

To Whom It May Concern:

We are writing to bring your attention to a project for streamlining ethics review of Canadian multi-centre public and population health research involving humans. The purpose of this project is to streamline ethics review of these multi-site studies through the rapid sharing of information among participating research ethics boards (REBs) using a secure web-based collaboration centre.

More specifically, this project responds to the expressed need of researchers and REBs for a rapid and robust ethics review process that can be employed during an influenza pandemic or other public health emergency. It builds upon and complements existing processes; and remains consistent with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* principle of “proportionate review”. It is designed to facilitate independent scientific and ethical review of research protocols, and to encourage the acceptance of forms and information sharing among REBs – including the sharing of recommendations and decisions. The objectives were to develop a short-term plan for responding to the current H1N1 influenza pandemic, and then to follow up with the development of a longer term solution. We have decided to extend the project to public and population health research in general.

This project grew out of the concern and interest of colleagues who decided to work collaboratively to address what they saw as an opportunity to advance research ethics during public health emergencies. The project Steering Committee has been working since summer 2009 on this project, with support from the Public Health Agency of Canada. We are pleased to send you the following information:

- A PowerPoint presentation briefly explaining the process;
- Questions and Answers concerning the project;
- Questions and answers concerning collaboration tools (the secure website and teleconference line);
- A flow chart outlining the process;
- A list of project Steering Committee members, including REB Chairs and Administrators, researchers, academics and other experts from federal bodies (included in the PowerPoint).

The Facilitation Team invites you to share the attached information with your colleagues. If you require further information, you are invited to contact the project Facilitation Team:

Streamlining Ethics Review of Multi-centre Public and Population Health Research
Pilot Project Facilitation Team
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Best regards,

The Project Team

Attachments:

PowerPoint presentation

Streamlining Project - Collaboration Tools

Streamlining Project - General Q&As

Streamlined Ethics Review - Process Flow Chart

Streamlined Ethics Review - Process Overview

Streamlined Ethics Review of Multi-centre Studies: Process Overview

November 24, 2009

Step 1: Application

- PI* submits application to PI-REB.
- CIs** notify CI-REBs of their participation in the multi-centre research project, and streamlined process.
- Upon request from PI-REB, Facilitation Team posts application on secure website, provides access information to participating REBs, and provides list of potential scientific reviewers.

Step 2: Review

- All CI-REB Chairs/delegates involved with the study review application package and share comments on secure website.
- Lead REB conducts expedited or full board review; participating REB Chairs/delegates have the option of participating during Lead REB review via teleconference.

Step 3: Response

- CI-REBs may***
 - 1) accept that the level of participatory review is satisfactory, and concur with the Lead REB's decision;
 - 2) require own expedited review; or
 - 3) require own full board review.
- CI-REBs conduct ongoing monitoring in own institutions and provide information about protocol changes.

*PI=Principal Investigator

**CI=Co-investigator or other stakeholder

***REBs are responsible for ensuring that they comply with all applicable laws, regulations and guidelines, including Part C, Division 5 of the *Food and Drug Regulations* (Drugs for Clinical Trials involving Human Subjects), the *Tri-Council Policy Statement*, and Title 45 of the U.S. Code of Federal Regulations, Part 46 (the *Common Rule*).

Streamlining Ethics Review of Multi-centre Public and Population Health Research Involving Humans: Pilot Project

The Project Steering Committee

February 2010

Presentation Objectives

- To introduce the streamlined ethics review process
- To obtain feedback, including feedback on evaluation mechanisms and indicators
- To identify REBs interested in joining the network

Background (1)

- Since SARS, research and REB communities have increasingly recognised the need for a streamlined ethics review process for multi-centre studies, that is highly efficient and adequately protects research subjects.
- Various REBs have worked individually and collectively to develop approaches and processes for the rapid review of research.
- The H1N1 pandemic increased awareness of the issue and interest in developing a mechanism that could be used across Canada.

Background (2)

- This streamlined process would inform public health practice while avoiding:
 - over-review, duplication & bureaucracy;
 - critical public health and clinical questions left unanswered;
 - harm resulting from un-tested interventions;
 - investigator frustration; and
 - REB over-work.

