



MICYRN Workshop

Ottawa, Ontario
December 12th, 2011

Research Ethics Harmonization

Introduction

This workshop was the third in a series, to bring together members from MICYRN-affiliated Research Ethics Boards with the objectives to:

1. Build trust through communication
2. Harmonize review
3. Improve quality of review

The collegial and strongly committed Working Group is comprised of members from self-standing pediatric REBs (Vancouver, CHEO, Sick Kids, Montreal Children's, Ste Justine, IWK); reps from regional and provincial REBs (Winnipeg, London, Alberta, Newfoundland); expert advisors in ethics, policy and law from the Center for Genomics and Policy (McGill University); and the Director, CIHR Ethics Office.

A first workshop sponsored through a CIHR MPD grant was held in February 2011 and had led to strong interest in working together on consideration of different models for ethics review of multi-jurisdictional studies. Since that meeting, there had been work between individuals at Ste Justine (Montreal), Sick Kids (Toronto) and C&W (Vancouver) to determine the feasibility of inter-institutional reciprocity agreements. It became clear that existing provincial (Quebec) or institutional policies (UBC) would have to be changed in order for local boards to accept the review of another institution. Work then began towards development of a "central" or federated (= 'joint') national REB. It is being proposed that this be comprised of the Chairs and other members from the MICYRN-affiliated REBs, such that all necessary local jurisdictional issues could be brought to bear in a joint deliberation. The federated committee would not replace local REBs, but could save the need for repeat full board reviews if a site Chair had the authority to expedite applications they/their delegate had approved at the federated REB.

A second workshop sponsored through a CIHR MPD grant was held in October 2011 and successfully undertook a 'mock review' of two novel Phase I/II clinical trials, and tested a purpose-developed Common Application form and the function of a federated committee comprised of the Working Group members. There was enthusiastic consensus to build on this success.

The agenda of this third workshop was to:

1. Understand the legislation that has been set on REB governance in Quebec, Alberta and Newfoundland
2. Review in detail the proposed Process for handling ethics applications, and Terms of Reference for the proposed federated REB and how this will integrate with existing Site REBs.

3. Review in detail the Common Application form to ensure this captures all the necessary information for multi-jurisdictional review.

Survey Results

Dr. Junker presented on the preliminary results of a survey that had been sent to 27 research networks to solicit their plans for multi-center research studies to be conducted in 2012. At the time of the meeting, 12 of 14 responding networks indicated plans for a total of 26 studies. Given the number of centers involved with each study, a total of 211 REB reviews would be conducted in the current system. (attached following)

Presentation: Harmonizing Ethics Review in Paediatric Research: *Quo Vadis?*

Ma'n H. Zawati (LL.M, LL.B.) presented on his review of the Provincial legislation in Quebec, Alberta and Newfoundland. Mr. Zawati is a lawyer and an Academic Associate at the Centre of Genomics and Policy at McGill University. Before joining the Centre, he completed his articling at Ménard, Martin, Avocats, s.e.n.c., a Montreal-based law firm specialized in medical and hospital liability as well as in legal psychiatry. Mr. Zawati coordinates the ELSI and Privacy Task Force of the Canadian Partnership for Tomorrow Project, a pan-Canadian research study of 300,000 Canadians that explores how genetics, environment, lifestyle and behaviour contribute to the development of cancer and other chronic diseases. (presentation attached following)

Discussion of Barriers and Review of the Proposed Process

Mr. Zawati concluded his presentation with the recommendation to proceed to develop reciprocity agreements between the organizations affiliated with MICYRN. However, the feeling of participants was that these would be difficult to negotiate, and even more difficult for REBs at various centers to accept.

There was agreement that the MICYRN-proposed process (attached following) respects the legislation in Quebec, Alberta and Newfoundland, such that the deliberations of the federated REB come back to the site or regional REBs who retain responsibility for issuing the ethics certificate of approval. There was unanimous agreement on the vision for a federated REB to have legislated authority and insurance, such that it could be a decision-making body with which organizations could sign MOU. However, it was recognized that this will require time and significant resources. It was also acknowledged that more data and 'ironing out' of details in the functioning of a federated REB was necessary.

