Draft Preliminary Recommendations
Of the CCTCC REB Accreditation Working Group
NOT ENDORSED BY the CCTCC. Only for the purpose of consultation.

1 PREAMBLE

The responsibility for human research protections lies with the Canadian government (including Health Canada), the granting councils, the institutions that receive grant funding from the councils, pharmaceutical companies that sponsor clinical trials, the researchers who conduct research involving human participants, the private and institutional Research Ethics Boards (REBs) that review such research and also with the public. The Canadian Clinical Trials Coordinating Centre (CCTCC) REB Accreditation working group (hereafter the “working group”) believes that all of these stakeholders need to be integrally involved in supporting efforts to enhance quality, efficiency and effectiveness of research involving human participants. The recommendations outlined in this document are only a first step towards development of a more robust national system of human research protection.

2 MANDATE AND TERMS OF REFERENCE

The CCTCC working group on developing a Pan-Canadian accreditation system for REBs that review clinical trials was established in April 2015. The Terms of Reference stipulated that the working group was to investigate the critical questions involved in the development of strategies to improve ethics review efficiency [The 2012 Clinical Trial Summit Action Plan], strategies to standardize the research ethics review process and for either the accreditation of REBs [The 2012 report of the Standing Senate Committee on Social Affairs, Science and Technology, Canada’s Clinical Trial Infrastructure] or for another approach to the development of a system for the evaluation and qualification of REBs. [The 2013 Strategy on Patient-Oriented Research (SPOR) External Ethics Advisory Committee report] The working groups initial terms of reference focused upon REB review of clinical trial studies, but a key question was whether their recommendations should be extended more broadly. As is made clear from the below recommendations, the working group believes that most of its recommendations should extend to all REBs and indeed to the broader spectrum of human research protections. Initial recommendation C pertaining to equivalency, is however, restricted to REBs that review and approve regulated clinical trials.

The working group created an interim report and with funding from the CCTCC retained a consultant to conduct interviews and acquire data to assist it in its deliberations and recommendations. The interim report requested that the working groups terms of reference be reframed so that rather than assuming that accreditation of REBs was the end goal, that it should be viewed as one indirect component for facilitating an increase in the efficiencies of ethics reviews. The initial recommendations that follow are informed by the information obtained by the consultant in the interviews but they are not limited by it.
They are the opinions of the working group which represents a diversity of expertise within the field of research and research ethics. The recommendations are initial recommendations only. The working group’s final recommendations will necessarily be informed by the feedback received from a broad call for comments from the REB, researcher and participant communities as is suggested below in Part 3.

3 PROCESS REQUIREMENTS

The working group believes that it is important to recognize a number of process requirements that they understand to be essential for their recommendations to be effective.

1. Engagement and Meaningful Consultation

The first step in this process must entail consulting with and obtaining feedback from the REB, researcher and participant communities to obtain input on the content of the recommendations and next steps. Crucial to the success of any efforts to assess and enhance the quality, and efficiency and effectiveness of research ethics reviews in Canada is the need for grassroots consultation and building a system or systems from the ground up. This includes the need for sufficient outreach to the research ethics community. This theme emerged from the consultant’s report as being a determining factor for achieving success in both harmonization / centralization efforts and for the uptake of any accreditation system. Systems such as the Ontario Cancer Research Ethics Board’s (OCREB’s) and CTO’s, built on meaningful community consultations are better able to address organizational and other requirements and ultimately are easier to operationalize. Without purposeful, early and continuous engagement with the impacted REB community, including soliciting and considering feedback on any proposals for any form or process of assessment, the necessary credibility required for buy-in and uptake of the system will not be created and the risk of failure will be significant. The need for engagement and consultation is not restricted to the research ethics community. Input from researchers as well as research participants should also be solicited, particularly as work on developing a more robust system for the broader spectrum of the protection of human research participants is undertaken.

