued, and a full package of the final documents for their records. Until there is the ability to issue a joint CoA, the CoA will be issued as outlined below.

4.6 If an REB decides to reject a study, they may do so at any time during the review and approval process, by notifying the BoR in writing and by contacting the PI/research team.

5. BOARD OF RECORD

5.1 The BoR for a multi-jurisdictional study will be determined based on the following criteria:

   a. If the study involves only one Health Authority, the Board of Record will be the REB representing that Health Authority.

   b. If there is more than one Health Authority involved, the BoR will be the primary location where research will take place or, if all sites are equally involved, the Health Authority where the PI holds their primary appointment.

   c. 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 majority of research is to occur.

   d. 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.
5.2 These are guidelines only and participating REBs will use their best judgement to determine the BoR on a case-by-case basis and, where appropriate, in consultation with the PI.

5.3 Once the BoR has been confirmed, the BoR administrator will discuss and agree with the PI on the most efficient way to submit the complete application to the BoR.

5.4 Upon receipt of the ethics application, the BoR will:
   a. Confirm via email to the participating REBs that the ethics application has been received, including the study title and PI name in the subject line (recommended for all harmonized study communications)
   b. Provide the PI with a copy of the Partner Contacts for Operational Approval

6. MINIMAL RISK MODEL

6.1 Delegated review will be conducted by the BoR in accordance with their usual practice.

6.2 Reviews will be conducted in a timely manner to ensure that local REB issues can be addressed within a reasonable timeframe.

6.3 If full reciprocity (see 4.5) is not chosen by all the participating REBs, all provisos resulting from the BoR’s delegated review will be shared with the participating REBs. The participating REBs will respond either by:
   a. Accepting the BoR’s review, or
   b. Conducting a proportionate and site specific review: avoiding duplication of provisos; submitting their provisos to the BoR; and indicating which proviso responses, if any, they need to review.

6.4 The BoR will compile the provisos and provide them to the PI as per their usual practices

6.5 The BoR will work with the PI to address all provisos.

6.6 The BoR will notify a participating REB of a PI’s responses only if specifically requested.

6.7 When all provisos have been satisfied, the BoR will notify the other REBs that the BoR is ready to issue a Certificate of Approval and confirm the certificate’s approval date.

6.8 All other participating REBs will send their Certificates of Approval with the confirmed approval date to the BoR.

6.9 The BoR will deliver the package of CoAs to the PI.

6.10 The BoR will deliver a complete set of study-related documents, including the CoA package, to each participating REB.
7. **ABOVE MINIMAL RISK**

7.1 Following the decision on which REB will form the BoR, the BoR will normally take the lead in determining whether the study is above minimal risk. If required, the BoR will consult with the affected REBs about the level of risk designation.

7.2 If the study does not require full board review, the BoR will follow the minimal risk process outlined in section 0.

7.3 If full board review is required, the board will consist of the BoR plus one or more voting members from each participating REB.

7.4 The Chair will be the Chair of the BoR.

7.5 Notice of the full board meeting will be sent out as quickly as possible to the REB administrators of the participating REBs in order to ensure they have a member available for the meeting date.

7.6 Participation in the full board meeting will be by one of the following methods:

   a. Attending in person
   b. Attending by video conference
   c. Attending by teleconference
   d. Submitting review comments prior to the meeting to be considered by the Chair in the decision process

7.7 A reasonable effort will be made by the BoR to accommodate the participation method chosen by additional members.

7.8 If, due to connectivity problems or last minute scheduling difficulties, a +1 REB member is unable to participate in the meeting, the meeting will continue and provision will be made by the BoR to have the absent REB member participate by other means.

7.9 Quorum will be defined by the BoR’s policy and, at a minimum, will meet the TCPS2 standards:

   a. At least two members who have relevant knowledge and expertise in the content area
   b. At least one member who is knowledgeable in ethics
   c. At least one member who is knowledgeable in the relevant law
   d. At least one member who has no affiliation with the institution, but is recruited from the community
   e. Quorum is based on who is present at the meeting (physically and remotely). This includes designated members of other REBs who participate in the collaborative review. In the event of a vote, the designated members of the other REBs are entitled to vote.
   f. Attendees who are voting members of their own REB will be considered voting members to meet the quorum.
7.10 The meeting minutes will record if a member of the involved REB(s) requests notification of a response by a PI to a proviso to ensure it has been met to their satisfaction.