Review of the Common Form

Review of the Form was a good exercise. In addition to 'word-smithing' there began to be discussion as to the format and content of information collected. Obviously much information is captured for REB deliberations, but some information is collected (particularly in electronic systems) for administrative-reporting purposes. MICYRN is about to launch a Sharepoint site where this document will be posted for further input. It is clear this group could make a significant contribution to development of a standard national form.

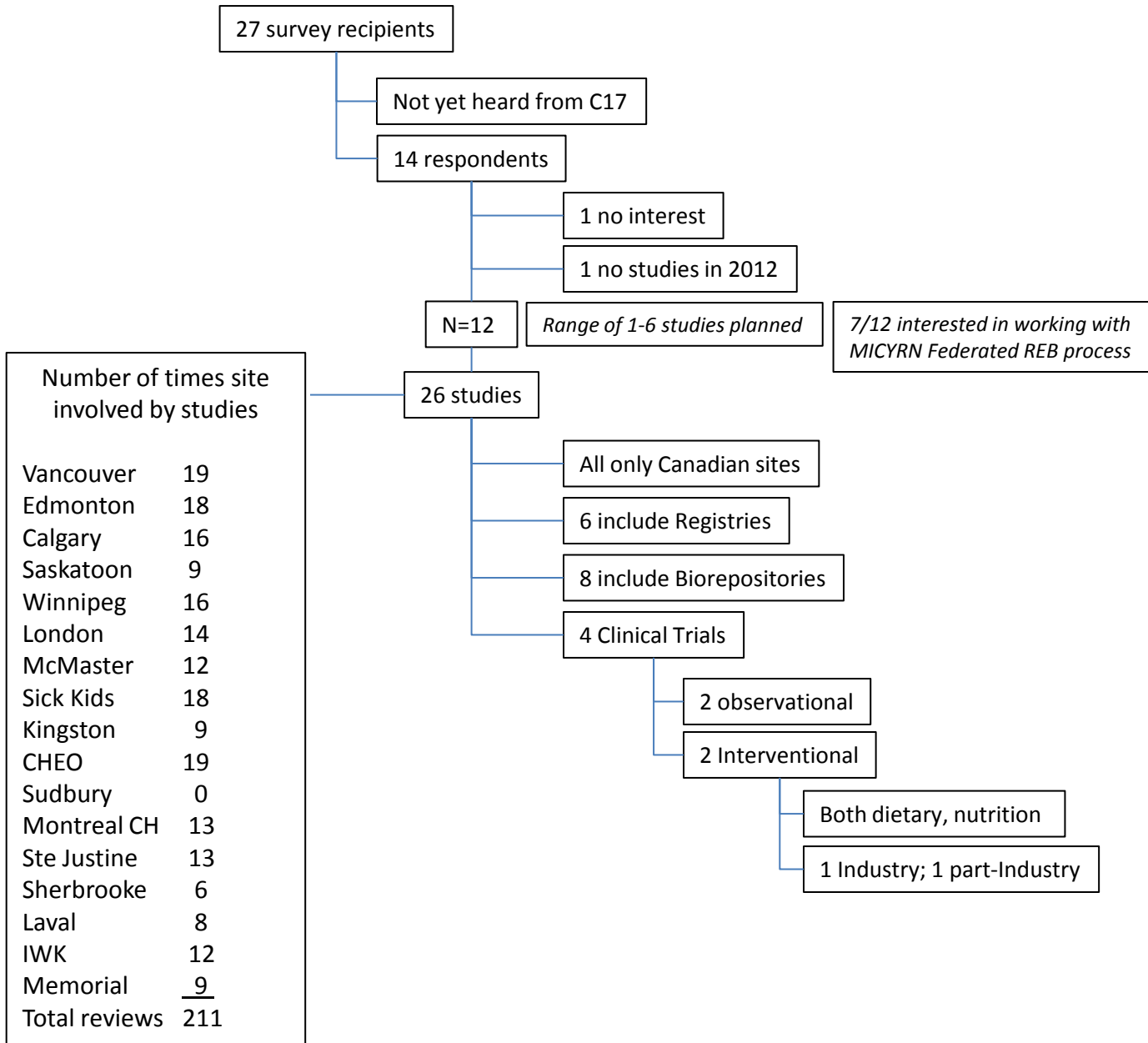
Conclusion

The meeting concluded with great enthusiasm to "just do it" – to begin to conduct review of multi-center studies. A proposed Phase I, will see the process tested, issues identified, and function evaluated. As laid out now, other points for Phase I:

- We will not seek insurance or Federalwide Assurance at this stage because that is a whole other level of complexity and cost.

- Meetings will be held quarterly, starting (est) May 2012. Ideally, tied to other national meetings of interest to the REB group (ie. CAREB)
- Studies reviewed will come from research networks who indicate an interest in collaborating to see this process work. (Survey to date shows 10 networks identified with 32 studies)
- The REB will be fully constituted according to TCPS2. There was recommendation to include 2 jurists, one from common law and one from civil law, cognizant of legislation differences between French and English Canada.
- All the documents related to each study will be held on the MICYRN Sharepoint site. The flow of all deliberations and communication will be made available on completion of the federated REB review and a study is 'found to be satisfactory'.

Survey of Research Networks about Multicenter Research Studies Planned for 2012



For the federated REB, what should be the minimum number of sites involved for a study to qualify as 'multi-center'?

- 6 responded 2 sites
- 4 responded 3
- 2 responded 4

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Harmonizing Ethics Review in Paediatric Research: *Quo Vadis?*

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Outline

- I. Multi-Jurisdictional Research
- II. Provincial Legislation Affecting REBs
 - Quebec
 - Alberta
 - Newfoundland and Labrador
- III. MICYRN Research Ethics Review: *Quo Vadis?*

