

INTRODUCTION TO RESEARCH ETHICS & BEST PRACTICES

*Centre intégré
universitaire de santé
et de services sociaux
du Centre-Ouest-
de-l'Île-de-Montréal*

Québec 

*Integrated Health
and Social Services
University Network
for West-Central Montreal*

WCMH Research Review Office

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TODAY'S TOPICS

- Research Ethics Historical Background
- Principals in Ethics and Resarch
- Review Process
- Multicenter Mechanism
- Nagano
- Research Team roles
- Lab set-up and Best Practices

HISTORY

- In-Vivo Human dissections - Roman Empire circa 3rd Century B.C. Revival 14th Century.
- Claude The Mengeli Twins 1943-45: Nazi experimentation on human subjects
- The Milgram Experiment 1974: Stanley Milgram's electric shock experiments and obedience



HISTORY

- Henrietta Lacks 1951: Genetics and biological material
- Beecher's Bombshell 1966: report and publication on problem studies.
- Thalylomide in Quebec for morning sickness: Drug Safety and Regulation



MAJOR ETHICAL PRINCIPLES

Respect for Human Dignity		
Respect for Persons	Concern for Welfare	Justice

LEVELS OF REGULATIONS

International	National	Provincial	Institutional
Nuremberg Code Declaration of Helsinki	Tri-Council Policy Statement Health Canada Requirements	PAM (Plan d'action ministériel)	WCMH Policies & SOPs

LAWS AND LIABILITIES

- Legislation

- Civil Code of Quebec (CCQ)
- Mental Health legislation
- Human Tissue Gift Acts

- Codes and Policies establish the **Standard of Care**

- Courts will often ask:

- Was the Standard of Care breached?

- Liability may be shared amongst the key players:

- Researcher
- Institution
- REC

RESEARCH ETHICS COMMITTEES

Triple Review Process		
Ethical	Scientific	Financial and Feasibility

RESEARCH ETHICS COMMITTEES

- An independent committee mandated to review all research involving human participants including:
 - Tissue
 - Blood
 - Saliva
 - Embryo
 - Fetus or derivative
 - Cadavers
 - information about a human (e.g., medical records, photos)
- The REC review systems are important societal mechanisms involved in the protection of human participants in research

WHAT MUST THE REC ASSESS?

- Scientific design & conduct of the study
- Feasibility of conducting & completing study
- Recruitment & retention of research participants
- Care & protection of research participants
- Care & protection of research participants' information
- Informed consent process
- Consideration for the Community
- Multi-site research (MSSS Mechanism in Quebec)

GRANT AGENCY FUNDING

Grant/protocol usually lacks key details:

- Potential benefits for participants
- Risks for participants, and how minimized
- Recruitment process
- Confidentiality protections
- Permissions to conduct research in proposed location

THE MULTICENTER MECHANISM

- A province-wide system for all recognized REC (Research Ethics Committees)
- Québec's Ministry of Health
- Goal: to minimize steps to obtain authorization to conduct research by eliminating multiple ethics committees reviewing one project.

Provincial (REC)