7.11 The BoR will address the provisos on behalf of the participating REB(s) unless instructed otherwise as in 7.10.

7.12 If a Joint certificate is being used, the BoR will notify the other REBs that they are ready to issue a joint CoA and confirm the approval date.

7.13 The BoR will deliver the Joint CoA to the PI.

7.14 If separate CoAs are being created for each REB, the BoR will wait to issue the CoA package until after the additional CoAs are received and will deliver the complete set of certificates to the PI.

7.15 The BoR will deliver the complete set of study documents to each participating REB, including the certificate/certificates.

8. CONTINUING REVIEW – MINIMAL RISK AND ABOVE MINIMAL RISK STUDIES

8.1 Continuing review activities, including approvals and communications with the PI, will be coordinated through the BoR.

8.2 The BoR’s forms will be used for each type of continuing review activity.

8.3 When available, the study team’s forms will be accepted for various continuing review scenarios, including: Local Serious Adverse Events, protocol deviations, periodic safety update reports and administrative letters. If the study team does not have a specific form for the purpose, they will use the forms provided by the BoR.

8.4 Upon submission by the PI of a continuing review activity, the BoR will determine if a consultation with the participating REBs is required, depending on whether:

   a. The continuing review activity is specific to the jurisdiction of a participating REB (e.g. security and privacy breach at a particular site, new funding, change in study team membership from an institution, addition of animal care ethics, addition of bio-safety factors or patient data to the protocol); and/or

   b. The information provided in the continuing review activity increases the overall risk to participants above the level approved in the original application.

8.5 If no consultation is required, the BoR will process the continuing review activity in accordance with their REB policies and procedures. The BoR will issue the appropriate documentation to the PI and will provide the other REBs with a copy of the related documentation.

8.6 ADDITION OF NEW SITES AFTER INITIAL ETHICS APPROVAL:

8.6.1 The PI will be asked to submit the added sites as a separate amendment prior to submitting other amendments for review and approval.

8.6.2 The originating REB will notify the affected REBs and request their decision re: harmonization.
8.6.3 The BoR will provide the new REB(s) with the original application and provisos to date for review and a decision on status.

8.6.4 If there are additional provisos related to the new REB:
   a. The new REB will communicate directly with the PI to resolve and copy the BoR on correspondence
   b. The PI will submit revised documentation to the BoR for review and approval
   c. The BoR approves the amendment for adding sites and advises the PI that other amendments (if any) may be submitted for review

8.6.5 If there are no additional provisos related to the new REB:
   a. The new REB submits a Letter of Acknowledgement to the BoR
   b. The BoR approves the new REB amendment and advises the PI that other amendments (if any) may be submitted for review.

8.6.6 The certificate date of the originating REB will be considered the default date for expiry and renewal purposes.

8.7 HARMONIZATION OF AN ETHICS FILE WHEN INITIAL APPROVAL WAS NOT HARMONIZED:

8.7.1 Designation of the BoR will be decided using the original decision criteria (see Section 0).

8.7.2 The harmonized certificate date will be the earliest of the participating REB’s expiry dates.

8.8 MINIMAL RISK CONTINUING REVIEW ACTIVITIES

8.8.1 If required, the BoR will facilitate consultation between the REBs to determine the specific disposition of the continuing review activity.

8.9 ABOVE MINIMAL RISK CONTINUING REVIEW ACTIVITIES

8.9.1 If full board review is required in accordance with regulatory and TCPS2 guidance, the BoR will follow the same process as outlined in the sections above for forming a full board and conducting the review.

8.9.2 If a full board review is not required, the BoR will facilitate consultation between the REBs to determine the specific disposition of the continuing review activity.

8.10 The participating REBs will be advised of the continuing review activity (event/outcome), and will be provided with a copy of the appropriate acknowledgement or CoA.

