How to obtain Institutional Authorization to conduct research in rehabilitation at the CIUSSS du Centre-Ouest-de-l'île-de-Montréal (CCOMTL)

To conduct rehabilitation research at the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal (CCOMTL), a researcher must have **research privileges** at the CCOMTL and must have obtain an **Institutional Authorization** from the "Personne Mandatée" (PM) of our institution[1].

Approvals with three levels of review are required to obtain the Institutional Authorization from the PM. For further details for each level, consult our research review office website:

(1) Scientific review.

(2) Ethics review.

(3) Feasibility review.

The research review office (RRO) supports and coordinates these evaluation processes through the Nagano platform. All the steps are illustrated in figure 1 below

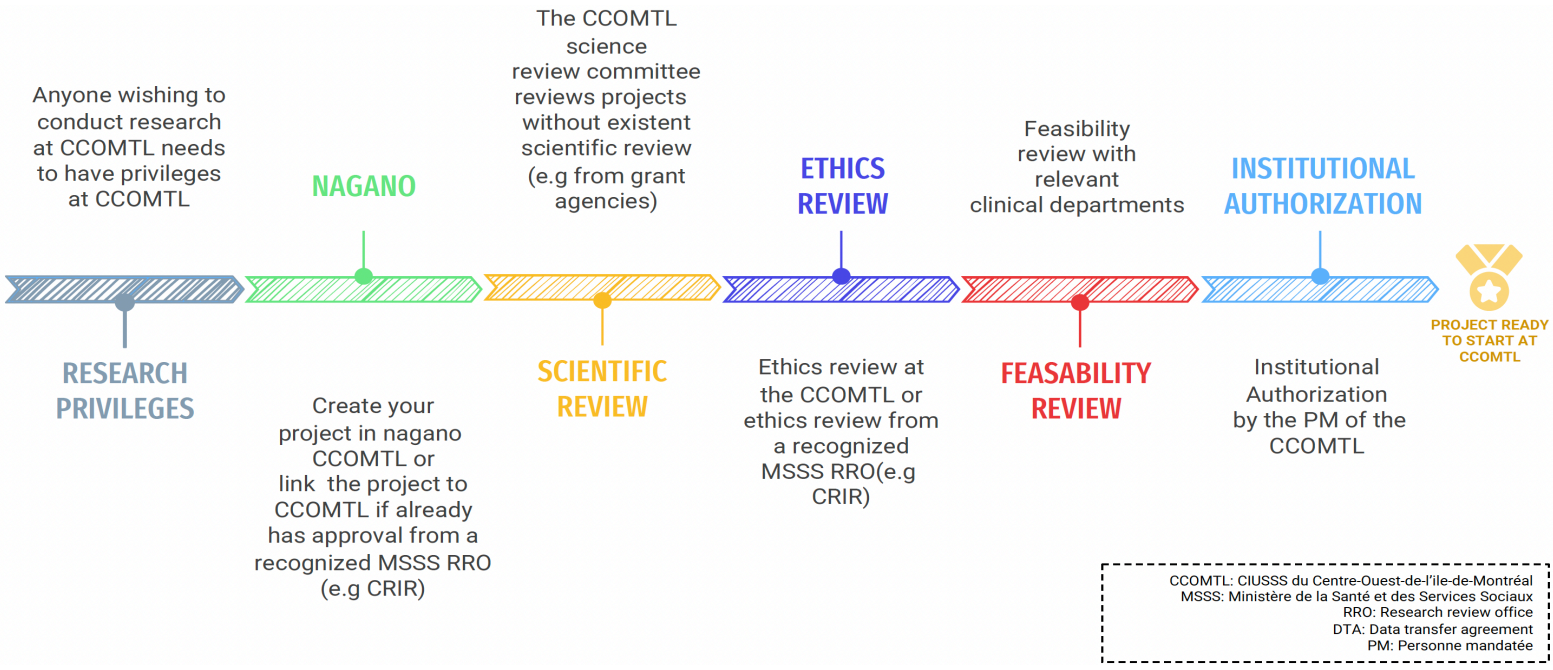

Fig 1: Process for obtaining institutional approval from PM at the CCOMTL

[1] The PM is responsible for ensuring that the entire review process is compliant, then decides whether to authorize the research. This is the final step which allows, or disqualifies, the start of research within one of our sites.

Depending on the nature of a research project and where recruitment takes place, researchers conducting rehabilitation research at CCOMTL may choose to submit at the most appropriate RRO and then **obtain Institutional Authorization from the PM at the CCOMTL**. Please refer to figure 2 below for an explanation of three potential trajectories. Details of these conditions A, B and C are found in the following description.

