

# The Quebec Multicentre Review Mechanism at the MUHC

May 26, 2008

Linda Furlini, PhD

Laura Galiana, M.Eng., pht.

David McLauchlan, M.Sc. (Candidate)

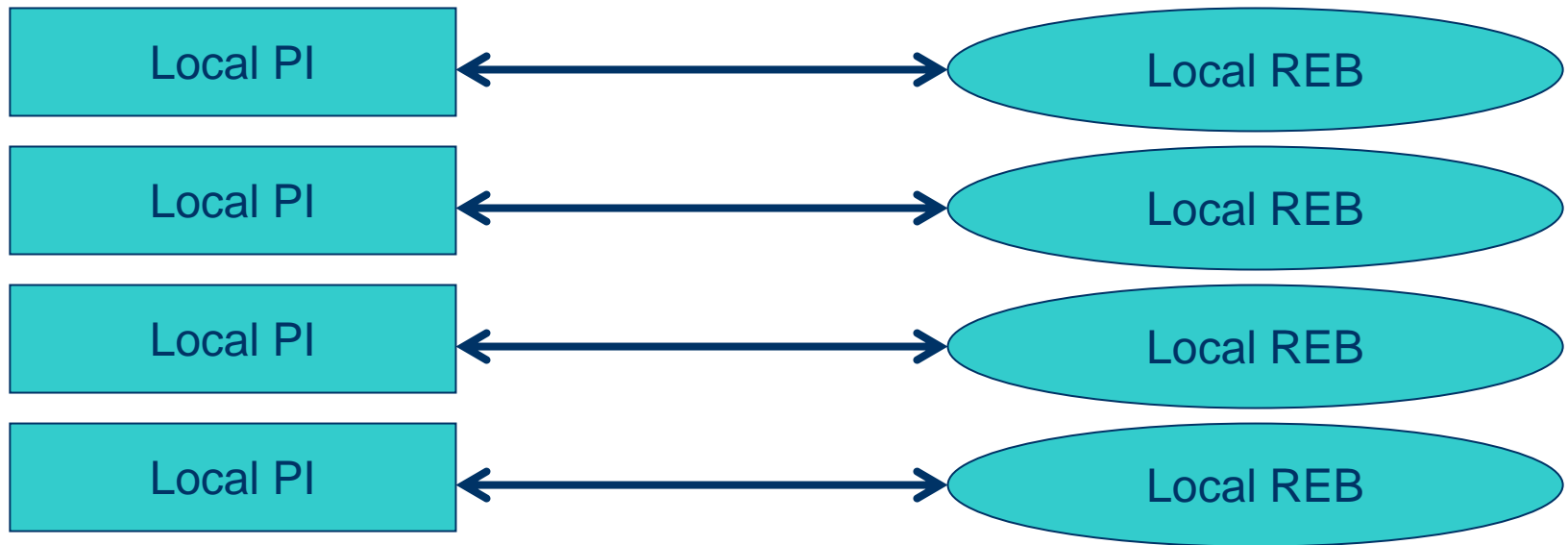
# Outline

- Overview of the Multicentre Ethics Mechanism
- How to Submit- Step by Step Process
- Resources/Forms

# Acronyms

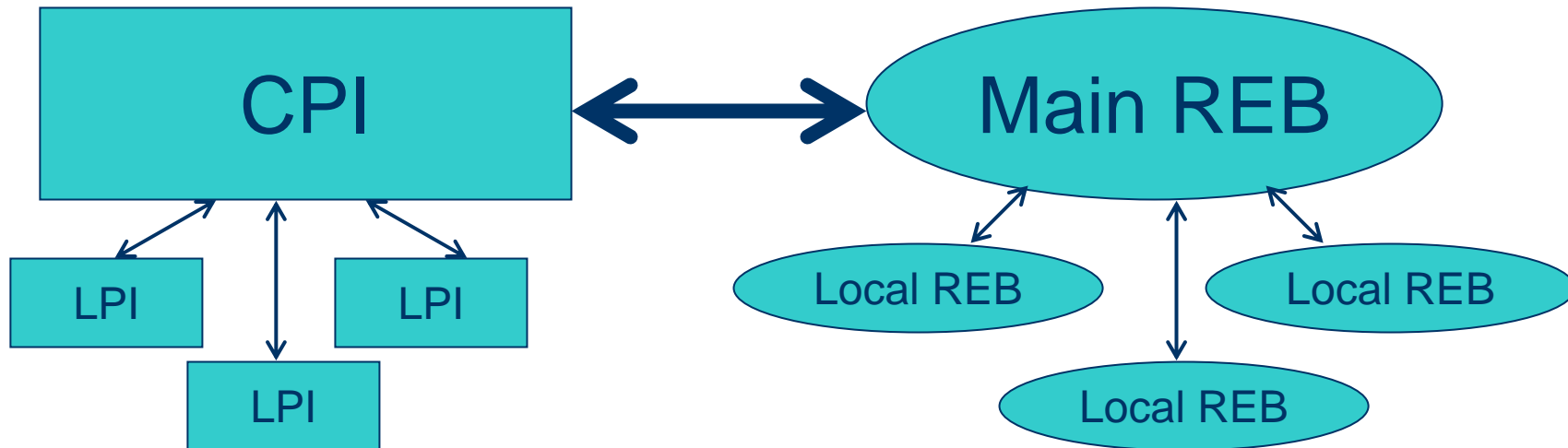
- CPI: Coordinating Principal Investigator
- LPI(s): Local Principal Investigator(s)
- REB(s): Research Ethics Board(s)
  - **Main or local**
- OCR: Office of Clinical Research
- SSA: Study Site Assessment
- SAE: Serious Adverse Event