9. PROVISOS FOR CONTINUING REVIEW

9.1 The BoR will address the provisos with the PI in conjunction with the participating REBs.

9.2 For SAEs and protocol deviations, the REB for the site of the occurrence will determine the response and take the required action, e.g. ensure retraining of study team members. The site REB will notify the BoR of their actions.

9.3 The meeting minutes will record if a member requests notification of the PI’s response to a proviso to ensure it has been met to their satisfaction.
9.4 If a participating REB requires review of the PI’s response, they agree to provide any additional comments or confirm their agreement within three working days of receipt of the PI response.

9.5 Once all ethical issues have been addressed, the BoR will notify the other REBs that they are ready to issue a Certificate of Approval and confirm the certificate date.

9.6 All other participating REBs will send their Certificates of Approval with the confirmed date to the BoR.

9.7 The BoR will deliver the package of CoAs to the PI.

9.8 The BoR will deliver a complete set of study-related documents, including the CoA package, to each participating REB.

10. STUDY CLOSURE

10.1 Individual REBs are responsible for ensuring that administrative requirements related to study closure are completed by the research team.

10.2 The BoR will be advised by the PI when the study is closing in any jurisdiction, using the customary continuing review procedures.

10.3 The BoR will notify the affected REB(s) and facilitate documentation of study closure activities.

10.4 If a participating REB is notified by the research team of closure at their site, the other REB will inform the BoR and provide the related paperwork for inclusion in the ethics application documentation.

10.5 The BoR will remove an REB from the study once the REB has confirmed all their requirements have been met.

10.6 The BoR will ensure that study closure documentation for each site is included in the BoR file.

11. PARTICIPANT COMPLAINTS

11.1 The contact details for participants to file a complaint will be listed for each REB on the informed consent and/or assent form(s).

11.2 The submission of a participant complaint will be managed jointly by the REB that receives it and the BoR, involving other REBs as outlined in 8.34.

11.3 The BoR will consult with participating REBs depending on the type of complaint, its jurisdiction, and whether the complaint results in an amendment being required.

12. DOCUMENTATION

12.1 The BoR will be responsible for maintaining complete documentation of the ethics application and all continuing review activities, including notification of study closure.

12.2 The BoR will share updated documents with the participating REBs. This may involve emailing or uploading documents to a shared repository.
13. SUPPORTING RESOURCES (available from the Resources tab at bcethics.ca)

Research Ethics Review Workflows (Minimal Risk and Above Minimal Risk)

Harmonized Review Cover Sheet (MSWord)

Partner Contacts for Operational Approval
Appendix B – Harmonized Minimal Risk Ethics Review Model – Initial and 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.
- 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.

Continuing Review

1. PI submits continuing review activity to BoR
2. Does the continuing review activity require REB consultation?
   - NO
   - YES
   2.1 BoR consults with affected REBs
3. BoR processes continuing review activity
4. BoR issues acknowledgement or Certificate/s of Approval (as appropriate)
5. BoR shares all approved research related documents with participating REBs

Last updated May 14, 2015
Appendix C – Survey Questions

Researcher

1. How did you initiate your submission or application?
   - Completed Harmonization Cover Sheet
   - Contacted my REB by phone or email
   - Contacted multiple REBs by phone or email
   - Submitted application to my REB
   - Contacted BCEHI

2. If the Harmonization Cover Sheet was used, how was it sourced?
   - BCEHI website (http://bcethics.ca)
   - REB Administrator sent it to us
   - Institution’s Website
   - Other

3. If ‘Other’ above, please explain

4. Date complete application was submitted (including all related documents)

5. How many times did the study team respond to provisos before approval was received?
   - There were no provisos
   - 1 - 2
   - 2 - 4
   - 4 - 6
   - >6

6. Did the study team request institutional approval prior to submitting the ethics application?

7. Did the study team have the required investigators confirmed before submitting the ethics application?

8. How efficient was the harmonized ethics review process for this study compared to previous ethics review processes?
   - more efficient
   - less efficient
   - about the same
   - don't know
   - not applicable