Development of Streamlined Process

- A group of interested and concerned individuals including REB Chairs and Administrators, researchers, academics, and other experts from federal bodies (the Public Health Agency of Canada, Health Canada and the Canadian Institutes of Health Research) have worked to develop a pilot project for streamlining research ethics review of public and population health research.
- The Steering Committee was formed in July 2009.
- A Facilitation Team from the Public Health Agency of Canada has been providing leadership and logistical support.
- Two face-to-face meetings were held with stakeholders.

Expert Steering Committee

Member	Affiliation
Pierre Deschamps	McGill University
Laurel Evans	Canadian Association of Research Ethics Board (CAREB) & REB, University of British Columbia
Lorraine Ferris	Dalla Lana School of Public Health, University of Toronto
Jamie Flamenbaum	Ethics Office, Canadian Institutes of Health Research
Ron Heslegrave	REB, University Health Network, University of Toronto
Mireille Lacroix	Office of Public Health Practice, Public Health Agency of Canada
Peter Monette	Bioethics, Innovation and Policy Integration Division, Health Canada
Diann Nicholson	REB, Izaak Walton Killam Health Centre, Dalhousie University
Ray Saginur	REB & Infectious Diseases, Ottawa Hospital & CAREB
Don Willison	Ontario Agency for Health Protection & Promotion, NCEHR & McMaster University
Tom Wong (Chair)	Centre for Communicable Diseases and Infection Control, Public Health Agency of Canada

Process Objectives

- To streamline multi-centre research ethics application and review processes in order to facilitate research that informs public health practice
- To foster protection of human research subjects, consistent with Canadian ethical and legal standards

Model Options

- The Steering Committee considered a number of options:
 - Consortium of REBs
 - Central REB
 - Private REB
 - Delegated review
 - Participatory review.
- A participatory review model based on mutual acceptance of forms and rapid sharing of information between REBs was selected.

Streamlined Ethics Review of Multi-centre Studies: Process Overview

Step 1: Application

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- CIs** notify CI-REBs of their participation in the multi-centre research project, and streamlined process.
- Upon request from PI-REB, Facilitation Team posts application on secure website, provides access information to participating REBs, and provides list of potential scientific reviewers.

*PI=Principal Investigator

**CI=Co-investigator

Streamlined Ethics Review of Multi-centre Studies: Process Overview

Step 2: Review

- All participating REB Chairs/delegates involved with the study review application package and share comments on secure website.
- Lead REB conducts expedited or full board review; CI-REB Chairs/delegates have the option of participating during Lead REB review via teleconference.

Streamlined Ethics Review of Multi-centre Studies: Process Overview

Step 3: Response

- CI-REBs may*** 1) accept that the level of participatory review is satisfactory, and concur with the Lead REBs decision; 2) require own expedited review; or 3) require own full board review.
- CI-REBs conduct ongoing monitoring in own institutions and provide information about protocol changes.

***REBs are responsible for ensuring that they comply with all applicable laws, regulations and guidelines, including Part C, Division 5 of the *Food and Drug Regulations* (Drugs for Clinical Trials involving Human Subjects), the *Tri-Council Policy Statement*, and Title 45 of the U.S. Code of Federal Regulations, Part 46 (the *Common Rule*).