# Ethics Review of Multicentre Studies: The Pre-April 2008 Mechanism



- Example: a study with four sites.
- Problems:
  - Duplication of administrative tasks at each site.
  - Inconsistency from site to site.

# Ethics Review of Multicentre Studies: The Post-April 2008 Mechanism



- Advantages:

- Less administrative responsibilities for the LPI and Local REB.
- Consistency throughout the province.

- Challenges:

- More administrative responsibilities for the CPI and Main REB

# **Ethics Review of Multicentre Studies: The Post-April 2008 Mechanism**

- Effective April 1, 2008
- Directive from the sous-ministre of Health and Social services
- The MUHC has a responsibility to ensure compliance for researchers who do not adhere to the Mechanism.

# Scope of the New Mechanism

- Research involving human participants
- Research in health and social services
  - Includes all data and biological materials
- Research is conducted partially or in full in more than one institution in the MSSS Network
  - Exclusions include: Universities, Private physician offices, laboratories
- Particular agreements within institutions are still operational

# Who can act as CPI?

- Resident of Quebec or conduct most professional activities in Quebec
- Affiliated with an MSSS network institution where the Multicentre Ethics Review Mechanism applies (i.e. MUHC)
- For a sponsored study: The role is designated by the Sponsor
- For a publicly funded Study: The PI (awarded grant) can act as the CPI or delegate the role

# Responsibilities of the CPI

- **Coordinates multicentre ethics submission in Quebec**
  - All correspondence with the main REB.
  - Initial submission to the Local REBs.
  - Coordinates the study with LPIs.
- **Also responsible for the conduct of the study at his/her institution.**

# Responsibilities of CPI

- Assure that the study has been reviewed for scientific merit
  1. Internally
    - Requests a “Scientific Review Assessment” at the MUHC
  2. Externally
    - Recognized Scientific peer review agencies or committees
    - an institution whose research centre receives funding from a Quebec or federal Granting Agency
    - a Quebec or federal granting agency, or of an agency recognized by one of the two
    - a university (i.e. program or thesis committee)
    - an organization recognized by the Organization of Economic Cooperation and Development (OECD) (i.e. INSERM, NIH)

# Responsibilities of the LPI

- Is leader of study at local institution
- Is responsible for the local research team and communicates with local co-investigator(s)
- Reports to the CPI and to local institution (e.g. SSA, SAE reporting)

# Communication

- Reciprocal Communication
  - CPI must communicate with LPI(s) and LPI(s) must communicate with CPI
- CPI is responsible for
  - communicating with Main REB (e.g. continuing review, amendments)
  - Communicating promptly with Local REB(s) about SAE's and urgent situations

## Quality Assurance (QA) and Education Program and the Multicentre Mechanism

- All studies at the MUHC are subject to Directed and Routine Quality Improvement (QI) Visits.
- All consent forms in use at the MUHC must mention in their confidentiality clause that representatives of the REB and QA staff will have access to records.