The engagement of stakeholders around topics such as research and healthcare can be justified on a number of grounds. Firstly, legitimacy and fairness demand that when research is funded by public funds, such as is the case with much of the health research in Canada, the public should be involved. Equally, fairness requires that those who will be most affected by the proposed change should be given a voice in the discussion. Greater involvement of the populations involved is also in-keeping with democratic principles [1], may provide greater support for the decisions made (assuming they are in-keeping with the expressed views), and could potentially lead to increased trust in the decision-makers and decision-making process. Finally, the involvement of the key stakeholders (including the public) allows for a wider range of perspectives that can lead to improved decisions [2]. Moreover, a failure to engage with relevant stakeholders can have negative consequences. Controversies surrounding genetically modified crops in Europe [3] and the marketing of nutrigenomics-based dietary advice in the UK [4] illustrate the ‘setbacks and uncertainties’ that can arise where there is a disconnect between innovation and social acceptance [5].
2. Moving forward based upon an evidence-informed approach

The recommendations in this report cannot be implemented without utilizing an evidence-informed process of change, which requires standards against which research ethics reviews can be assessed and metrics/ways to judge whether the standards are being met. Such a process will require additional work to be undertaken to identify and develop appropriate tools or measures of evaluation in order to assess the benefits or improvements gained through any changes implemented. Markers of quality, effectiveness and efficiency are not readily available nor is there a common understanding of how quality, effectiveness and efficiency are defined.

3. Stakeholder Input and Support

Enhancing quality, effectiveness and efficiency of REB reviews and human participant protections cannot happen in a vacuum and cannot be accomplished without infrastructure support (financial and administrative including technology solutions) for REBs at all levels, i.e. national, provincial and institutional/organizational. In addition, it cannot be accomplished without the combined support of the key stakeholders impacted by research ethics review and human participant protection requirements. Each of the recommendations outlined below will require active support and assistance from different key organizations if they are to become a reality.

The working group believes that these key stakeholders need to be consulted concerning these recommendations, and commitments to support of the objectives of this working groups mandate and its final recommendations, needs to be obtained and maintained, prior to and throughout any implementation process. The key stakeholders include, but are not limited to the organizations and associations that might participate on the External Advisory Board described in Recommendation A.

It is hoped that the consultation process described in 1. (above) will reveal other individuals, organizations, associations or institutions that may be willing to support these recommendations.

4. Initial Recommendations

A. Establish a national strategic leadership forum as an initial step toward development of a governance model for human research protections in Canada. The leadership forum would be modelled after the US Secretary’s Advisory Committee on Human Research Protections (SACHRP). It would be funded by and accountable to the key stakeholders involved in the area of human research protections. Potential key stakeholders are suggested in this document. (See 5.A) The final determination of which organizations would participate in the proposed external governance body, what the scope of authority of the leadership forum would be, and criteria for membership in it must be informed by the call for comments and the stakeholder input and support described in 3.3. above.

B. Commence discussions with potential partners for the development of a mandatory registry of REBs. The Registry would potentially be managed by the PRE with collaboration and input from
CAREB and the CCTCC. Registration would provide access to a suite of education and training opportunities for example via CAREB and N2/Collaborative Institutional Training Initiative (CIIT).  

C. A meeting of key stakeholders (including the Canadian Institutes of Health Research – CIHR –, Health Canada, CAREB, PRE and representatives from the provincial harmonization initiatives) should be convened to discuss the potential imposition of a mandated equivalency requirement for all REBs that review and approve regulated clinical trials. Equivalency would be against established standards such as the Association of Accredited Human Research Protections (AAHRPP) accreditation, Clinical Trials Ontario (CTO) qualification, or Ministère de la Santé et des Services sociaux (MSSS) designation standards.  

D. Investigate and report on the national and provincial legislative barriers to Pan-Canadian acceptance of a review by another Canadian or a central REB. This would include investigating the private REB model to determine how it has overcome these issues.  

E. Investigate and report on the institutional liability issues involved with Pan-Canadian acceptance of a review by another Canadian or a central REB, including recommended solutions (e.g. appropriate legal agreements, shared insurers, etc.  

F. Investigate the feasibility of developing more formalized requirements and processes for sharing and/or posting of reviews of the same or similar studies, including the development of a precedent database  

G. Undertake a prioritization exercise to identify the top education / training priorities for research ethics boards.  

H. To facilitate awareness of existing efforts in the area of REB improvement, the 2013 Streamlining Research Ethics Review (SHRER) Committee report and its appendices should be more broadly disseminated and its recommendations reconsidered as applicable in today’s context.  