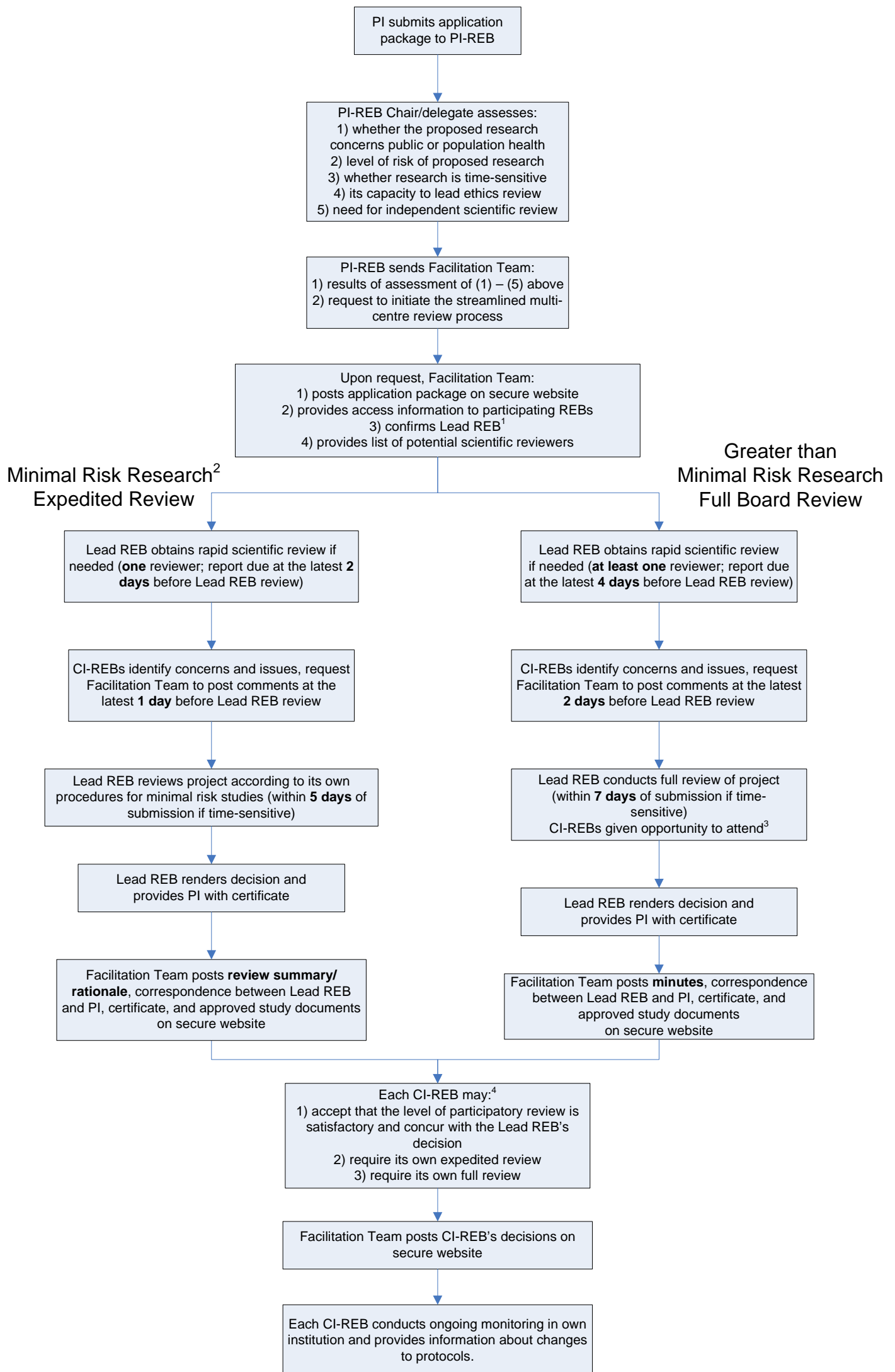
Enhanced Protection for Human Subjects

“Firm in principle yet flexible in practice”

- In accordance with applicable guidelines and norms, while permitting application of additional, institution-specific standards
- Builds upon time-tested REB processes, Lessons Learned from process test and implementation-to-date
- Enhances quality of response, through the rapid sharing of information, use of templates, checklists, etc., as well as monitoring and evaluation
- Facilitates participation by REBs in consultative processes, even under adverse conditions (e.g., during pandemic, when travel to meetings and meetings themselves may be discouraged)
- Focuses on central research ethics issues, not administrative variability