# Quality Assurance and Education Program

- Promotes a culture of ethical conduct among all members of the research community
  - **Routine QI Visits**
    - Random, not-for-cause
    - To support and educate
  - **Directed QI Visits**
    - For-cause

# How to submit: MUHC CPI (pre-day 1)

Submits to the MUHC Central Intake Coordinator ([newstudy@muhc.mcgill.ca](mailto:newstudy@muhc.mcgill.ca)):

- MSSS M-EVAL application form
- - Research protocol
  - Investigator's brochure (if applicable)
  - List of suggested reviewers form

OR

- Scientific merit approval from a recognized scientific committee

# How to submit: MUHC CPI (pre-day 1)

- The Central Intake Coordinator forwards the CPI:
  - Instructions for scientific merit review, if applicable
  - A provincial study reference number
  - Assignment to an MUHC REB of record (Main REB)
  - When favorable scientific merit is received, confirmation of scientific merit approval and instructions for REB review

May 1, 2008

**To:** Dr. xxxxxxxx xxxxxxxxxx, Coordinating Principal Investigator  
**From:** Sheldon Levy, Central Intake  
**Cc:** Laura Galiana and xxxxx xxxxx  
**Subject:** Quebec Multicentre Research Review - MUHC Investigator

This notice is to acknowledge your submission of study documents for REB review received on xxxx xx, 2008. We note you have been designated by the study sponsor as the Coordinating Principal Investigator (CPI) for Quebec and the plan is to conduct the research at the MUHC, and at least one other Quebec hospital. All REB submissions must indicate Day 1 of the review period.

For questions concerning the submission process contact **Sheldon Levy** at local 36077 or [sheldon.levy@muhc.mcgill.ca](mailto:sheldon.levy@muhc.mcgill.ca)

The proposal entitled "*Risk-benefit Ratio of Extended Thromboprophylaxis to Prevent Venous Thromboembolism among Patients Undergoing Hip or Knee Replacement Surgery: An Administrative Database Validity Study*" will be reviewed by the Biomedical C (BMC) Research Ethics Board (REB) and the reference number assigned to the study is: **MP-CUSM-xxx-08-xxx**

As the Coordinating Principal Investigator, you are responsible to submit three (3) complete packages including the "Formulaire de demande d'évaluation d'un projet multicentrique", science review and supporting documents to each Local REB at the institutions of the Local Investigators.

For questions concerning the REB review process contact **xxxxx xxxxx** at xxxxx or [xxxx@xxxx.mcgill.ca](mailto:xxxx@xxxx.mcgill.ca)

The mailing address for the MUHC REB is:

xxxxxx xxxxx xxxx  
Research Ethics Office  
xxxxxx xxxxx, Room xxxx  
Montreal, Quebec, xxx xxx

In addition to the REB review the complete central review includes a Site-Specific Assessment (Convenience évaluation) by each participating site. The assessment consists of reviews of the study's resource utilization, contract, budget, and as needed for advertising and pharmacy use.

For questions concerning the Site-Specific Assessment, contact **Laura Galiana** at local 43048 or [laura.galiana@muhc.mcgill.ca](mailto:laura.galiana@muhc.mcgill.ca)

Once the required reviews are completed, you will forward the written decisions to **Laura Galiana**. The Associate Director of Clinical Research of the MUHC will then issue correspondence stating the final decision concerning conduct of the study at the MUHC. It is the information from these documents that you will need to provide to the other Quebec Investigators and their Local REBs.

# How to submit: MUHC CPI (pre-day 1)

- CPI contacts MUHC REB of record coordinator for:
  - Required number of copies of initial application forms
  - Date of REB Meeting
- CPI contacts local PIs for:
  - Addresses of local REBs
  - Application process to local SSAs (may be delegated to local PI)
- The RI MUHC Office of Clinical Research will notify the CPI about the required MUHC SSA (contact info and applicable forms)

Dr.XXXX,

I have received a copy of your application form for a Quebec Multicentre Project (M-EvAL)

**Study ID:**

**Title:**

**Central Principal Investigator:**

**Local Principal Investigator:**

**Sponsor :**

Based on my review of the application form, you must have the following Site-Specific Assessments reviewed at the MUHC (please contact the persons below directly to submit all the appropriate documents to review your study):

**Impact Analysis Review**

Contact: Elizabeth Hillyer, [elizabeth.hillyer@muhc.mcgill.ca](mailto:elizabeth.hillyer@muhc.mcgill.ca), x34329

Required documents:

- MUHC Impact Analysis Form (see attached)
- Study protocol

**Pharmacy Review**

Contact: Denise Kalyvas, [denise.kalyvas@muhc.mcgill.ca](mailto:denise.kalyvas@muhc.mcgill.ca), x44932