I. Explore process measures to improve efficiency in clinical trial review investigations including the feasibility of a national on-line system for multi-centre reviews.  

5. Rationale for Recommendations  

A. The Need for a National Strategic Leadership Forum  

Human research protections and the subset of those protections that represents research ethics review in Canada lack a clearly defined governance model and appropriate resourcing. Despite previous proposals over the past decade efforts to establish a national program of assessment of human research protections in Canada have remained at a standstill. The two most significant reasons why past efforts have failed relate to lack of formal leadership and lack of resources, in particular, funding and support. There is a need for identified leadership as there is no clear authority that would either undertake the required consultative work (see 3.1. above) or provide the necessary practical support for the implementation of any proposed assessment model.  

The US and UK systems while markedly different in both model and scope, have each had the support and endorsement of either a combined group of impacted stakeholder organizations (AAHRPP - US) or the national Health Research Authority (HRA - UK). The Institutional Review Boards (IRBs) accreditation
program in the US is a part of an over-all human research protections framework that includes the Common Rule and the Office of Human Research Protections (OHRP) as well as SACHRP. SACHRP is a legislated committee that is responsible for advising the Secretary for Health and Humans Services on matters related to human research protections. When discussions pertaining to accreditation were occurring in the US, SACHRP established an accreditation sub-committee. In the current context of the discussions pertaining to the Notice of Proposed Rulemaking (NPRM), they have established a sub-committee on the NPRM.

There is historical support in Canada for establishing a strategic national leadership forum. In February 2013 the SHRER Committee concluded that a national strategic leadership forum should be created to:

- Facilitate communications between the various streamlining and harmonization initiatives
- Provide strategic insight into opportunities for national collaborations; and
- Identify potential groups to take responsibility for moving forward on the SHRER Committee recommendations.

On a national scale, there has been little to no cross-communication between the various streamlining and harmonization initiatives. There is no national leadership body charged with considering how Pan-Canadian collaborations or reviews should be developed. There needs to be an authoritative leadership group if efficiencies in ethics reviews are going to be able to be implemented on a national, as opposed to a provincial basis. The SHRER Committee recommendations were not taken forward in 2013. The current working group is making essentially the same recommendations again in 2016. The working group believes that if the recommendations are not implemented this time, this working group’s report is destined to become a new tab in the binder of the next accreditation working group. Most significantly such a failure will signal a lack of official support for a more robust system of human research protections in Canada. At the very least, this failure to act will negatively impact trust in the research ethics community regarding future endeavors.

The working group is not recommending the creation of a separate institution or organization that would serve as the governing body for human research protections in Canada. Rather it is suggesting that a strategic leadership forum with varied (and changing) representation from across the country with local, provincial, regional and national interests in research ethics should be invited to participate in the forum. These key leaders should be funded to meet at least quarterly and otherwise as needed to provide strategic advice, direction related to national centralization and harmonization initiatives as well as accreditation and registration recommendations, and ultimately a governance model for human research protections in Canada. Membership on the leadership forum should include representation from the relevant private sector.

The working group suggests that the leadership forum should be funded by and accountable to an external advisory board, made up of representatives from: The PRE, Health Canada, the Tri-Councils [CIHR, Natural Sciences and Engineering Research Council of Canada (NSERC), Social Sciences and Humanities Research Council of Canada (SSHRC)], Innovative Medicines Canada (IMC), CAREB, HealthCareCAN, NAPHRO and most importantly Innovation, Science and Economic Development Canada.
There may of course be other stakeholder organizations who should be considered, but the number of organizations would need to be somewhat restricted so as to remain manageable.

Enhancing the quality, efficiency and effectiveness of research ethics review and human research protections in Canada is directly linked to both economic and health and wellness benefits for Canada. The working group notes that one stakeholder who has not been significantly involved at the Canadian national table in these discussions is ISED. It is worth noting that Ontario’s initiatives (CTO and OCREB), which arguably have achieved the most success in harmonization and centralization of research ethics processes, have the support of the provincial counterpart, i.e. Ontario’s Ministry of Research and Innovation (MIT). Significantly, they also have the largest amount of dedicated funding for their initiatives.