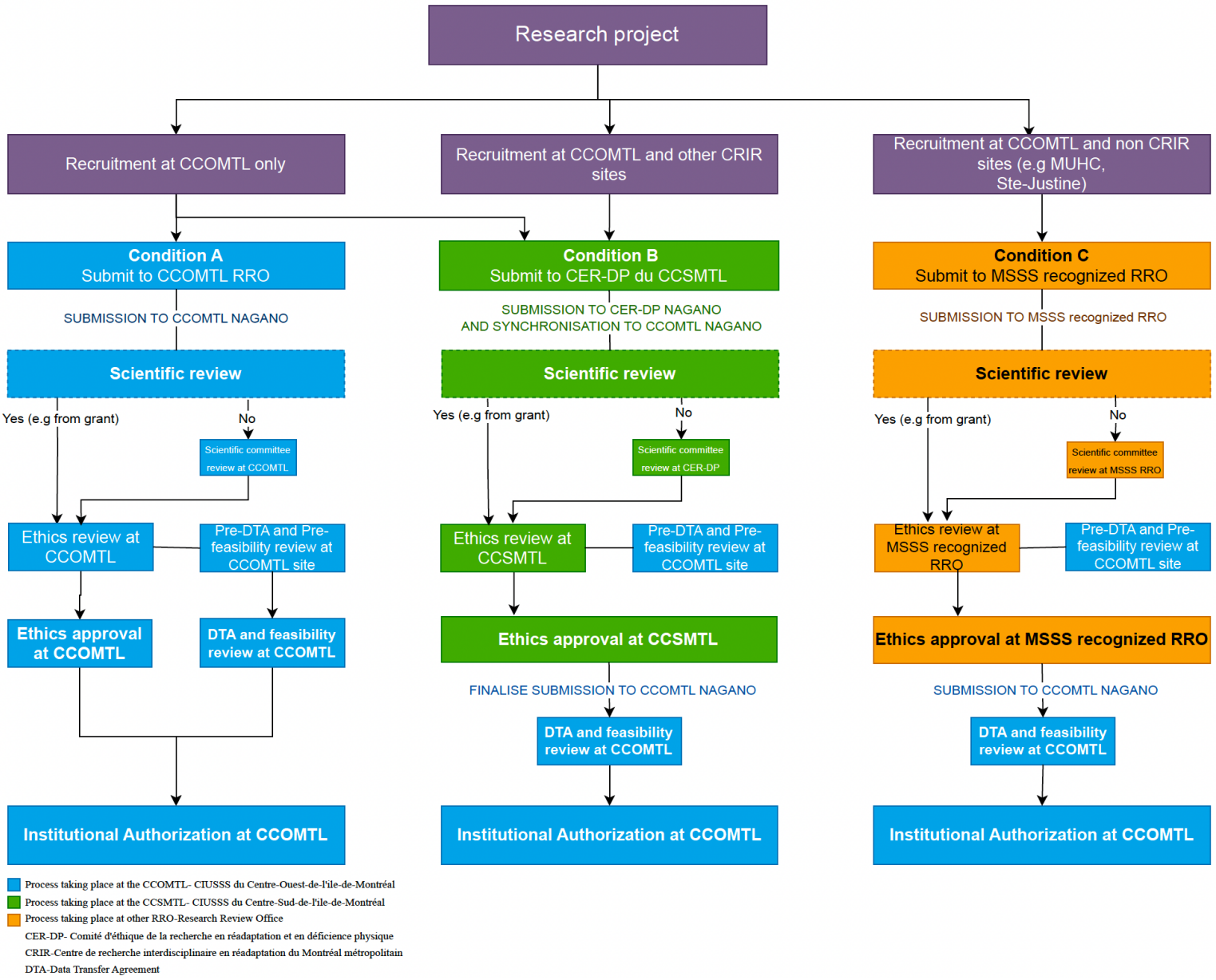

Fig 2: Project trajectory to obtain Institutional Authorization at CCOMTL

Condition A: Submission to CCOMTL research review office

A researcher can submit a project for authorization to the CCOMTL RRO if recruitment is taking place only at CCOMTL site. At the CCOMTL, the RRO includes two research ethics committees: Medical/Biomedical and Psychosocial, for more details refer to the CCOMTL website.

Steps to submit a project to obtain Institutional Authorization at the CCOMTL:

1) In CCOMTL Nagano form, Section: *Type of project:*
    a) Choose "psychosocial research" when creating the project.

Most rehabilitation research projects from CRIR affiliated researchers would fall under this committee. If you are unsure about the category, please email cer@jgh.mcgill.ca.

2) Add the following emails as users on the project:
    a) Clinical coordination team main email **(savoirs-readaptation.ccomtl@ssss.gouv.qc.ca) and**
    b) Email of the **clinical research coordinator (CRC)** responsible for the targeted sites:
        i) chantal.robillard.mab@ssss.gouv.qc.ca for MAB, MACKAY, Miriam Home, CLSCs and
        ii) lucas.gomessouza.ccomtl@ssss.gouv.qc.ca for Constance-Lethbridge, JGH, Richardson, Maimonides, Sinai, Catherine Booth
3) In section: Finance and feasibility questions:
    a) In sub section: *1-feasibility: sites, department & program implicated*; choose the CCOMTL sites implicated.
    b) In sub section: *7-contractual feasibility*; complete all fields with "NO".