I. Multi-Jurisdictional Research

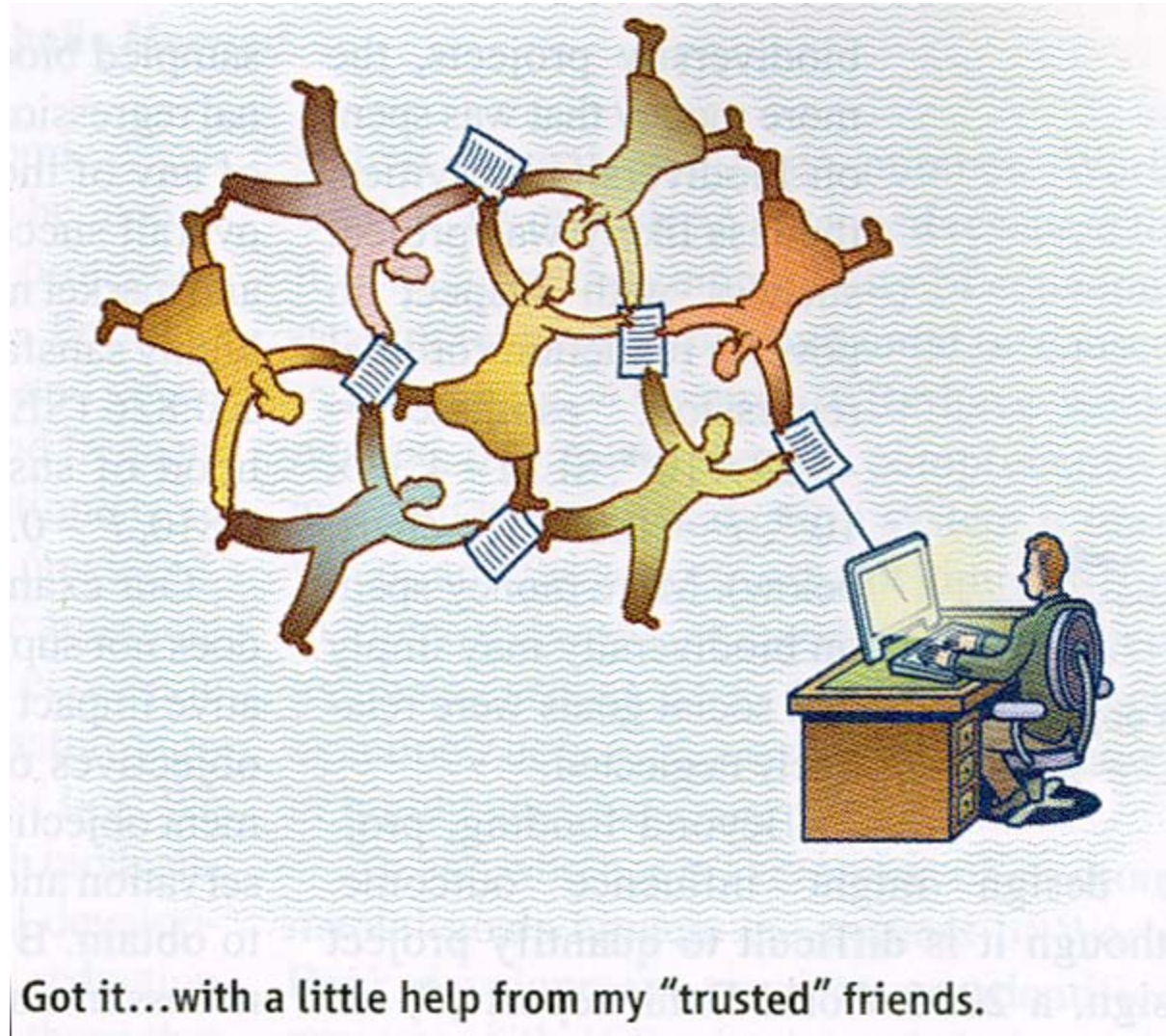




I. Multi-Jurisdictional Research

- Independent Ethics Review by Several REBs
- “This model follows the same research ethics review process as when the research only involves a single REB review. The REBs involved at each participating institution conduct an independent research ethics review and provide their separate decisions, either concurrently or sequentially. The level of ethics review for research that involves multiple REBs and/or institutions shall be proportionate to the risk involved in the research [...]” (Application of 8.1 TCPS 2).

I. Multi-Jurisdictional Research





I. Multi-Jurisdictional Research

- Research Ethics Review Delegated to an External, Specialized or Multi-Institutional REB
- “Institutions may allow research on specialized content or research methods to be reviewed by an external, specialized or multi-institutional REB, where such a body exists. External, specialized or multi-institutional REBs may be established regionally, provincially/territorially or nationally, as necessary. Two or more institutions may choose to create a single joint REB, or to appoint an external REB, to which they delegate research ethics review. This delegation of review may be based on geographical proximity or other considerations such as resources, volume of reviews or shared expertise.” (Application of 8.1 TCPS 2)

I. Multi-Jurisdictional Research





I. Multi-Jurisdictional Research

- Reciprocal REB Review
- “Multiple institutions may enter into official agreements under which they will accept, with an agreed level of oversight, the research ethics reviews of each other’s REBs. This might involve specific agreements between institutions for sharing their workload. Alternatively, institutions may decide that reciprocity agreements should be established for the ethics review of each relevant research proposal on a case-by-case basis.”(Application of 8.1 TCPS 2)



One more thing...



I. Multi-Jurisdictional Research

- Article 8.1
- “[...]The institution remains responsible for the ethical acceptability and ethical conduct of research undertaken within its jurisdiction or under its auspices irrespective of where the research is conducted.”