Streamlined Ethics Review for Multi-Centre Studies: Pilot Process

2010-02-16



Notes: All timelines are counted in calendar days. Amendments follow the same review process as new applications for review.
 1-Lead REB for the ethics review may be the principal investigator's REB (PI-REB), or co-investigator or other stakeholder's REB (CI-REB), if requested.
 2-Minimal risk as defined in the Standard Operating Procedures, based on the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.
 3-Attendance may be via teleconference or in person.
 4-Research Ethics Boards are responsible for ensuring that they comply with all applicable laws, regulations and guidelines, including: (a) Part C, Division 5 of the *Food and Drugs Regulations* (Drugs for Clinical Trials Involving Human Subjects); (b) the *Tri-Council Policy Statement*; and (c) Title 45 of the U.S. Code of Federal Regulations, Part 46 (the *Common Rule*).

Streamlining Ethics Review of Multi-centre Public and Population Health Research Involving Humans: Pilot Project

General Q&As

This document explains the project's background, approach and implications for participating REBs.

Q1: Which issue does this project address?

A1: Proposed research projects involving humans must be reviewed by a research ethics board (REB) in order to ensure that they meet ethical standards and that the rights and interests of research subjects are adequately protected. When a proposed study is to be conducted in more than one institution (what is termed multi-centre research), it generally needs to be reviewed by more than one REB, which may put pressure on concerned REBs for quick review, and can be time consuming and challenging for researchers who may decide to limit the scope of their research or to not conduct it at all.

Q2: How did this project come about?

A2: Since SARS, researchers and REBs have increasingly recognized the need for a streamlined ethics review process for multi-centre research involving humans – that is, for a process that is efficient, is more rapid, and adequately protects human subjects.

The H1N1 pandemic has increased awareness of the issue, and led to renewed interest in developing a mechanism that could be used across Canada. Though Canadian REBs have been working individually and collectively to develop approaches and processes for the ethics review of multi-centre research, there seems to be no pan-Canadian initiative.

In the spring of 2009, a small group of individuals involved in research and research ethics review decided to launch an initiative aimed at finding solutions for the challenges associated with the ethics review of multi-centre research.

Q3: What are the objectives of this project?

A3: Initially, the project's objectives were to develop a process for streamlining ethics review of multi-centre pandemic influenza research involving humans that can be used whether research sites are located in a single province or territory, or span several provinces and territories. The project has now been expanded to include all public and population health research.

This review process facilitates communication among REBs reviewing the same research proposal, reduces the number of applications for ethics review that researchers need to make for each study, and enhances ethics review through sharing of information and

comments about proposals, thus fostering protection of human subjects and possibly shortening timelines for approval through concurrent reviews.

Q4: Who is involved?

A4: A Steering Committee composed of interested REB Chairs and Administrators, researchers, academics and other experts from federal bodies (the Public Health Agency of Canada, Health Canada and the Canadian Institutes for Health Research) is leading the project. A group of project champions is also publicising the project and sharing core documents within their regions. All these individuals are involved on a personal basis and do not necessarily represent their institutions.

See Appendix A for list of Steering Committee members and Appendix B for a list of project champions.

Q5: What is PHAC's role?

A5: PHAC's role is to facilitate the streamlined review process. It has been providing funding and logistical support since early summer 2009 – including coordinating the activities of the Steering Committee, helping to publicize the project, and serving as a communication link between the project Steering Committee and stakeholders.

Q6: What approaches were considered?

A6: The Steering Committee considered several options:

- A consortium of REBs,
- Central REB,
- Private REB,
- Delegated review,
- Participatory review.

Q7: Which was chosen and why?

A7: The last option, participatory review was selected because it reduces the workload of co-investigators and their REBs, and facilitates inter-REB collaboration (and thus, enhanced review), while leaving decision-making authorities and responsibilities with each REB.

The streamlined process is also:

- In accordance with applicable guidelines and norms, while permitting application of additional, institution-specific standards;
- Builds upon time-tested REB processes, Lessons Learned from process test and implementation-to-date;
- Enhances quality of response, through the rapid sharing of information, use of templates, checklists, etc., as well as monitoring and evaluation;

- Facilitates participation by REBs in consultative processes, even under adverse conditions (e.g., when travel to meetings and meetings themselves are discouraged);
- Focuses on central research ethics issues, not variability in administrative practices.