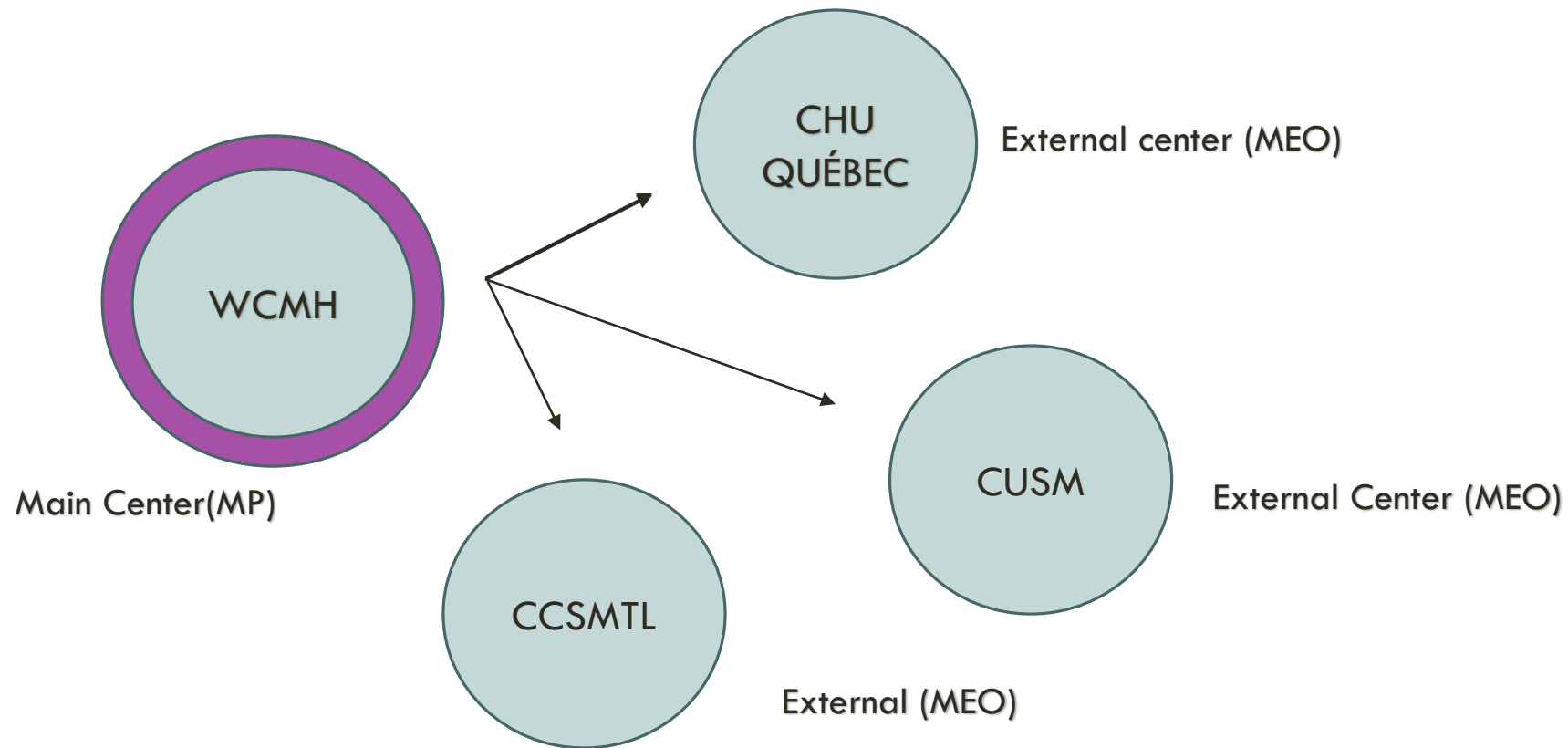
National (IRB)

International (IRB)

Institutional

Academic

THE MULTICENTER MECHANISM



WHAT IS A CENTER?