⇒ This step notifies the site department head or CRC to start the **feasibility process** and the **data transfer agreement (DTA)**[2] process.
- The researcher and/or RRO will receive the **feasibility letter** from the CRC of the directorate of Academic affairs and research ethics (DAARE) after the project has been evaluated by the Research Feasibility Assessment Committee (also known as Pre-feasibility (pré-CI)).
- The researcher will also receive the initial **DTA evaluation form** from the CRC of the DAARE after the project has been evaluated by the Research Feasibility Assessment Committee.

4. Respond to conditions from the RRO in Nagano to receive ethics approval prior to Institutional Authorization letter before starting the project.

5. After receiving the Institutional Authorization, please contact one of our CRCs. They will help you with the next steps in the project, such as recruitment.

[2] If any data is being transferred between institutions, or if the data collected for the data bank is not being kept at our institution, an evaluation of the risk is conducted by the Directorate of academic affairs & research ethics. Should the risk be important, a **Data Transfer Agreement (DTA)** between the CCOMTL and the establishment of affiliation of the researcher will be needed.

Condition B: Submission to Comité d'éthique de la recherche en réadaptation et en déficience physique (CER-DP) of the CIUSSS du Centre-Sud-de-l'Île-de-Montréal (CCSMTL)

A researcher can submit the project for approbation to the CER-DP if recruitment involves more than one CRIR partnering establishment or recruits only at CCOMTL.

The CER-DP has expertise in physical disability; physical, sensory, and motor rehabilitation; as well as social participation. The office will assess any related projects submitted by CRIR researchers and researchers from other establishments if it involves a CRIR partnering establishment.

The CER-DP has a greater experience/knowledge with rehabilitation projects. Also, they have a formal agreement for multi-center evaluation of projects with the CCOMTL. This implies that, if your project is being submitted to more the one CRIR site, it would be beneficial for you to have one centralized evaluation.

Even if submitted at the CER-DP, the project **will need** to obtain **Institutional Authorization from the CCOMTL RRO**. To do so, the two Nagano platforms (CCSMTL + CCOMTL) must be synchronized by linking the project between platforms. This will reduce substantially the time to fill out forms in the CCOMTL Nagano.

1. Link the CCSMTL Nagano project to CCOMTL Nagano by completing the following:
    a. In the CCSMTl Nagano F0 form at the initial creation of the project:
        i. Choose **CIUSSS du Centre-Ouest-de-l'Île-de-Montréal site** and
        ii. Add the **contact of the local researcher** in, section: *General information; 9-participating sites.*

⇒ This step generates an email with a link to the mailbox of the person designated as contact.
- To activate this link, you need access to Nagano CCOMTL
- To obtain access to the platform send an email to cer@jgh.mcgill.ca
- Once you have Nagano access, click on the link in the email (email sender: Nagano CCOMTL and email subject: Invitation: projet MP-xxx) you will have received to create the project. This will link the project submitted on Nagano CEP-DP to the form submitted on the Nagano CCOMTL.
  *** Be careful to choose **create project**

2. When choosing the CCOMTL site on CCSMTL Nagano, the CER-CP will notify the site department head or CRC at the CCOMTL to start the **feasibility process** and the **data transfer agreement (DTA) process**.
    - The researcher and/or CEP-DP will receive the **feasibility letter** and the initial **DTA evaluation form** from the CRC of the DAARE after the project has been evaluated by the Research Feasibility Assessment Committee of the CCOMTL[3] (also known as Pre-feasibility (pré-CI)).

[3] Comprises of Representatives from head of department/services (Associate director, program managers, CAPs) of the Directorate of rehabilitation and multidisciplinary services Program managers, Site representatives, Clinical research coordinators

3. Once the ethics certificate from the CER-DP has been obtained, submit the approved documents to the CCOMTL Nagano to obtain the Institutional Authorization. Please make sure to add the relevant files as follows:
    a. In section: *Project files; 12- department/ program head support letter,* upload the **feasibility letter.**
    b. In section: *Site specific assessment/ feasibility; 7-contractual feasibility,* complete all fields with "NO"
    c. In section *Project files, 17- supplementary documents,* upload the **DTA evaluation form.**

4. Wait to receive Institutional Authorization letter from the CCOMTL before starting the project.
5. After receiving the Institutional Authorization, please contact one of our CRCs. They will help you with the next steps in the project, such as recruitment.

Condition C: MSSS recognized research review office

A researcher can submit a project for authorization to an MSSS recognized RRO if recruitment is taking place at CCOMTL and non CRIR sites (e.g MUHC, Ste Justine etc.)

1. Contact the research representatives at the MSSS website for appropriate procedures for project submission for ethics approval.
2. Once the ethics certificate has been obtained from a MSSS recognized RRO, submit the approved documents to the CCOMTL Nagano to obtain the Institutional Authorization. Please make sure to add the relevant files as follows:
    a. In section: *Project files; 12- department/ program head support letter,* upload the **feasibility letter.**
    b. In section: *Site specific assessment/ feasibility; 7-contractual feasibility,* complete all fields with "NO"
    c. In section *Project files, 17- supplementary documents,* upload the **data transfer agreement (DTA) evaluation form.**

3. Wait to receive the Institutional Authorization letter from the CCOMTL before starting the project.
4. After receiving the authorization, please contact one of our CRCs. They will help you with the next steps in the project, such as recruitment.