B. The Need for a Registry of Research Ethics Boards in Canada

In its interim report of September 2015, the working group recommended that a registry of research ethics boards operating in Canada be developed. Discussions were held with CAREB and the CCTCC. CAREB is not resourced to develop such a tool at this point in time. In order to implement the recommendations of this report concerning a system of assessment, education, and communication, it is necessary to know which organizations in Canada have authorized research ethics boards, which private corporations operate research ethics boards, and which of these review and approve sponsored clinical trials. Having such a registry would facilitate communication of information and educational materials and it could assist REBs reviewing the same or similar studies in efforts to become more consistent. If a mandated equivalency requirement is adopted and implemented (see 4.C below), it will be necessary to know which REBs review and approve regulated clinical trials. In the US, the Federal Wide Assurance registry system for federally authorized IRBs is maintained and operated by the OHRP. The system is now merged with the US Food & Drug Administration requirements. The Canadian counterpart of OHRP is the PRE. Accordingly, the working group recommends that the PRE commence consultations with CAREB, Health Canada, CCTCC and other key stakeholders (e.g. N2) concerning the development and implementation of a mandatory registration mechanism. A positive incentive for such registration would be the provision of a suite of training and educational materials (see 4.H below). Careful consideration needs to be given to what information / data needs to be collected in the registry, as well as how to ensure that there is an effective mechanism for ensuring that the registry is kept up to date.

C. The Possible Implementation of an Equivalency Requirement for REBs that review and approve regulated Clinical Trials.

In order to operationalize efforts toward efficiency, a mechanism to facilitate cooperation between REBs seems intuitively necessary and establishing a baseline standard for operations, whether it be through a formal accreditation process, a qualification process similar to that of Clinical Trials Ontario, or a provincial designation system like the Quebec model seems to be a pre-requisite. While the investigations of the consultant did not reveal direct evidence of the impact of accreditation / qualification or designation upon efficiency of REB review (multi-site), the working group does believe
that some mechanism for assessing or evaluating REBs would likely have an impact on efficiency by providing a standardized due diligence process to facilitate cooperation and eventual reciprocity among REBs.

REBs that review regulated clinical trials are subject to numerous provincial, national and international regulations and guidelines. In Canada, very few if any REBs review only regulated clinical trials. While the need to ensure quality, consistency and efficiency of REB reviews extends to all research ethics boards, the most pressing requirement from a national economic and regulatory perspective is to ensure that those REBs that review regulated clinical trials meet common standards. There are operational standards such as the International Conference on Harmonization: Good Clinical Practice: Consolidated Guidelines (ICH-GCPs), the Canadian General Standards Board (CGSB) Standard and the US regulatory requirements that can be referenced, but there is no process in place to ensure that these applicable standards, guidelines and regulations are being applied in similar ways across REBs or between jurisdictions. The working group recommends that any move to require REBs that review and approve regulated clinical trials, to meet existing provincially or internationally developed qualifications standards be investigated and discussed by all key stakeholders, including those organizations and institutions that support REBs that review regulated clinical trials, representatives from the provincial streamlining initiatives, CCTCC, Health Canada and IMC. The working group believes, and it is supported by the data from the consultant’s report, that there is no need to reinvent the wheel when it comes to developing an assessment system for REBs to review regulated clinical trials. Consideration should be given to utilizing or adopting existing standards. This includes the AAHRPP accreditation standards that most privately operating REBs in Canada adhere to, the CTO qualifications standards, and the MSSS designation standards. REBs would not necessarily have to become AAHRPP, CTO or MSSS “qualified” but they would be required to demonstrate equivalency in some verifiable way. Given the legislative and/or liability issues that were noted during the consultant’s discussions (see below) this may be a pragmatic approach that recognizes and builds on the work conducted by the provinces, while working toward the national standards that a Pan-Canadian assessment system might be seen to provide.

D. Investigating the Legislative Barriers to Pan-Canadian REB acceptance of a review by another Canadian or a central REB.