Required documents:

- M-EVAL Form
- Study protocol
- Investigator's brochure or product monograph
- [MUHC Pharmacy Exemption Form](#) available on the web-click on link (only if requesting an exemption to dispense drug)
- Sponsor letter of agreement for billing (if applicable)

**Contract and Budget Review**

Contact: Sasha Lee, [Sasha.lee@muhc.mcgill.ca](mailto:Sasha.lee@muhc.mcgill.ca), x42334

Required documents:

- Confidentiality agreement (have this reviewed by MUHC before signing)
- MUHC Contract and Budget Review application (contact for electronic version)
- Study protocol
- Contract or contract amendment (MS Word version with track changes enabled)
- Detailed study budget in MS Word or MS Excel

**MUHC Access to Clinical Information**

Contact: Filitsia Chronopoulos, [filitsia.chronopoulos@muhc.mcgill.ca](mailto:filitsia.chronopoulos@muhc.mcgill.ca), x48087

- [MUHC Access to Health Record Form](#) available on the web-click on link
- Study protocol

**Public Relations and Communications (PRC) Review** (This is to be done after the advertisement is approved for content by the Main REB). PRC verifies the use of the MUHC logo

# Possible MUHC SSA reviews

- Depending on the study, the following reviews may be necessary:
  - Impact analysis review (for resource utilization)
  - Pharmacy review
  - Contract and budget review
  - Access to clinical information for research purposes review
  - Public Relations and Communications review (for advertisements)
- Once approvals are obtained, they are to be forwarded to the RI Office of Clinical Research

# What to submit: MUHC CPI (Day 1)

- Required number of copies of complete initial application form (M-EVAL) to MUHC REB of record
- 3 copies of complete M-EVAL form to each local REB
- MUHC required SSA application forms
- Local required SSA application forms (if not delegated to local PI)

## How to submit: MUHC LPI (pre-day 1)

- External CPI will submit MSSS M-EVAL to [newstudy@muhc.mcgill.ca](mailto:newstudy@muhc.mcgill.ca)
- External CPI (and LPI) receive MUHC memo with:
  - Mailing address of MUHC REB (Local)
- LPI receives notification from RI MUHC Office of Clinical Research concerning required MUHC SSA

# How to submit: MUHC LPI (Day 1)

- External CPI submits to Local MUHC REB 3 complete packages of M-EVAL
- MUHC LPI submits applicable application forms to the required MUHC SSA
  - Once approvals obtained, they are to be forwarded to Office of Clinical Research

# **MSSS M-EVAL application:**

<http://ethique.msss.gouv.qc.ca/site/170.282.0.0.1.0.phtml>

## **To be completed by the CPI**

### **11 Sections**

1. Schedule for preliminary review by local REBs
2. Relevant documents for ethical review
3. General information
4. Scientific Aspects
5. Benefits, Risks and Inconveniences
6. Justice
7. Privacy and Confidentiality
8. Respect for Autonomy
9. Research Integrity
10. Data or Biological Material Banking
11. CPI's Declaration

## FORMULAIRE DE DEMANDE D'ÉVALUATION D'UN PROJET MULTICENTRIQUE (Doit être rempli par le chercheur principal coordonnateur)

Le genre masculin, employé pour alléger le texte, désigne autant les femmes que les hommes.

Numéro de référence donné au projet par le CÉR principal : **MP-** \_\_\_\_\_

### SECTION 1 – ÉCHÉANCIER AUX FINS DE L'EXAMEN PRÉLIMINAIRE DES CÉR LOCAUX

Date du dépôt du dossier à tous les CÉR et établissements en cause (jour 1) :	
Date d'échéance de la réception des commentaires des CÉR locaux (trois semaines après la date du jour 1) :	
Date de la réunion du CÉR principal :	

### SECTION 2 – DOCUMENTATION PERTINENTE AUX FINS DE L'EXAMEN DU PROJET SUR LE PLAN DE L'ÉTHIQUE

#### REMARQUE

Vous devez soumettre, au **CÉR principal** compétent, un dossier complet présenté dans le format défini par le comité et en autant de copies que celui-ci le demande. Vous devez également déposer trois copies du dossier complet à **chacun des CÉR locaux des établissements en cause** avec une lettre indiquant que la demande porte sur l'examen préliminaire du projet et que celui-ci a été soumis à un CÉR principal. Cette lettre donnera également les coordonnées du CÉR principal et les informations pertinentes concernant l'établissement en cause (ex. : nombre de sujets pressentis, département dans lequel s'effectuera le recrutement). Enfin, le dossier doit être déposé auprès des établissements où le projet sera mené, en partie ou en totalité, aux fins de l'examen de la convenance, et ce, en autant de copies que chacun des établissements le demande.

