Optimizing the ethics review process in multisite research projects

Manon St-Pierre
Director of Research, Innovation and Knowledge Transfer
Quebec Department of health and social services (MSSS)

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Presentation outline

1. The Quebec context
   a) Evaluation of research projects in the health and social services network
   b) Multisite research projects: Key findings since 2008

2. Process initiated by the MSSS in January 2013

3. Next steps
1. The Quebec context
Institutions in the health and social services network

Under the Act respecting health services and social services

• 268 public and private institutions in the health and social services network
• Only the 180 public institutions are concerned by this process to optimize the review of multisite projects
• Universities are not part of the health and social services network

Research ethics boards (REBs) that report to the board of directors of an institution in the health and social services network

• 54 REBs in the public institutions
• 14 of these REBs already serve more than one institution under an inter-institution agreement
1998: Ministerial Action Plan on Research Ethics and Scientific Integrity (MAP)

The boards of directors of the institutions are accountable for the research activities that take place therein and for the protection of persons who participate in such activities.

The institution must be able to guarantee:

1. the scientific quality of the research: examination by a committee of the institution or a peer review panel recognized by the institution

2. respect for persons: review by a REB

3. appropriate use of the resources allocated for research activities: assessment of the suitability of a project for an institution by an individual or committee of the institution
2008: Mechanism regulating the ethics review of multisite projects within the health and social services network

• A first experience of cooperation between the institutions of the health and social services network, with one REB acting as the main REB and various local REBs

• Forms and form letters used by all the institutions and the REBs

• At each institution participating in the project, the person appointed by the board of directors indicates in a letter to the main REB, that he/she authorizes the researcher to conduct the project within the institution’s walls when the 3-step review (scientific, ethics and suitability) set forth in the 1998 MAP has been completed to his/her satisfaction
2008: Overview of the multisite mechanism

1. The REB of each institution concerned studies the project

2. These local REBs provide a main REB with their comments

3. The main REB reviews the project and the local REB’s comments. It asks the researcher to make the necessary changes.

4. The main REB tells the local REBs that it accepts the project.

5. The local REB recommends that its institution endorse the main REB’s decision.

6. Each institution tells the main REB if the project is accepted by the REB.

7. The main REB informs the researcher.
Observations following application of the mechanism

- Shared findings, taken from
  - 2010 balance sheet (survey of REBs and researchers)
  - Problems noted by REBs (annual reports)
  - Discussions with certain groups (researchers, funding agencies, industry, etc.)

- Negative elements
  - Administrative burdens
  - Inconsistency of REB requirements
  - Unnecessary delays that hinder research project completion

- Positive elements
  - Improved climate of trust among the REBs of the health and social services network
  - Ethics review done by the main REB was recognized with no major difficulty by the authorities responsible for authorizing research projects in the local institutions
Consensus…

• Consensus on the need to take action to optimize the process

• Consensus on the **objective**
  – The medium-term objective is to ensure that a project conducted in more than one institution of the health and social services network is subject to **one ethics review only** [Quebec Department of higher education, research, science and technology (MESRST), MSSS, Quebec fund for health research (FRQS)]

• Consensus to establish **cooperation** mechanisms: MSSS, institutions, researchers, promoters, FRQS and 4 integrated university health networks (RUISs)
2. Process initiated by the MSSS in January 2013
Ongoing approach and objective

• The MSSS is pursuing the process that it initiated in January 2013, in which the 4 RUISs officially agreed to take part, to promote recognition of ethics reviews in the public institutions in its network

• The RUISs were set up to promote, in their service territory, the coordination, complementarity and integration of the patient care, teaching and research missions of the institutions

• The objective of this process is to ensure that in time, a research project conducted in more than one institution of the health and social services network is subject to one ethics review only which is recognized by the other institutions involved
A resolution by the boards of directors of the institutions in the health and social services network

• The boards of directors of all institutions of the health and social services network were invited, through the health and social services agencies, to adopt a resolution to:
  – Give their agreement in principle to recognition of the ethics reviews
  – confirm that they will work together with the RUISs and REBs to establish the terms by which an institution can recognize an ethics review performed by an outside REB

• With a few rare exceptions, all the boards of directors have adopted such a resolution
Mobilizing the network

• The 4 RUISs held a consultation in their service territories which brought together stakeholders to discuss issues relating to the recognition of ethics reviews:
  – Research centre directors, REB chairs, researchers, sponsors of clinical trials for pharmaceuticals, etc.

• As agreed, they tabled their proposals with the MSSS in the summer of 2013
Recognition of ethics reviews

- A preliminary analysis was made by the MSSS
- In the fall of 2013, regular discussions between representatives of the RUISs, FRQS and MSSS led to a joint review of these proposals
- Although certain differences were noted, the 4 proposals received are, for the most part, relatively similar with respect to the proposed means to allow for the recognition of ethics reviews for multisite research projects in the health and social services network
- A harmonized operating proposal for Quebec as a whole is expected, for application both within and among the RUISs
3. Next steps
Introduction of new terms

- The basic premise of the new ethics review model for multisite research projects applicable to the public institutions of the health and social services network is that only one REB will conduct the ethics review.
- Any ethics review performed by a competent REB of a public institution of the health and social services network, or by the central REB, will immediately be recognized by the institutions involved in the research project, whether or not they have a REB within their walls or they belong to the RUIS territory in question.
- This model is based on implementation of the following elements during the transition period of 16 months:
  - Maintain billing by the institutions of the REBs in question for the ethics review and continuous follow-up of the multisite projects.
  - Monitor the REBs’ activities associated with the ethics review of research projects funded by private companies.
  - Set up a task force to establish the optimal funding mechanisms for REBs.
The model ultimately proposed

1. The researcher presents his/her project to the REB of his/her institution or the REB of the primary place for recruiting participants, which becomes the evaluating REB for the health and social services network.

2. The evaluating REB studies the project and gives the researcher and ethics authorisation.

3. The researcher submits to every institution where he/she aims to carry out his/her research:
   - a positive recommendation from a scientific committee
   - the ethics authorization obtained from an evaluating REB
   - The researcher requests an examination of the project’s institutional suitability.

4. The person appointed by the board of the directors of the institution authorizes the researcher to conduct the project within the institution’s walls.

5. Passive follow-up is ensured by the evaluating REB, in collaboration with each institution and its REB, if it has one.
The process continues in collaboration with stakeholders

- In April 2014, all interested players received a notice from the MSSS outlining the terms adopted and the next steps
- The RUISs and FRQS are key partners for implementing the new terms
- The chairs and coordinators of all REBs in the health and social services network will be invited to attend a meeting with the RUISs and MSSS, in September 2014, for a presentation and discussions on:
  - the selected orientations
  - the draft Reference framework for the recognition of ethics reviews in the health and social services network
  - specific terms for the transition period
The process continues in collaboration with stakeholders

- Additional information meetings and training sessions will be organized in October and November 2014 for key stakeholders, which include the institutions, REBs and researchers.
- The new terms for recognition of ethics reviews will take effect on December 1, 2014.
- Task forces will be set up to:
  - develop suitable communication strategies for the duration of the process.
  - determine optimal financial support mechanisms for the REBs.
  - harmonize the various forms required for the multisite ethics review process.
  - assess the implementation process and take prompt action, as required.
Thank you for your attention!

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