CENTER, INSTITUTION, SITE

- CCSMTL
- CHU QUÉBEC
- CHU STE-JUSTINE
- CUSM

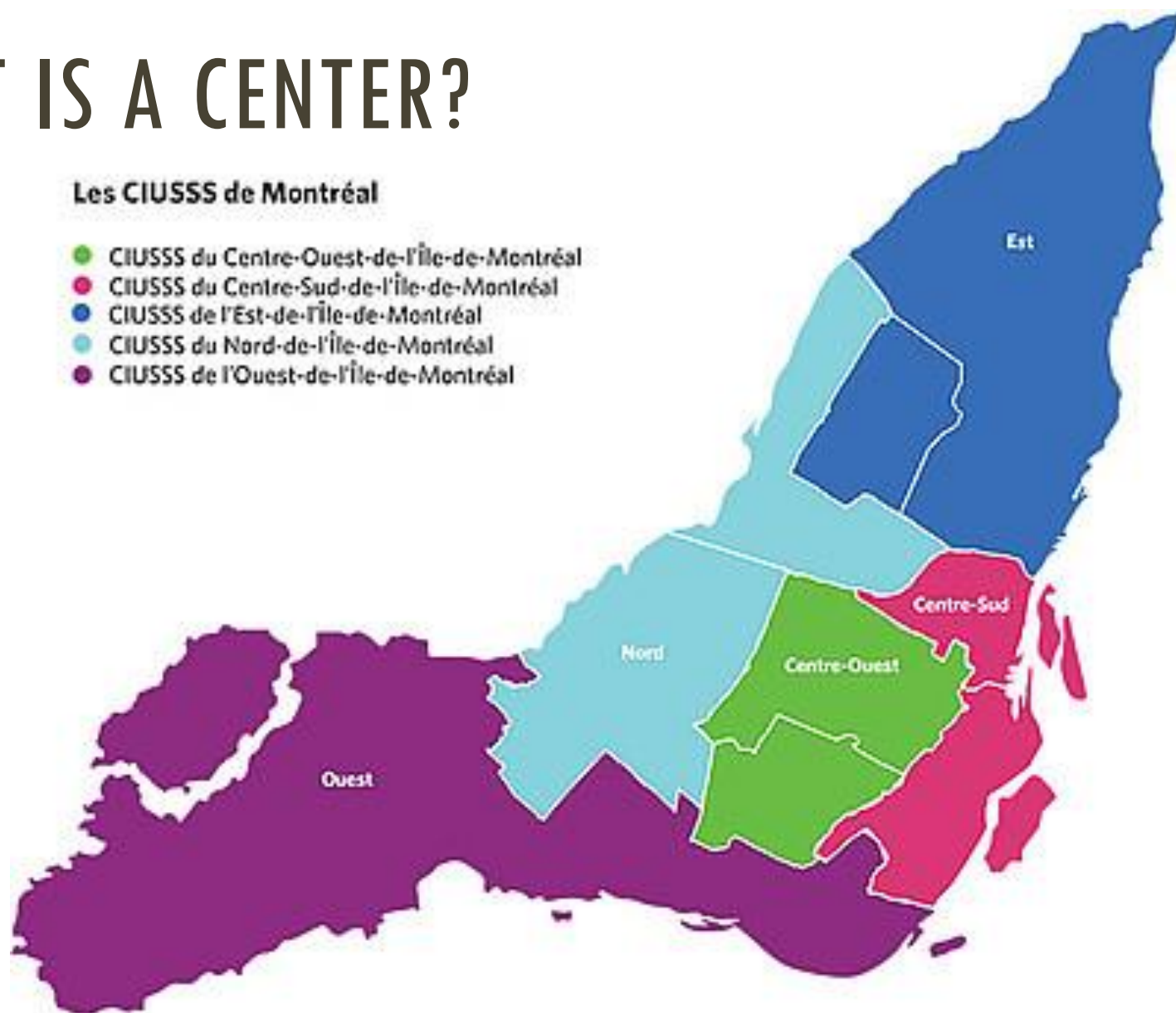
INSTALLATION

- Hospital
- CLSC
- Residences
- Birthing homes
- Rehabilitation centers

WHAT IS A CENTER?

Les CIUSSS de Montréal

- CIUSSS du Centre-Ouest-de-l'Île-de-Montréal
- CIUSSS du Centre-Sud-de-l'Île-de-Montréal
- CIUSSS de l'Est-de-l'Île-de-Montréal
- CIUSSS du Nord-de-l'Île-de-Montréal
- CIUSSS de l'Ouest-de-l'Île-de-Montréal



HOW TO CHOOSE THE MAIN CENTER?