9. Please provide any additional comments on the harmonized ethics review process

Board of Record Administrator

1. How was the initial ethics application submitted?
2. Date initial application received by Board of Record

3. Date assigned to reviewer(s)

4. Date when all reviewer comments/provisos had been received by the administrator

5. Date first provisos submitted to PI

6. Date final response received from PI

7. How many proviso items issued were from the Board of Record reviewers?

8. How many proviso items issued were from reviewers outside the BoR?

9. Were any provisos received from additional reviewers that duplicated provisos issued by the Board of Record?
   Yes No

10. In your opinion, were any provisos submitted by additional reviewers for broader (non-local) issues?
    Yes No

11. Date of Certificate of Approval

12. Date the PI was notified of approval by your institution

13. How much time did you spend coordinating the initial review and approval phase?
   < 1 hr
   1 - 2 hrs
   2 - 4 hrs
   4 - 6 hrs
   6 - 10 hrs
   10+ hrs

14. If this had been a single jurisdiction study, approximately how much time would you have spent coordinating the initial review and approval phase?
   < 1 hr
   1 - 2 hrs
   2 - 4 hrs
   4 - 6 hrs
   6 - 10 hrs
   10+ hrs

15. How difficult was the harmonized review process for this study?
    [Sliding scale] 0% (not difficult) to 100% (very difficult)

16. Please provide any additional comments on the harmonized review process
Board of Record Reviewer

1. How much time did you spend reviewing the application?
   - < 1 hr
   - 1 - 2 hrs
   - 2 - 4 hrs
   - 4 - 6 hrs
   - 6 - 10 hrs
   - 10+ hrs

2. How many provisos did you submit?
   - 0
   - 1 - 2
   - 2 - 4
   - 4 - 6
   - 6 - 10
   - 10 +

3. How difficult was the harmonized review process for this study?
   [Sliding scale] Not difficult | Neutral | Very difficult

4. Please provide any additional comments on the harmonized review process

Other REB Administrator

1. Did your institution opt for accepting the BoR review unconditionally prior to receipt of provisos? (Full Reciprocity)
   - Yes
   - No

2. If 'No', please explain why not

3. How much time did you spend coordinating the review process on behalf of your REB?
   - < 1 hr
   - 1 - 2 hrs
   - 2 - 4 hrs
   - 4 - 6 hrs
   - 6 - 10 hrs
   - 10+ hrs

4. If this had been a single jurisdiction study, how much time would you have spent coordinating the review process?
   - More
   - Less
   - About the same

5. How difficult was the harmonized review process for this study?
   [Sliding scale] Not difficult | Neutral | Very difficult
6. Please provide any additional comments on the harmonized review process

Other REB Reviewers

1. How much time did you spend reviewing the application, including any provisos from the Board of Record?
   - < 1 hr
   - 1 - 2 hrs
   - 2 - 4 hrs
   - 4 - 6 hrs
   - 6 - 10 hrs
   - 10+ hrs

2. Did you read the initial review provisos/comments?
   - Yes
   - No
   - There were none

3. When did you read the provisos?
   - Before reading the ethics application
   - After reading the ethics application
   - After formulating my own provisos
   - N/A, there were none

4. Did the received provisos help to reduce your review time?
   - Yes
   - No
   - Not applicable

5. If No, please explain

6. How many additional provisos did you submit?
   - 0
   - 1 - 2
   - 2 - 4
   - 4 - 6
   - 6 - 10
   - 10 +

7. What was your level of agreement with the review conducted by the BoR?
   - [Sliding scale] Strongly Agree | Neutral | Strongly Disagree
8. How difficult was the harmonized review process for this study?  
   [Sliding scale] Not difficult | Neutral | Very difficult

9. Please provide any additional comments on the harmonized review process
Appendix D – Qualitative Interview Questions

REB Reviewer Questions

1. What advice would you give to a first time reviewer of a harmonized ethics application? For example, provisos from other REBs; how to communicate; questions to ask before reviewing.
2. What are the benefits of the harmonized process for REBs?
3. What are the drawbacks / challenges of the harmonized process for REBs?
4. How will the harmonized process affect ethics reviews?
5. If there was one thing you could ensure is implemented for harmonization, what would it be and why?
6. How could the effectiveness / quality of ethics reviews be increased?
7. What other observations would you like to share?

