

Streamlining Ethics Reviews

CTO Conference March 9 2017

BC Ethics Harmonization and The CCTCC
REB Accreditation Working Group Report
and Responses

BC Ethics Harmonization Initiative

- ❖ Project funded by Michael Smith Foundation for Health Research (MSFHR)
- ❖ Collaboration of largest Universities and Health Authorities in BC includes ALL REBs in the province that review and approve regulated clinical trials
- ❖ Have developed a collaborative model for minimal risk and above minimal risk reviews. Is now working incredibly efficiently, has buy-in, SOPs etc.
- ❖ Willing to pilot a sponsored clinical trial – so far no takers but capacity is there
- ❖ At end of the funding term, (Five years) had discussions about sustainability
- ❖ **Unanimous** submission of all the partners to MSFHR for resources to continue the project (IT and Human) was approved

BCEHI Sustainability

- For multi-jurisdictional studies, have created a common certificate of approval and are now working on automating the workflow so that everything can be accomplished online.
- With additional funding from MSFHR of approximately \$125K, group is working on creating a shared common application form for multi-jurisdictional studies, as well as a workspace for application review and monitoring of multi-jurisdictional studies, leveraging off of UBC's RISE software platform.
- Have one year to accomplish
- Contacts / Leads are:
 - Terri Fleming, Island Health , Terri.fleming@viha.ca
 - Jean Ruiz, UBC, jean.ruiz@ors.ubc.ca
 - Sarah Bennett, SFU, sarah_bennett_2@sfu.ca

Web-site is: <https://bcethics.ca>

CCTCC REB Accreditation Working Group Report

- Working Group established by CCTCC and Health Canada April 2015
- In response to 2012 Summit Action Plan, 2012 Senate Report and the SHRER report for SPOR 2013
- Submitted final report in August 2016. CCTCC and Health Canada issued a Public Response January 2017. Working Group submitted a brief response to CCTCC/HC on March 3rd 2017.
- Full package of report, appendices and public response can be found at:

<http://www.cctcc.ca/index.cfm/our-initiatives/report-on-the-canadian-experience-of-research-ethics-boards-rebs-harmonisation-and-centralisation>

Seven Recommendations

1. **Distribute the SPOR SHREER report widely and take action on the applicable recommendations.**
2. **Establish a registry of REBs that review and approve clinical trials that could ultimately be expanded to encompass all REBs in Canada**
3. **Actively pursue regulatory options for standards equivalency for REBs that review regulated clinical trials**
4. **Coordinate REB education and training efforts and conduct a needs assessment of REB education requirements**
5. **Investigate the feasibility of various approaches to sharing REB reviews of multi-centre research, including a possible online system**
6. **Conduct a study of real and perceived barriers to the acceptance of other REB reviews and publicly report on findings and solutions**
7. **Establish a national strategic leadership forum**

Response

- 1. Distribute SHRER report
- **Done. No action on its recommendations but action on the CCTCC report recommendations**
- 2 Establish a registry of REBs.....
- **Investigate feasibility, responsible bodies CCTCC, Panel on Research Ethics and Health Canada**
- 3. Actively pursue regulatory options for standards equivalency of REBs.....
- **Investigate feasibility, look at other instruments such as law, regulations, ICH Guidance, SOPs etc.**
- 4. Coordinate REB education and training.....
- **Consider assisting by establishing mechanisms for collaboration**

Recommendations and Responses

5. Investigate approaches to sharing including possible national online system and data warehouse.....

Topic has been extensively studied, provinces have done considerable work to harmonize. Ongoing efforts for sharing should be promoted and additional collaboration where possible should be established.

6. Conduct study of real and perceived barriers (turf and privacy).....

Topic is currently being studied by a variety of stakeholders including the GE3LS network in genomics.

7. Establish a National Strategic Leadership Forum.....

Health Canada and CCTCC will work in 2017 to further consider the feasibility of this recommendation.

STAY TUNED FOR FURTHER DEVELOPMENTS

Working Group Members

- Laurel Evans (Chair) Director Research Ethics, UBC
- Karine Morin (Co-chair) Executive Director, Platforms, Alberta Innovates
- Janet Manzo, Executive Director, OCREB
- Stuart Nicholls, Methodologist, CHEO/Ontario Child Health SPOR Unit
- Kathy Brodeur-Robb, Executive Director, C17 Council
- Marianne Vanderwel, Quality Management Consultant
- Raphael Saginur, Chair, Ottawa Hospital REB, Chief, Division of Infectious Diseases
- Ken Jenkins, Manager, Research Ethics, Capital Health
- Marie Hirtle, President, Biotka Inc.
- Patrick Sullivan, Partner, Taylor-Veinotte-Sullivan Barristers
- **OBSERVERS:** Peter Monette, Health Canada, Genevieve Dubois-Flynn, CIHR, Sharon Freitag, St. Michaels Hospital, Susan Zimmerman, Secretariat on Responsible Conduct of Research