



a place of mind

THE UNIVERSITY OF BRITISH COLUMBIA

The Long and Winding Road to Ethics Harmonization in BC





History & Funding

2007 – 2010 Initial Planning & Consultation

2010 – 2011 Phase 1: 3 Universities then 8 partners

2011 – 2015 Phase 2: Model Development, and Testing

Spring 2014 Watershed development, project management taken over by the funder Michael Smith Foundation for Health Research.

Governance structure revised to have one group of high level senior leaders and a working advisory committee comprised of administrators and chairs

8 Partners



**Fraser Health Authority
Interior Health Authority
Island Health Authority
Northern Health Authority
Simon Fraser University
University of Northern BC
University of Victoria
University of British Columbia**

Michael Smith Foundation

Has been incredibly patient and deferential of the participants and the process.

Being left coast, not in our nature to be top down.

Have been working on collaborative models for minimal risk, above minimal risk and sponsored clinical trial studies **for most of Phase 2**

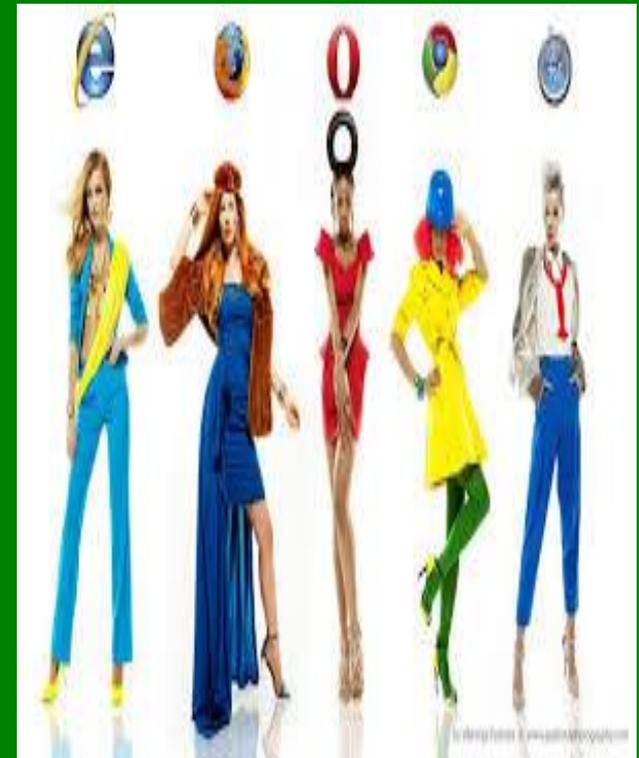


Reciprocity Agreement

**Executed by the 8 partners,
effective April, 2013**

**Allows for exchange of information
and alternative review processes,
including straight reciprocity and
two-step review**

**Has allowed us to try various
models**



MODELS

Formal testing and evaluation of a minimal risk model started in the fall of 2014. Goal is to try to apply it to every multi-site study that is submitted to any of the 8 partner boards.

In the case of minimal risk studies, multi-site means 3 institutions or more.

One of the accomplishments of the past four years has been that there has been a lot of relationship building.



PATIENCE

They Say It's A Virtue. But Being Virtuous Is Not Necessarily Satisfying.

DYADS

When minimal risk model was finally agreed upon, a large number of dyads or “two institution” arrangements were already in place.

Decision was made to leave those arrangements out of the model process as they are working quite well and are unique in process depending upon the relationships.

Nonetheless many have switched to the minimal risk model because it is easier and makes things less complicated.



MODELS

Should be noted that although it comprises six boards, UBC is considered “one” institution because as early as 2006 it had established a “one board of record agreement” between all of UBC’s affiliated REBs.



Minimal Risk Model

Proportionate collaborative review

- Option to choose straight reciprocity
- Submission on individual institution's form but have developed a "coversheet" for assistance in consolidating information
- Once submitted, conversation is held about who should be the BOR **based upon some agreed upon criteria** but flexibility is built in
- If straight reciprocity not opted for, after review by BOR, modifications/provisos are sent to the others for a site specific proportionate review. If the other Board needs to see the response, they must indicate that
- **Turn-around times have been stipulated, 2-3 days for determining BOR, two weeks for provisos**
- Have agreed to a format for a joint certificate of approval
- Continuing review by BOR unless increase of risk or site specific issues



Above Minimal Risk Model

Board of Record + 1

In addition to the BoR, a voting member from each of the involved REBs joins the BoR for the review meeting either in person, by teleconference or video-conference or they can just submitting comments in writing.

Considered Virtual Board and BOR Review with Provisos but opted for BOR + 1 because of less administrative burden and it allows for flexibility in participation in the full board discussion and by having that participation, will enhance education and trust building.



Above Minimal Risk Model

Board of Record + 1 Continuing Review

Comes into Board of Record and assessment is made, whether it either increases the risk or is of interest / importance to one or any of the other sites.

If no, BOR handles the amendment and notifies the other boards.

If yes, and is an amendment that doesn't require full board review, basically handled in accordance with the minimal risk model

If yes, and is a Full Board amendment, is handled in the same way as new above minimal risk applications.



Sponsored Clinical Trial Model

Developed Pilot Process August 2013

Similar to AMR model, but for the pilot, assumed a UBC Board would always be the BOR, and the RISE system would always be used.

Guest Reviewer capacity has been built in for all UBC Boards with administrators for each of the other 7 partners.

For all models, have the capacity to add sites post-approval but they have to accept the determination of which Board is to be the BOR.

After pre-review the other sites receive the application and as in the AMR model, participate in the review in person, or otherwise

REB approval is granted as a multi-jurisdictional approval with a “multi-jurisdictional” certificate of approval listing all sites

Continuing review would follow the AMR model

Sponsored Clinical Trial "Pilot"

Once agreed upon the "SOP", Director of BCEHI solicited assistance from BCCRIN to disseminate a call for multi-site pilot model testing.

Needed a UBC site and at least two others in BC.

Had some minimal interest but in the end, no "takers".

Sponsors were interested in cross-national coordination but didn't need a process that was just within BC



Conclusions and Next Steps?

Collaborative review more work and takes more up-front time than a single institutional review but it does save researcher's from multiple submissions.

Easier when you have an on-line system and only 8 partners. The other institutions are getting used to working in RISE

Most intra-BC multi-site studies are minimal risk

Does require good relationships and communication.

May be the interim process to a move to straight reciprocity, UBC  Other Institutions this is already happening.



Conclusions and Next Steps

Sponsored Clinical Trials

Michael Smith has asked the Pilot working group to get back together...

UBC has prioritized getting its Boards SOPs aligned 100% with the CAREB / N2 SOPs.

UBC is reviewing the CTO qualifications manual and working on getting to the point where they could be CTO qualified.

Other BC institutions may agree to do the same



Thank You

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