Streamlining and harmonization initiatives are being implemented in most Canadian provinces. There is no national organization facilitating cross-communication between those initiatives, and although there are some disease specific initiatives working on the feasibility of a single national review, there is no organization that is looking at the issue from the perspective of sponsored clinical trials. The US NPRM proposes the requirement for a single IRB review of studies conducted at multiple US sites and some US sponsors (notably the National Institute of Health – NIH) are currently requiring single IRB (within the US) review of multi-site studies that they fund. The US Federal and State legislative landscape with respect to IRB review is considerably more complex than Canada’s. There are thousands of IRBs in the US, compared to hundreds in Canada. Despite initiatives such as the Canadian Cancer Clinical Trial Network (3CTN) ethics working group and other investigations into the feasibility of a single national REB for Pan-Canadian studies, the conclusion consistently reached is that a single REB approach in Canada is problematic and not feasible. One of the reasons consistently cited as a barrier to Pan-
Canadian acceptance of another (extra-provincial) REB review is provincial legislation, most specifically, provincial privacy legislation. For instance, the health information legislation in Alberta requires that research involving the health information of residents of Alberta be reviewed and approved by a designated Albertan REB and that reports of their decisions are reported to the Alberta privacy commissioner. Legislation can be amended and repealed. If the goal of a single Canadian REB review of a Pan-Canadian study is important for national economic reasons, a formal legal review of all of the legislative barriers including current provincial privacy laws should be undertaken, with the aim of recommending possible solutions for overcoming those barriers, either through legal agreements or legislative change.

The private REBs operating in Canada, have overcome some (but not all) of these challenges. They have developed systems and processes that have operationalized an initial review for a lead site, followed by approvals of additional sites with the secondary review focusing upon local site issues and local PI qualifications. The feasibility of public institutions adopting the private REB model for studies that are Pan-Canadian in nature, should be investigated, including the operational aspects as well as leadership and resources. It is worth noting that many medical schools in the United States outsource the ethics review of industry sponsored trials to central IRBs.

E. Investigate and report on the institutional liability issues involved with Pan-Canadian acceptance of a review by another Canadian or Central REB

Despite statements contained within the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2:2014), and the existence of a report commissioned by Health Canada the public institutional REB community continues to believe that institutional liability issues are a significant barrier to non-local (external) REB review of studies conducted at their respective institutions. These concerns are being expressed by both the academic and the health authority REB communities. The working group recommends that a formal investigation of the institutional liability issues related to non-local (external) REB review be undertaken, with an aim to recommend various options for overcoming those issues, including, for example, appropriate individual or blanket / master agreements, acknowledgement of shared insurers etc. The results of this investigation should be made public on research ethics related web-sites (e.g. the PRE, CAREB and provincial harmonization initiatives) and broadly disseminated to the REB community.

F. Investigate the feasibility of more formalized requirements for sharing and/or posting of reviews.

The need for and importance of education is a top priority and a key issue for most of the REB community. Access to education can be considered as a way to improve quality of research ethics reviews, particularly if it is not just in relation to the rules and regulations, and content of the standards, but also and more helpfully, if it involves substantive ethical issues, and for example, sharing of reviews. The potential for developing a precedent database should be investigated. Transparent sharing of information and REB determinations in multi-site studies would help lead to more consistency in reviews, and could assist in the development of standards and metrics against which to assess REB performance. It could also help with timeliness of reviews by allowing REBs to avoid having to re-debate
the same issues in the course of their reviews. Due consideration would of course, need to be given to intellectual and privacy rights, particularly in the context of privately sponsored clinical trial studies.

Despite an apparent desire to innovate, REB administration mostly do not have the resources and are generally not trained researchers who have the requisite skills to conduct research into quality, effectiveness and efficiency of REB reviews. Even within the academic community, funding for this kind of investigation is generally sort term, fragmented and *ad hoc*. [6] Significantly, the results do not always involve or filter down to the REB administration community.

The working group believes that providing access to a suite of training and education materials (through CAREB, N2 and others) through completion of the registration process would provide an incentive to REBs to register their REBs and to continue to keep their registrations current. (See 4. B above).

