Ministère de la Santé et des Services sociaux

Direction générale de la planification, de la performance et de la qualité

Quebec Multicentre Framework 2014

for Public Health and Social Services Institutions

2015 Clinical Trials Conference

Toronto, March 5, 2015

Québec

Multicentre Research in MSSS institutions

- One step further: from 2008 to 2014

- Implementation: February 1st, 2015

- Transition: until March 31st, 2016

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- *Framework for Public Health and Social Services Institutions to authorize research conducted at more than one site*
- In French: November 21st, **2014**
- In English: McGill University Web site (Medicine)

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- **Effective: February 1st, 2015**
- Transition Period: ending March 31st, 2016

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A network approach

- For public institutions under the *Act respecting health services and social services*
- 180 MSSS institutions.
- **34** MSSS institutions, as of April 1st, 2015 (Bill 10).
- These institutions are all covered by the same **liability insurance** program.
- 40 of these institutions have established an REB.
- REBs established by a University do not participate.

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Our goals

- Protect the participants involved in the research.
- Streamline research ethics review within the RSSS network of public institutions.
- Foster research excellence
- Create a dynamic in which the expertise of the 40 REBs established by MSSS institutions is made available to the other public institutions participating in the same network.

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MSSS Research Ethics Boards

- 40 public institutions have a REB (more or less)
- Most of them are « designated » by the Health Minister
- Designation renewed every 3 years
- All REBs file an **annual report** with the MSSS

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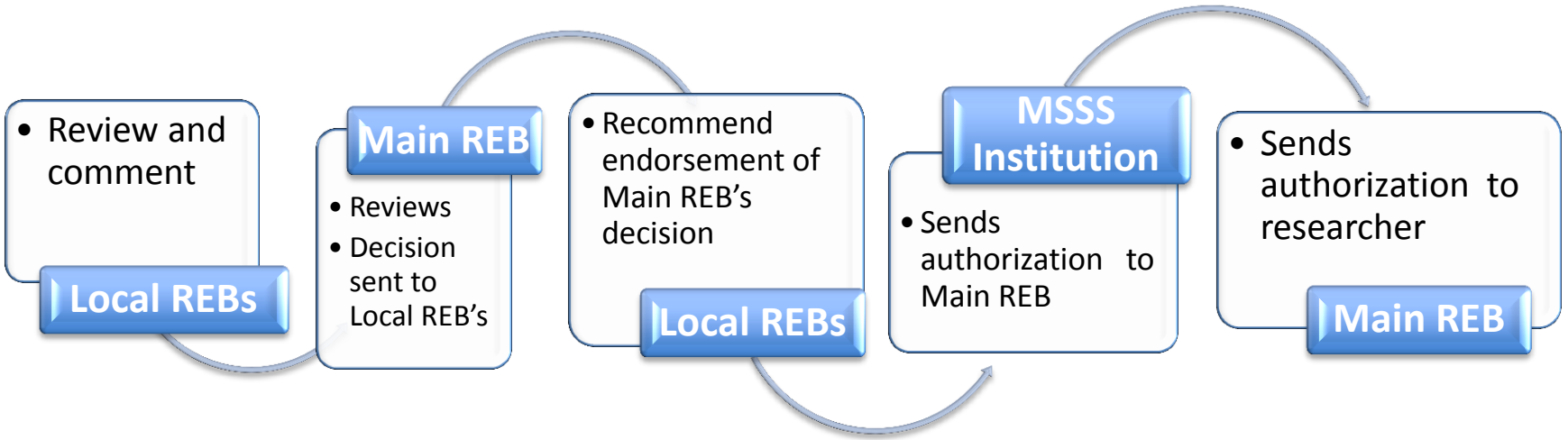
Quebec Multicentre Mechanism 2008



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One Ethics Review, endorsed by each participating institution