REB Administrator Questions

1. What advice would you give to an administrator who is facilitating a harmonized ethics application for the first time?
2. What do you see as the benefits of the harmonized process for REB administrators/managers?
3. What challenges might REB Administrators face in full implementation of the harmonization process?
4. What guidance or support materials would you recommend to an REB administrator assigned to a harmonized application?
5. If there was one thing you could change about the harmonization process for MR studies, what would it be and why?
6. What other observations would you like to share?
Appendix E – Glossary

**Board of Record (BoR):** Determined by agreement between those REBs under whose auspices the multi-jurisdictional study is being conducted. The Board of Record serves as the primary authority for the ethical oversight of the human research project.

**Board of Record Administrator:** Responsible for central coordination of a harmonized review. Acts as the liaison between participating REB staff, the Board of Record reviewer and the research team.

**Board of Record Reviewer:** Conducts the initial review of a harmonized study; Board of Record reviewer provisos are distributed to reviewers of the other REBs involved in a harmonized review for response and additions before delivery to the researcher.

**Collaborative Review:** Distinguished from maximal reciprocity in that each of the participating REBs are involved in the review process resulting in a set of combined provisos delivered by the Board of Record to the researcher.

**Continuing Ethics Review:** Any review of ongoing research conducted by a REB occurring after the date of the initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles of the TCPS2.

**Cover Sheet:** Form that facilitates sharing information about a harmonized ethics application, in particular the level of risk, type of study, and participating sites and to assist in the determination of the BoR.

**Delegated Review:** The level of ethics review assigned to minimal risk research projects and performed by a REB member in accordance with the provisions of the institutional polices applicable to the REB and in accordance with the TCPS2.

**Dyad:** Ethics application that is reviewed and approved jointly by two REBs.

**Full Board Review:** The level of REB review assigned to above minimal risk research projects. Conducted by the full membership of the REB, it is the default requirement for the ethics review of research involving humans.

**Harmonized Research Ethics Review:** Ethical review of a research project jointly by two or more REBs in BC party to the BC Research Ethics Review Reciprocity Agreement.

**Initial Ethics Review:** The initial assessment of ethical acceptability of a research project through consideration of the foreseeable risks, the potential benefits and the ethical implications of the project.

**Institutional approval:** (May also be called a Letter of Authorization to Conduct Research). Granted by a health authority(s) involved once operational approval, ethical approval and all contract requirements and approvals for the project are complete.

**Joint Certificate of Ethical Approval:** A certificate of ethical approval issued by the Board of Record on behalf of all REBs involved for a multi-jurisdictional research project.

**Maximal Reciprocity:** Highest level of reciprocity acceptable to a REB for its ethical review of a multi-jurisdictional study, based on 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.
Minimal Risk Model: The process developed and used by BCEHI partner organization REBS for conducting the harmonized research ethics review of minimal risk studies.

Minimal Risk Research: Human research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.

Multi-Jurisdictional Research: Human research that is conducted under the auspices or jurisdiction of more than one institution, and which requires an ethics review by more than one REB, in accordance with the relevant institutions policies.

Operational Approval: (May also be called a Department Agreement/Approval, or Operational Review.) Approval for the operational requirements of research projects proposed to be conducted:

- in whole or in part within health authority facilities/programs/departments; and/or
- that involve health authority staff/physicians/patients or their personal information; and/or
- that use site resources regardless of any research funding source.

Other REB | Reviewer | Administrator: Within the harmonized model, refers to any participating REB and its staff that is not the Board of Record.

Proportionate review: The assessment of foreseeable risks, potential benefits, and ethical implications to determine the level of scrutiny a research proposal will receive.

Reciprocity Agreement: Agreement between the Parties of the BCEHI for an overall approach to the research ethics review of multi-jurisdictional studies involving human participants that avoids duplicative and/or redundant ethical reviews.

Research Ethics Board (REB): A body of researchers, community members, and others with specific expertise (e.g. in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution’s jurisdiction or under its auspices.

RISe: Online research administration tool hosted by UBC that allows researchers and administrators to manage ethics applications online.

Site lead: A researcher who has responsibility for oversight of research conducted at a location secondary to the principal investigator’s research site/s.