**G. Undertake a prioritization exercise to identify the top education/training priorities for REBs.**

As part of our recommendations we advocate for a prioritization exercise to be undertaken to identify important educational and training needs. Such an exercise might draw on the reporting guideline community. Reporting guidelines are a checklist, flow diagram, or explicit text to guide authors in reporting a specific type of research, developed using explicit methodology [7]. The development process often include a Delphi survey – a multi-round consensus building process[8]. This process was used by Geisser and colleagues to develop a list of important aspects of ethics review[9], but has been used in research prioritization exercises [10]. Other approaches include the stakeholder engagement process developed by the UKs James Lind Alliance to brings patients, care givers and clinicians together in Priority Setting Partnerships (PSPs) to identify and prioritize the Top 10 uncertainties, or 'unanswered questions', about the effects of treatments that they agree are most important. The PSP could be used as a model to bring together researchers, the REB community, as well as funders to identify a 'Top 10' education and training requirements.

**H. Re-visit the SHRER report recommendations and more broadly disseminate the SHRER document and the appendices.**

The recommendations that the SHRER advisory committee made to the SPOR Working Group and the SPOR National Steering Committee in 2013 continue to resonate with the members of this working group. Despite the passage of three years, most of these recommendations continue to be worth pursuing. Given the passage of time, the results of this working group’s activities, the development of CTO, and other developments within the research ethics field some changes have to be considered. However, the working group members (some of whom were on the SHRER advisory committee) were struck by the similarity in the recommendations made by both groups.

Related to this recommendation is the suggestion that appendices C.1 and C.2 to the SHRER report which reflect common elements for an REB initial application form for clinical trials, and the common elements for an adult informed consent form for clinical trials should be republished and more broadly disseminated, specifically targeting the various provincial streamlining and harmonization initiatives for information and possible consideration in the development of any common informed consent forms or application forms for their provincial initiatives.
I. Investigate the feasibility of a national on-line system for multi-center reviews

Quality, effectiveness, and in particular efficiency of REB reviews are enhanced by secure on-line systems that automate and streamline the ethics review processes and are accessible to REBs and researchers regardless of their physical location. On-line systems facilitate compliance, accessibility, transparency and reporting of metrics. They also facilitate collaborative sharing of information. The harmonized system in Quebec struggled to become accepted and effective until a shared on-line system was developed. OCREB has had an online system for five years, allowing it to vastly improve its operations and productivity. CTO recognized from the outset that the only feasible way for it to develop an efficient system to support a single REB review of multi-centre research in Ontario was to create a single portal for the online submission and review of REB applications. British Columbia’s harmonized review process which involves multi-party collaborative reviews, operates more efficiently when an online system is utilized. Virtually all private REBs operating in Canada have online systems. They are an acknowledged cost of doing business without which, they would be unable to compete.

If Canada is serious about making research ethics reviews more efficient, it needs to investigate the feasibility of developing a shared on-line system or robust inter-operability of existing systems for at least those sponsored clinical trials that are being conducted at multiple sites across Canada.

5. CONCLUSION

At the outset, the working group suggested that a staged approach be taken. The data collected by the consultant reinforces the advisability of proceeding iteratively after consultation with and feedback from all stakeholders concerned with human research protections. We continue to feel that, as many respondents said, “it is important to take the time to do things properly and have the right people involved as further steps are taken.”

6. REFERENCES


7. **GLOSSARY OF ACRONYMS**

AAHRP - Accredited Human Research Protections
CAREB - Canadian Association of Research Ethics Boards
CCTCC - Canadian Clinical Trials Coordinating Centre
CGSB - Canadian General Standards Board
CIHR – Canadian Institutes of Health Research
CITI - Collaborative Institutional Training Initiative
CTO - Clinical Trials Ontario
HRA – Health Research Authority
IMC – Innovative Medicines Canada
IRB - Institutional Review Board
ICH-GCPs - International Conference on Harmonization: Good Clinical Practice: Consolidated Guidelines
ISED - Innovation, Science and Economic Development Canada
OHRP – Office of Human Research Protections
MIT - Ministry of Research and Innovation
MSSS - Ministère de la Santé et des Services sociaux (Ministry of Health and Social Services)
NIH - National Institute of Health
N2- Network of Networks
NPRM - Notice of Proposed Rulemaking
NSERC - Natural Sciences and Engineering Research Council of Canada
OCREB – Ontario Cancer Research Ethics Board
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