- Outre le présent formulaire, le dossier complet comprend au moins les documents suivants. Veuillez indiquer, en cochant les cases correspondantes, ceux qui accompagnent le présent formulaire.
  - le **rapport d'évaluation du comité scientifique** ayant approuvé le projet, lequel contient les coordonnées de ce comité, la décision que celui-ci a rendue ainsi que les questions, les préoccupations et les commentaires qu'il a formulés ;
  - une lettre contenant le **nom et les coordonnées des présidents des CÉR locaux** ou, en l'absence de CÉR, le **nom et les coordonnées des établissements en cause** ainsi que l'engagement du chercheur principal coordonnateur à informer lesdits CÉR et établissements du nom et des coordonnées du CÉR principal ;
  - le **résumé du projet**, dans un langage aussi peu technique que possible<sup>1</sup> ;
  - le **protocole de la recherche** proposée (clairement présenté comme tel et daté), accompagné des documents justificatifs et des annexes ;
  - lorsque la recherche porte sur un produit à l'étude (tel qu'un médicament, un produit de santé naturel ou un instrument médical), le résumé de toutes les données de tolérance, pharmacologiques, pharmaceutiques et toxicologiques publiées sur le produit évalué ainsi que le résumé de l'expérience clinique acquise à ce jour concernant ce produit (ex. : **brochure de l'investigateur** récente, lettre de non-objection de Santé Canada<sup>2</sup>) ;
  - un document attestant les **compétences du chercheur principal coordonnateur** pour mener à bien le projet, si elles ne sont pas encore connues de l'établissement ou du CÉR (ex. : curriculum vitae, attestation de recherche, privilège ou champ de pratique de recherche, preuve du droit de pratique délivré par un ordre professionnel) ;
  - la liste de toutes les **démarches entreprises auprès d'autres CÉR** en vue de faire approuver le projet soumis, celle de toutes les décisions antérieures importantes (ex. : décision négative ou demande de modification du projet) prises par d'autres CÉR ou autorités ayant un pouvoir réglementaire (au Canada) à propos de ce même projet ainsi que la liste des changements apportés au projet de recherche à la suite de ces décisions. Les raisons des précédentes décisions négatives doivent être fournies, le cas échéant ;

1. Bien que le formulaire de demande d'évaluation du projet produit par le Ministère puisse tenir lieu de résumé du projet, certains CÉR exigent malgré tout un tel résumé ; cela explique pourquoi le Ministère le demande.

2. Ce document doit être déposé préalablement à l'approbation finale du CÉR principal.

# MSSS M-EVAL Application Form

- Day 1:
  - The REBs (main and local) receive their applications for ethics review.
  - SSAs received by the appropriate bodies at all participating institutions
- 3 weeks after Day 1: Local REBs must submit their comments to the main REB.
- Main REB meeting date: 2 weeks after-main send preliminary decision

# MUHC Website:

<http://www.muhc.ca/research/ethics/3/>

## Research Ethics Office (REO)

### How to Submit for Review

#### Quebec Multicentre Studies

As of April 1, 2008, the Ministère de Santé et des Services sociaux du Québec (MSSS) requires that all Quebec multicentre research be reviewed by a central review mechanism. For detailed information, please refer to the MSSS website:

[http://ethique.msss.gouv.qc.ca/site/fr\\_mecanismemulticentrique.phtml](http://ethique.msss.gouv.qc.ca/site/fr_mecanismemulticentrique.phtml)

You may download the MSSS application forms directly from the MSSS website.

<http://ethique.msss.gouv.qc.ca/site>

An [MSSS Application for Initial Review in English](#) is available for your reference.

New applications for research review are submitted to [newstudy@muhc.mcgill.ca](mailto:newstudy@muhc.mcgill.ca)

For questions concerning the process please contact [Sheldon Levy](#) at 514-934-1934, local 36077

Review procedures for Quebec multicentre research vary according to the role assigned to the Investigator by the Study Sponsor. Refer to the information at the link below that describes the Investigator's role at the MUHC:

**[MUHC Investigator as Coordinating Principal Investigator](#)**

**[MUHC Investigator as Local Investigator](#)**

**[Submission Information for Non-MUHC Investigator](#)**