- Research projet

with

- Recruitment in **more than 1** MSSS institutions

- 1 Ethics Review

and

- Each institution will have to give authorization for the research to proceed

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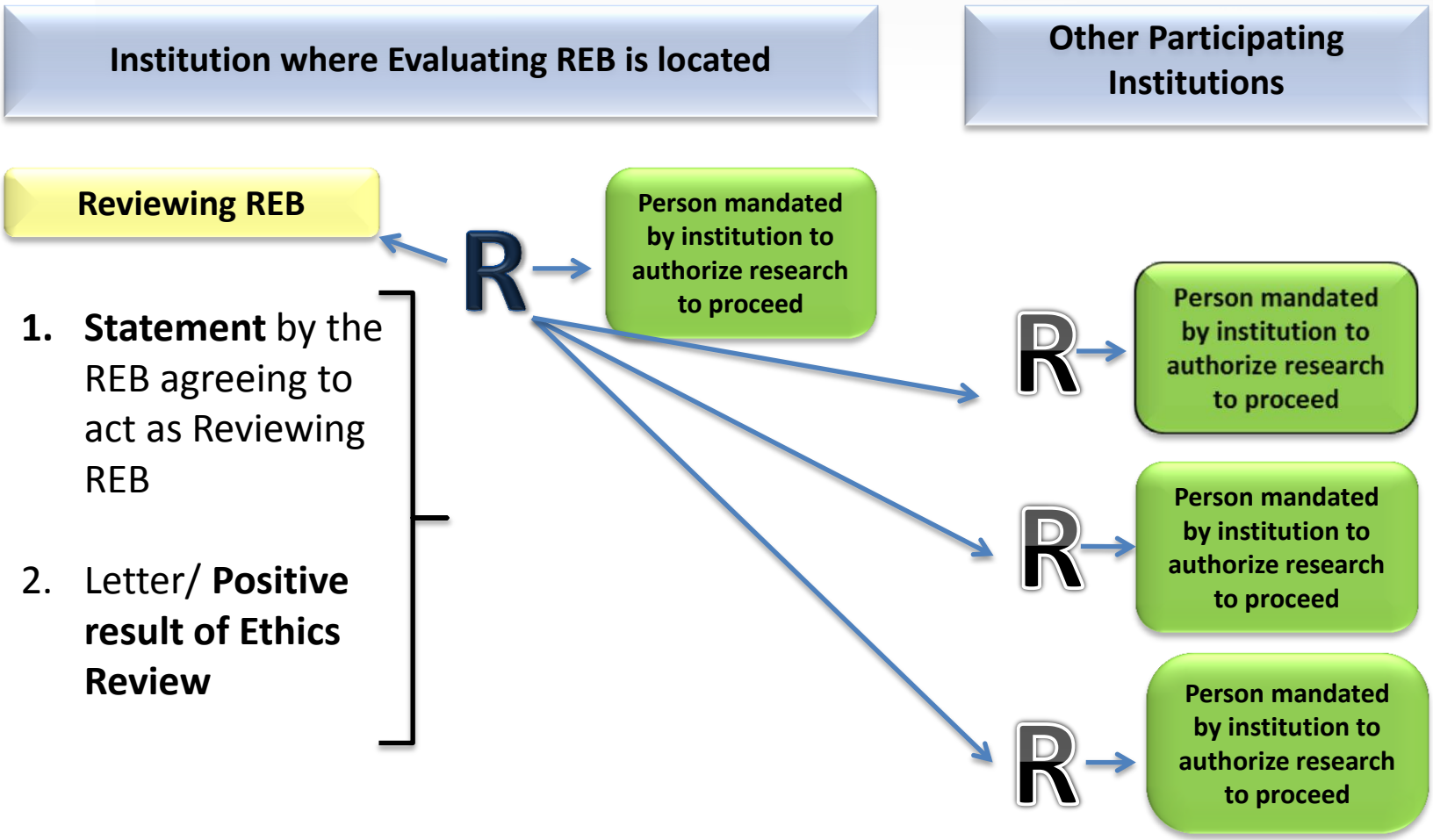

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Authorization by each participating institution

- « An REB approval applies to the ethical acceptability of the research, and **does not**, in itself, **constitute authorization** for the research to proceed. » *Tri-Council Policy Statement* (2014), p. 72.

- Under the *Act*, authorization can be given by the Executive Director or a person formally mandated by the institution to authorize research (art. 169)

- Authorization is given by this person upon receiving documents to the effect that the research project has undergone a :
  - Positive Scientific (scholarly) review,
  - Positive Ethics review, and
  - Positive Site specific assessment.

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How it works for Clinical Trials:

1. Researcher, chosen by sponsor, asks an REB to act as Reviewing REB.

2. The REB issues a **Statement** and fixes a date for the Ethics Review.

3. Copy of this Statement is provided to the other researchers. They use it to request a **site-specific assessment** of the project in their own institution.

- 1 **Ethics Review**

and

- Each **institution** will have to give authorization for the research to proceed

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How it works for Clinical Trials:

The researcher who asked for the Ethics Review:

4. Answers comments from the Reviewing REB.

5. Provides the Reviewing REB with a final version of the research documents.

- Consent form should be clearly marked to identify where each institution will insert administrative data.

→ - 1 **Ethics Review**

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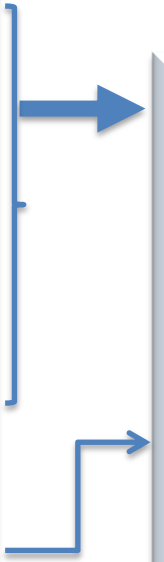
How it works for Clinical Trials:

6. The researcher who asked for the Ethics Review receives a letter from the Reviewing REB stating:

- Ethics Review is positive;

- Positive Scientific Review has been received.

7. Copy of this letter is provided to the other researchers. They use it to request the authorization to proceed in their institution.



- 1 Ethics Review

and

- Each institution will give authorization for the research to proceed

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How it works for Clinical Trials:

8. Each one of the researchers, including the one who asked for the Ethics Review, gets an **Authorization letter** from its own institution.