TCPS2 | Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: A joint policy of Canada’s three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or “the Agencies.” This Policy expresses the Agencies’ continuing commitment to the people of Canada to promote the ethical conduct of research involving humans.
Appendix F – Application Data

Table i – The BCEHI partner REBs that acted as Board of Record on pilot studies

<table>
<thead>
<tr>
<th>BoR</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BC Cancer Agency</td>
<td>0</td>
</tr>
<tr>
<td>Children’s &amp; Women’s</td>
<td>3</td>
</tr>
<tr>
<td>Interior Health Authority</td>
<td>6</td>
</tr>
<tr>
<td>Island Health</td>
<td>4</td>
</tr>
<tr>
<td>Fraser Health</td>
<td>0</td>
</tr>
<tr>
<td>Providence Health Care</td>
<td>0</td>
</tr>
<tr>
<td>SFU</td>
<td>3</td>
</tr>
<tr>
<td>UVIC</td>
<td>3</td>
</tr>
<tr>
<td>UBC-BREB</td>
<td>6</td>
</tr>
<tr>
<td>UBC-CREB</td>
<td>0</td>
</tr>
<tr>
<td>UBC-Okanagan</td>
<td>1</td>
</tr>
<tr>
<td>UNBC</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>26</strong></td>
</tr>
</tbody>
</table>

Table ii – Initial ethics application submission method

<table>
<thead>
<tr>
<th>Submission method</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>In RISe</td>
<td>13</td>
<td>54.17</td>
</tr>
<tr>
<td>In another online platform</td>
<td>4</td>
<td>16.67</td>
</tr>
<tr>
<td>Via email attachment</td>
<td>4</td>
<td>16.67</td>
</tr>
<tr>
<td>In hard copy</td>
<td>2</td>
<td>8.33</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>4.17</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>24</strong></td>
<td><strong>100.00</strong></td>
</tr>
</tbody>
</table>

Information was unavailable for two studies.

Table iii – Measure of pilot process efficiency for researchers
(studies with investigators confirmed before submitting ethics application)

<table>
<thead>
<tr>
<th>Efficiency</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>More efficient</td>
<td>6</td>
<td>37.50</td>
</tr>
<tr>
<td>About the same</td>
<td>3</td>
<td>18.75</td>
</tr>
<tr>
<td>Less Efficient</td>
<td>3</td>
<td>18.75</td>
</tr>
<tr>
<td>Don’t know or not applicable</td>
<td>4</td>
<td>25.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>16</strong></td>
<td><strong>100.00</strong></td>
</tr>
</tbody>
</table>

Data was unavailable for seven studies.

Table iv – Institutional approvals requested prior to ethics submission; includes studies involving at least one health authority.
Information was unavailable for five of the studies that involved at least one health authority REB.

**Table v – Board of Record time spent reviewing**

<table>
<thead>
<tr>
<th>Estimated time</th>
<th>Dyad &amp; 3+</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 hr</td>
<td>7</td>
<td>29.17</td>
</tr>
<tr>
<td>1 - 2 hrs</td>
<td>7</td>
<td>29.17</td>
</tr>
<tr>
<td>2 - 4 hrs</td>
<td>5</td>
<td>20.83</td>
</tr>
<tr>
<td>4 - 6 hrs</td>
<td>4</td>
<td>16.67</td>
</tr>
<tr>
<td>6 - 10 hrs</td>
<td>1</td>
<td>4.17</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>100.00</td>
</tr>
</tbody>
</table>

**Table vi – Other REB time spent reviewing**

<table>
<thead>
<tr>
<th>Estimated time</th>
<th>Dyad &amp; 3+</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 hr</td>
<td>7</td>
<td>20.00</td>
</tr>
<tr>
<td>1 - 2 hrs</td>
<td>14</td>
<td>40.00</td>
</tr>
<tr>
<td>2 - 4 hrs</td>
<td>7</td>
<td>20.00</td>
</tr>
<tr>
<td>4 - 6 hrs</td>
<td>3</td>
<td>8.57</td>
</tr>
<tr>
<td>6 - 10 hrs</td>
<td>4</td>
<td>11.43</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>100.00</td>
</tr>
</tbody>
</table>