Q8: How does the pilot project work?

A8: The main steps in the process are as follows:

- Investigators involved in a particular research project and their REBs agree to implement the streamlined process.
- The principal investigator (PI) submits an application for ethics review to his/her usual REB; Co-investigators (CIs) at other sites do not need to submit applications to their own REBs because these REBs are able to see the PI's application on a secure website.
- The Lead REB (usually the PI-REB, or in extenuating circumstances, an alternate) requests Facilitation Team support for the review process – principally by posting documents on the secure website, and by helping CI-REBs to gain access to that website.
- Scientific review and Lead REB research ethics review then proceed more or less as usual, except that: (i) timelines for “turnaround” are specified for time-sensitive research projects, and (ii) REBs can share comments about the research project with one another via the secure website, prior to board review, and via teleconference, during full board reviews.
- Each REB then makes its own decision concerning the research [(i) accepts that the level of participatory review has been satisfactory and comes to the same decision as the Lead REB's decision; or (ii) requires its own expedited review; or (iii) requires its own full board review]; and provides the rationale and documentation for that decision to the Facilitation Team, for posting on the secure website.
- All REBs follow-up as usual (monitor, conduct annual reviews, consider changes to protocols...).

Q9: As participants in this process, what do REBs need to do differently?

A9: REBs that agree to participate in this process agree to accept the application forms of other REBs, to apply shorter timelines for time sensitive research proposals, and to share their comments about research proposals with other involved REBs via a secure website or teleconference.

Q10: What are the timelines?

A10: The streamlined process was implemented in early November, 2009.

Appendix A
Streamlining Ethics Review of Multi-centre Pandemic Research Involving Humans:
Pilot Project
Steering Committee Members

Member	Affiliation
Pierre Deschamps	Adjunct Professor Faculty of Law McGill University Montréal
Laurel Evans	CAREB; Associate Director Ethics University of British Columbia Vancouver
Lorraine Ferris	Professor Dalla Lana School of Public Health Toronto
Jaime Flamenbaum	Senior Ethics Policy Advisor Ethics Office Canadian Institute of Health Research Ottawa
Ron Heslegrave	Chair Research Ethics Board University Health Network (UHN) Mount Sinai Hospital Toronto
Mireille Lacroix	Senior Policy Analyst Coordinator of Streamlining Project Secretariat Public Health Law and Ethics Program Office of Public Health Practice Public Health Agency of Canada Ottawa
Peter Monette	Senior Policy Analyst Bioethics, Innovation and Policy Integration Division Health Canada Ottawa
Diann Nicholson	Director Research Ethics Administration IWK Health Centre Halifax
Ray Saginur	Chief Division of Infectious Disease Chair Human Research Ethics Board Ottawa Hospital – Civic Campus Ottawa
Tom Wong	Director Community Acquired Infections Division Public Health Agency of Canada Ottawa
Don Willison	Senior Scientist, Ontario Agency for Health Protection and Promotion, Toronto; Assoc. Professor, part time, Dept. of Clinical Epidemiology and Biostatistics McMaster University Hamilton

Appendix B
Streamlining Ethics Review of Multi-centre Pandemic Research Involving Humans:
Pilot Project
Project Champions

Name	Affiliation
Judith Abbott	Health Research Ethics Board, U. of AB.
Patricia Caetano	Manitoba Health and Healthy Living
Laurel Evans	Office of Research Services, UBC; CAREB
Lorraine Ferris	Dalla Lana Sch. Of Public Health, University of Toronto
Diane Martz	Research Ethics Office, University of SK.
Diann Nicholson	Research Ethics Administration, IWK, Halifax
Shelley Rempel-Rossum	Research Ethics Board Coordinator, U. of MB.