- The Principal Investigator's affiliation
- Participant recruitment
- Research axes

A 5-STEP AUTHORIZATION PROCESS

1. Research Privileges

2. Reviews

- Research Ethics Committee (REC) *
- Science Review Committee *
- Feasibility Review Committee
 - *Institutional Contract

2. Institutional Authorization (IA)

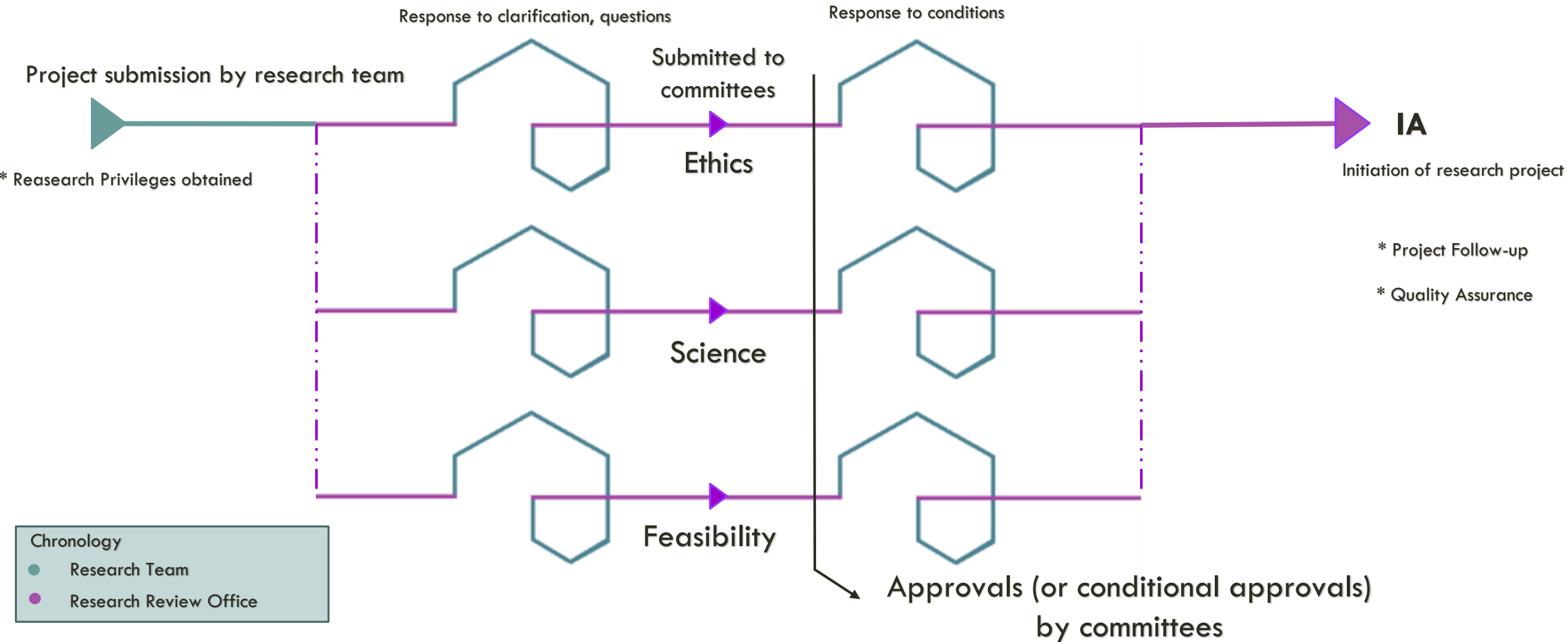
3. Project Follow-up (e.g. Amendment, renewal, addition of external site, etc.)

4. Quality Assurance (On-site Visit, Education)

5. Project Closure

* Main center only

NAGANO PROCESS



THE RESEARCH TEAM

Principal Investigator	Collaborator	Coordinator	Other Stakeholder	Other Staff	Institution
Main PI Site PI	Academic Clinical	Ethics Research Site	Sponsor CRO Funding Agency	Clinical Research	RRO Review Specialist Committee Members PM

LAB SET-UP AND BEST PRACTICES IN RESEARCH ETHICS

Participant Number

Nominal Data

De-nominalized Data and Case Report Forms

Regulatory Documents

Task Delegation Form

Lab logistics

Accreditation and Certification

TRAINING FOR RESEARCH TEAMS

EPTC2

<http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

CADRE RÉGLEMENTAIRE du MSSS

<http://ethique.msss.gouv.qc.ca/didacticiel/?lang=en>

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<http://ccomtl.nagano.ca>