

ETHICS REVIEW IN QUEBEC : The New Mechanism for Multicentre Projects

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THE QUEBEC CONTEXT (1)

Ethical Review is required for :

- All clinical trials (Federal regulation 1024)
- All projects involving minors (<18) or disable adults (Quebec Civil Code, section 21)
- All projects taking place in an institution within the Health & Social Services Network (MSSSS, Ministerial Action Plan)

THE QUEBEC CONTEXT (2)

Currently, there are :

- 64 REB in the health network
 - 45 designated (c.c. section 21)
 - 19 non designated
- 9 designated REB in Quebec Universities
- 1 central REB (to review projects subject to c.c. 21 taking place in settings without designated REB)

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74 REB under the Minister of Health Authority

THE QUEBEC CONTEXT (3)

Based on an independent inquiry conducted in 2006, the main problems are :

- Multiple ethical reviews for multicentre projects
- Lack of resources (HR, \$)
- Some legal requirements (c.c. sections 21 & 24)
- Control of experimental drugs
- Double standard : Public vs Private

THE NEW MECHANISM FOR MULTICENTRE PROJECTS (1)

Current context :

1 ethical review per site



" x " sites = " x " ethical reviews



Multiple consequences

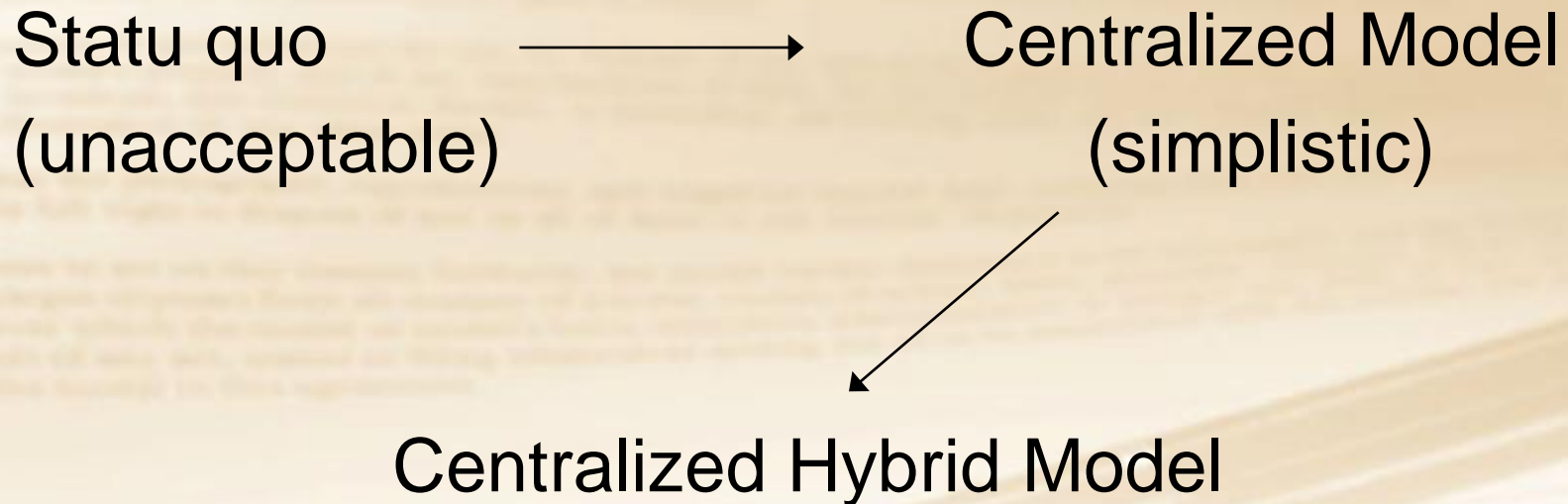
THE NEW MECHANISM FOR MULTICENTRE PROJECTS (2)

Consequences under the current regime :

- Delays (multiple ethical reviews)
- Useless costs (" x " times the same review)
- Different, sometimes contradictory requests from REB
- Multiple consent forms (for the same project)
- Researchers are demotivated
- Unequal treatment of research subjects
- Loss of credibility for the overall ethical process and requirements
- Etc.

THE NEW MECHANISM FOR MULTICENTRE PROJECTS (3)

Overall agreement on the problem. However, the solution is not so simple...



THE NEW MECHANISM FOR MULTICENTRE PROJECTS (4)

Why the centralized model is too simple to be true (simplistic) ?

- Institutional suitability (ex : over-solicitation of research subjects)
- Local considerations (ex : language)
- Local responsibility and governance
- Strong resistance
- Regulations (FDA, NIH, etc.)

THE NEW MECHANISM FOR MULTICENTRE PROJECTS (5)

Since April 1, 2008 : A hybrid model :

– One stop service –

1 Principal REB \longleftrightarrow 1 Head Researcher



local REB

THE NEW MECHANISM FOR MULTICENTRE PROJECTS (6)

How it works... (in brief)

- ➔ Local REB have 3 weeks to do a preliminary review in a expedited fashion
- ➔ The principal REB does a full review and must take into account comments provided by local REB
- ➔ The principal REB renders its decision and sent it to local REB

THE NEW MECHANISM FOR MULTICENTRE PROJECTS (7)

How it works (in brief)

- Key component : The local REB must approve, or reject the decision made by the principal REB
- The local REB forwards its decision to the principal REB within a two week delay
- The principal REB issues its final decision : the letter specifies to the head researcher which institutions have concurred

THE NEW MECHANISM FOR MULTICENTRE PROJECTS (8)

And the costs ?

Current regime

3 000 \$/Review

n = 10

10 X 3 000 \$ =
30 000 \$

New mechanism

Expedited local review : 850 \$

Principal REB review : 5 000 \$

n = 10

1 x 5 000 \$ = 5 000 \$

9 x 850 \$ = 7 650 \$

12 650 \$

THE NEW MECHANISM FOR MULTICENTRE PROJECTS (9)

Timelines :

- Announcement : November 15, 2007
- January – March, 2008 : Training +
4 Demonstration Projects
- April 1, 2008 : The new mechanism is effective for all institutions within the Health and Social Services network

THANK YOU !

For further information :
www.ethique.msss.gouv.qc.ca