II. Quebec

- Section 21 *Civil Code of Quebec*
- “[...] Such an experiment must be part of a research project approved and monitored by an ethics committee. The competent ethics committees are formed by the Minister of Health and Social Services or designated by that Minister among existing research ethics committees; the composition and operating conditions of the committees are determined by the Minister and published in the *Gazette officielle du Québec* [...]”.

II. Quebec

- Section 21 *Civil Code of Quebec*

Répertoire des comités d'éthique du Québec

	santé et services sociaux					
	établissements	comités d'éthique en	CER désignés	CER non désignés	CE cliniques	CE mixtes
1 - Bas-Saint-Laurent	5	5	-	2	2	1
2 - Saguenay - Lac-Saint-Jean	4	5	1	1	3	-
3 - Québec	14	26	13	3	10	-
4 - Mauricie et Centre-du-Québec	6	8	2	1	4	1
5 - Estrie	6	10	3	4	3	-
6 - Montréal-Centre	42	70	34	13	23	-

II. Quebec

- Section 21 *Civil Code of Quebec*

Comité central d'éthique de la recherche du ministre de la Santé et des Services sociaux

En vertu de **article 21 du Code civil du Québec** (C.c.Q.), les projets de recherche qui impliquent des mineurs et des majeurs inaptes ou dont l'inaptitude est subite doivent obligatoirement être approuvés et suivis par un comité d'éthique de la recherche (CÉR) institué ou désigné par le **ministre de la Santé et des Services sociaux**.

Mécanisme multicentrique

Mécanisme encadrant l'examen éthique et le suivi continu des projets multicentriques



Un projet de recherche multicentrique est un même projet mené dans plusieurs établissements. Ce type de recherche est très courant dans le domaine de la santé et

07.06.2010 Le ministère de la Santé et des Services sociaux établira un bilan de l'application du mécanisme multicentrique dans les établissements du réseau. Ainsi, au cours des prochaines semaines, les divers intervenants qui utilisent le mécanisme seront invités à s'exprimer sur leur

III. Alberta

- Section 49 *Health Information Act*:
- “A person who intends to conduct research using health information in the custody or under the control of a custodian or health information repository must submit a proposal to a research ethics board for review by that board containing
 - (a) the information specified by the regulations, and
 - (b) any other information required by the research ethics board.”

III. Alberta

- REBs designated under the *Health Information Act*:
 - ❑ Alberta Cancer Research Ethics Committee (Alberta Health Services);
 - ❑ Research Ethics Review Committee (College of Physicians and Surgeons of Alberta);
 - ❑ University of Alberta Health Research Ethics Board (HREB) Panel A Biomedical Research and Panel B Health Research (University of Alberta);
 - ❑ Conjoint Health Research Ethics Board (University of Calgary);
 - ❑ Human Subject Research Committee (University of Lethbridge); and
 - ❑ Community Research Ethics Board of Alberta (CREBA) (Alberta Innovates – Health Solutions)

IV. Newfoundland and Labrador

- Section 9 of the *Health Research Ethics Authority Act*
- “(1) A person shall not engage in health research involving human subjects without first obtaining approval for the research from the research ethics board or a research ethics body approved by the authority under section 8.”

IV. Newfoundland and Labrador

- Section 7 of the *Health Research Ethics Authority Act*



HREB Meeting dates 2011

IV. Newfoundland and Labrador

- Section 8 of the *Health Research Ethics Authority Act*

Under “Approval of other research ethics bodies”

“The authority may approve a research ethics body if

- (a) it is a not-for-profit body; and
- (b) it is established in conformity with the principles respecting the appointment of members to a research ethics board contained in the tri-council policy statement for the purpose of reviewing applications for approval of health research involving human subjects in accordance with this Act.”

V. MICYRN Research Ethics Review – *Quo Vadis?*

	Single MICYRN REB	Reciprocal Review
Quebec	Difficult	X
Alberta	X	X
Newfoundland	Possible	X

V. MICYRN Research Ethics Review – *Quo Vadis?*



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Thank you !!!



Proposed Process for MICYRN Research Ethics Board Review