Streamlining Ethics Review of Multi-centre Public and Population Health Research Involving Humans: Pilot Process

Collaboration Tools

*In order to facilitate the exchange of information among participating REBs, the **Streamlining Ethics Review of Multi-centre Public and Population Health Research Involving Humans** project uses an existing web-based platform known as “CNPHI”. This document explains how to use the secure platform and its tools.*

Q1: What is the Canadian Network for Public Health Intelligence (CNPHI)?

A1: The Canadian Network for Public Health Intelligence (CNPHI) is a collection of secure web-based public health applications developed by Public Health Agency of Canada (PHAC) for the exchange of public health intelligence between local and provincial/territorial health departments; affiliated organizations involved in public health surveillance, outbreak response, and related work; and PHAC.

CNPHI is housed on several dedicated (CNPHI only) servers at the National Microbiology Laboratory in Winnipeg.

Q2: What is the Multicentre Interim REB Response Collaboration Centre?

A2: This Collaboration Centre is housed within CNPHI, and was initially¹ created to facilitate timely ethics review of multi-centre pandemic influenza and other public health emergency research projects, by providing a venue for secure exchange of project information and related communications.

Q3: Who should apply for access to CNPHI?

A3: The Chair and Administrator of each REB interested in participating in the streamlined process, as well as one member of the administrative team (the member tasked with management of research applications and related documents), are encouraged to apply for access to CNPHI, to ensure that REB officials have timely access to documents posted there.

Q4: How do REB members apply for access to CNPHI?

A4: The research project’s Lead REB (as defined in the SOPs and at the end of this document) completes the *Key REB Contact Information* spreadsheet, and sends it to the Facilitation Team (as defined in the SOPs and at the end of this document). The Facilitation Team then forwards the contact information to CNPHI Membership Services,

¹ In January, 2010, the Streamlining project Steering Committee decided to expand the project to include all public health and population health research.

confirming to Membership Services that listed REB officials are to be given access to the Multicentre Interim REB Process Collaboration Centre within CNPHI, as soon as their applications for CNPHI accounts and signed User Agreements have been received and reviewed by Membership Services.

Additionally, each listed REB official must apply for CNPHI access by:

1. Connecting to the CNPHI main page at <https://www.cnphi-rcrsp.ca/cnphi/index.jsp?linkId=56410>



2. Following the “Read User Agreement” link to the User Agreement, which he/she should then print, read, complete², sign, and fax to CNPHI Administration at (519) 826-2244;
3. Following the “Apply for New Account” link to the on-line “Access Request”, completing the request³, and submitting it.

CNPHI Administration will then send each applicant a CNPHI user name and password.

For those already having CNPHI accounts, Membership Services will expand their access within CNPHI to include the Multicentre Interim REB Process Collaboration Centre, as soon as the Facilitation Team (as defined in the SOP and at the end of this document) indicates that they should do so.

Q5: As a general rule, how long does it take to add new members/grant them CNPHI access?

A5: Once the CNPHI administrator has received and reviewed electronic applications and signed User Agreements, access can be granted within one or two days. In emergencies, access can be granted immediately.

Q6: Will members continue to have access to CNPHI if they travel or their computer “crashes”?

² For application purposes, the name of the Collaboration Centre is the Multi-centre Interim REB Process, and referral is by Louise Yazdani of the Facilitation Team

³ Again, for application purposes, the name of the Collaboration Centre is the Multi-centre Interim REB Process, and referral is Louise Yazdani of the Facilitation Team.

A6: Being a web-based application, CNPHI is accessible through the internet from any computer, and from anywhere in the world.

Access is occasionally affected by server maintenance requirements; however, most maintenance is scheduled for off-hours (evenings and weekends).

Q7: How is confidential information protected?

A7: REBs sending confidential documents to the Facilitation Team for posting can protect such documents by:

- Password-protecting them in *Word*;⁴ or
- Saving, then password protecting them in *Acrobat*;⁵ or
- Sending hard copies to the Facilitation Team by courier.

However, it is important to note that “password protect” and “encryption” functions are software-specific. Therefore, REBs considering using programs other than *Word* and *Acrobat* to protect documents should check with the Facilitation Team first, to ensure compatibility. *Microsoft Outlook*-protected documents, for example, cannot be opened by Health Canada and PHAC personnel, because neither institution uses *Microsoft Outlook*.