9. Recruitment can start in the institution when the Authorization letter has been issued.

- Each **institution** gives authorization for the research to proceed

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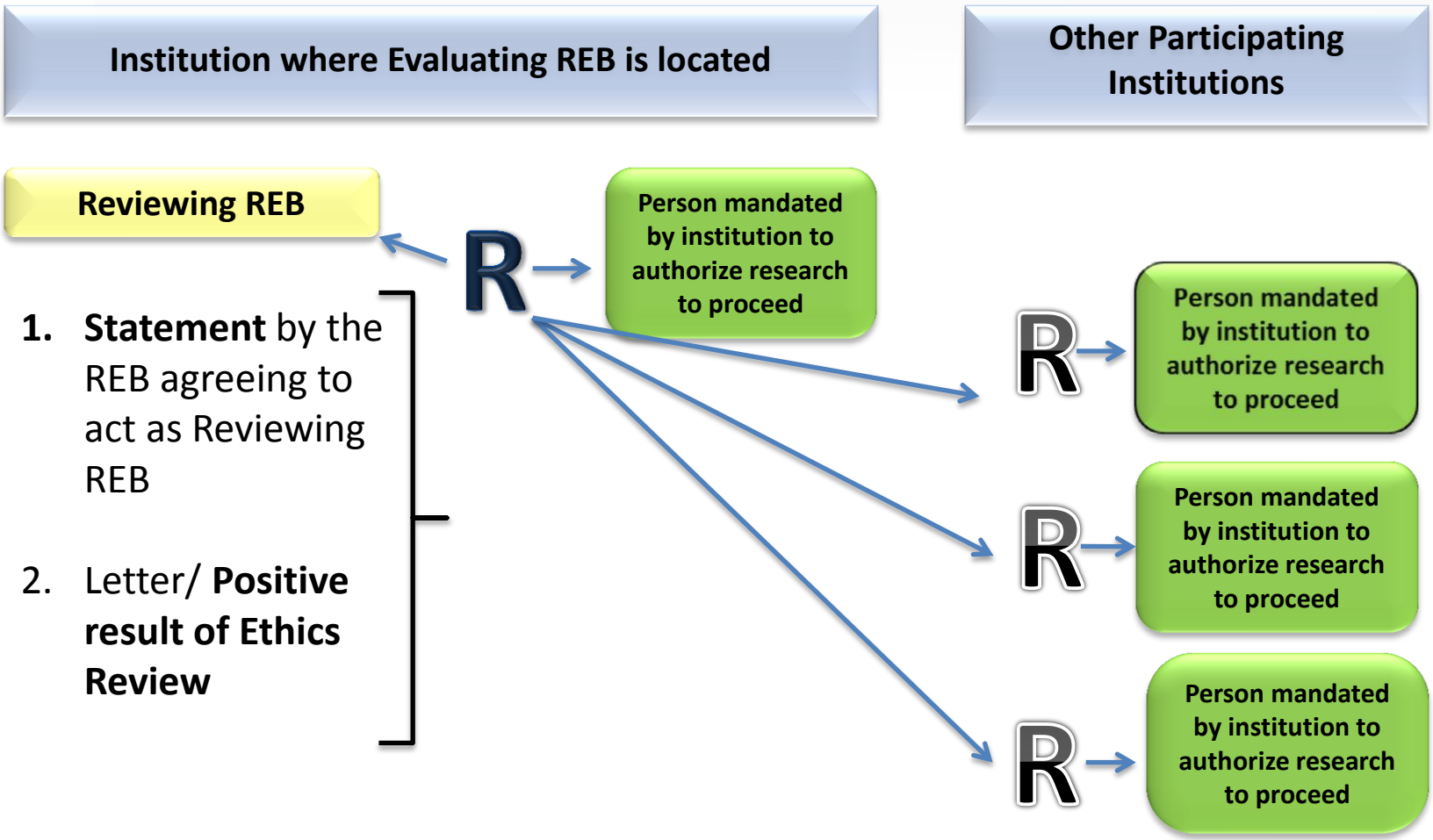

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Ongoing oversight:

10. Reviewing REB receives copy of Authorization letter from each site.

11. Oversight notification is transmitted to REB:

- if applicable at all sites, by the researcher who asked for the Ethics Review
- by the site researcher, when it pertains to his site.

13. Reviewing REB informs each institution of its oversight decisions.

- 1 REB for **Ethics Ongoing oversight**

and

- Each institution **endorses** the oversight decision

OR, stops the project

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Transition period till March 31st, 2016

- Funding
  - Working Group
  - Billing unchanged for Industry sponsored projects
- Consent forms
  - Working Group, with Fonds de recherche du Québec
- Monitoring
  - Data collection for the first 12 months
- Support
  - Phone and e-mail
- Web site: http://ethique.msss.gouv.qc.ca

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