The Facilitation Team’s role in relation to such documents is as a “courier” only. The Team recognizes that such documents remain the property of the sender, and acts to protect such documents by:

- Posting them on the secure website, where they are accessible only to those REBs participating in their review;
- Deleting them from the original sender’s e-mail, once they are posted.

Q8: Where are research project documents situated within the Multicentre Interim REB Process Collaboration Centre?

A8: Upon entering the Collaboration Centre, users should select “Documents Manager” from the menu on the left of the screen. They will then see:

- Their research project *folder* (e.g., folder entitled *MCR 2009-002*) in the middle of the page, under “*Root*”;
- Project *binders* on the right, containing documents such as the research protocol, comments on the protocol, science review, comments on the science review, (REB) review report/minutes.

Note that within the Collaboration Centre, *binders* are situated *within folders*; and not the reverse.

Q9: Is it possible to limit access to information posted in CNPHI to the REBs of institutions involved in a specific project?

⁴ For example, in *Word* 2003, select Tools/Options/Security/Password to Open and/or Password to Modify.

⁵ For example, in *Acrobat* 7.0, select Document/Security/Secure This Document/Restrict Opening and Editing Using Password.

A9: Yes. A new folder is created in CNPHI for each research proposal and related communications. The Facilitation Team grants access to specific folders based on REBs participation in the review of each proposal.

Q10: Who can submit comments on a protocol, and can the identity of the submitting individual be masked?

A10: The process for submitting comments to the Facilitation Team for posting is at the discretion of each REB. For example, a REB may permit individuals to submit comments directly to the Facilitation Team for posting; or may instead collect and summarize comments from its members, before submitting them on behalf of the institution – with or without the inclusion of identifying information.

Q11: Who can post comments and other research project documents on the secure website?

A11: For the time being, the Facilitation Team will be responsible for posting all comments and other research project documents on the secure website. Therefore, documents to be posted should be sent to the Facilitation Team c/o Louise.Yazdani@phac-aspc.gc.ca and Josie.Sirna@phac-aspc.gc.ca.

This approach will be reconsidered once participating REBs are more familiar with Collaboration Centre tools and their properties.

Q12: Who can download documents?

A12: Collaboration Centre users are able to download documents, but do so on the understanding that such downloads are for the use of their own REB members only.

For more information, please refer to the CNPHI *User Policy* and *User Agreement*.

Q13: Who can create new binders?

A13: For the time being, the Facilitation Team will be responsible for building each project's folders and binders within the Collaboration Centre.

Q14: Is CNPHI training available?

A14: Once User Agreements are in place, users can "attend" a scheduled training session (scheduled sessions usually occur weekly), or can request a special training session. Training is by web conferencing, and therefore requires simultaneous access to telephone and internet.

Other Communication Questions

Q1: Do Lead REBs have access to a dedicated on-demand teleconference line, to permit CI-REB participation in full board reviews?

A1: Yes, a dedicated teleconference line has been set up for this pilot project.

REBs should always “book” their teleconferences through the Facilitation Team, to ensure that the teleconference line is available/to prevent “double booking”.

Key Concepts

Facilitation Team

The Facilitation Team is a small group of Public Health Agency of Canada employees responsible for providing technical and logistical support to the Streamlining Ethics Review – Pilot Project Steering Committee, and to participating Research Ethics Boards.

Lead Research Ethics Board (Lead REB)

For the purpose of this project, the Lead REB is the REB that is coordinating and leading the *initial* ethics review of a research proposal. The Lead REB may be the Principal Investigator's REB (PI-REB), or collaborating investigator's or other stakeholder's REB (CI-REB) agreed to by the REBs participating in the review of the research proposal.

It is important to note that such participating REBs do not delegate their authority to the Lead REB. Participating REBs remain responsible for making their own decisions regarding the research – that is, for deciding whether to accept that the level of participatory review was satisfactory and concur with the Lead REB's decision, or require their own expedited or full board reviews.