CLINICAL TRIALS ONTARIO

661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
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www.ctontario.ca

Documented Institutional Ethics Requirements
Hôpital Montfort

Mission and Values

We are a Francophone academic health sciences center that provides quality care in both official languages and works with its partners to improve the health of communities. It is our belief that the contribution of research participants is crucial to our education and research mission. Our daily actions are guided by the values of compassion, commitment, excellence and respect.

Hôpital Montfort, an essential institution to the Franco-Ontarian Community, has to:

- Promote French language services and the active offer of services in French,
- Promote French culture,
- Foster solidarity among Franco-Ontarian minority,
- Protect the Franco-Ontarian community against assimilation.

Hôpital Montfort's REB member are fully bilingual, thus we are able to review research project should they be submitted in English or French.

Linguistic Requirements

Our Standard Operating Procedures (SOP) or « P*rocédure Fonctionnelle Normalisée* (PFN) » for linguistic requirements can be consulted on our web site at the following link:

PFN 110.001 « *Contexte linguistique du CÉR de l'Hôpital Montfort*

This PFN recognises that there are two official languages in Canada, hence, recruitment and consent materials (e.g., informed consent forms, assent forms, diaries, questionnaires, etc.) should at the outset be inclusive of both the French and English speaking population. Accordingly, researchers have the obligation of providing recruitment and consent materials in another language only if participants cannot read or understand English or French (Application of article 4.1 of the TCPS 2).

When a project is carried in only one of the two official languages, the researcher will have to justify this approach to the REB. It is up to the REB to approve the exemption. This justification must be included in 4.2 in the Centre Initial Application (CIA) form in CTO Stream. The institutional representative will decide if they approve the exclusion prior to providing their signature on the initial application form, and the REB of Record will ensure this is appropriate from an ethical perspective.

Researchers are responsible for ensuring the accuracy of the translation for the materials they submit. The Montfort REB has the ability to evaluate all documents in both official languages and can counsel researchers on the equivalency, readability and accuracy of translated materials. Research teams adopting the strategy to translate the approved English consent form are urged to communicate with Johanne Pomerleau. She will facilitate access to Montfort's resources and process to evaluate their equivalency.

Johanne Pomerleau is also available to assist the REB of Record should they have any questions regarding French-language materials.

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Please note since PFNs are not translated in English, our Research Ethics Office staff is available to support researchers and answer questions regarding our policies. We accept submission in both official languages.

Informed Consent Form Requirements

At Hôpital Montfort the patient's clinical documentation as well as laboratory findings and imaging results are available only within the electronic chart and more modules will be added progressively. Hence, patient's clinical records are still hybrid (paper and electronic). Montfort adopted a separate process to identify patients who participate in research projects. Thus from a risk management perspective, this ensures that clinical staff is informed, in a timely manner, that a patient under their care is also a research participant. The information is available on a specific screen in the patient electronic file thus accessible by all healthcare professionals. Therefore, the following paragraph should be inserted in the **risk section** of the consent form for drug trials, medical devices, natural health products or food only when patients are involved and it is optional for observational study:

> Addition to the main consent form
> The title of the study as well as the name of the principal investigator will be added to your electronic health record in order to ensure that hospital staff from various departments involved in your care can factor in your participation in the study. Accordingly, you understand that this information will be available to all persons who have access to your health record.
>
> Addition to the genetic consent
> No genetic information collected during the study will be transmitted to the clinical team or added to your health record without your permission.

Resources in French such as templates are available on our Web site: Template for recruitment poster

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SRERS Administration
Hôpital Montfort

Linguistic Requirements

The following elements will be evaluated by Hôpital Montfort:

- The equivalency all documents in both official languages will be compared when a project is recruiting both Anglophone and Francophone participants. Please note that all documents have to have been reviewed and approved by Hôpital Montfort before the recruitment can start with its clientele (even if the REB of Record has already provided ethics approval for the materials).
- Francophone participant can have their questions about the research project answered in French. Hence, documentation given to participants should provide a contact number of a member of the research team that will be able to answer them in French.

Those requirements are consistent with our linguistic policy.

Access to clinical and medical Records

Patient records at Montfort are a combination of paper and electronic formats. Also care providers at Hôpital Montfort can document their observation in either official languages. Therefore, it is very likely that a patient charts will have notes in both French and English. For retrospective study it is recommended to have a feasibility study done as it will inform the team about the format in which the data will be available (electronic, scanned or paper) and when. The following link will give you the service fee for extracting information:

- information sheet for Health data and information service fee structure

Contractual requirement

The research project will start the recruitment activities after the contractual agreement for the Clinical Trial has been signed by the authorized signing Officer on behalf of Hôpital Montfort.

Reminder: Institutional Research Administration Requirements

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

CTO Stream

Collaborators:

The following collaborators must be given a role on all Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

Email: denisprudhomme@montfort.on.ca
Role: Institutional Representative

Email: jpomerleau@montfort.on.ca
Role: Institutional Representative

This access is automatically granted when the Centre Initial Application is created. **When Hôpital Montfort is the Provincial Applicant site the research team should immediately create the CIA for Hôpital Montfort (right after creating the PIA)**. This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the PIA prior to submission.

Institution Representative in application forms

The Primary Institution Representative must be indicated as follows in the applications within CTO Stream:

Title: Dr.
First Name: Denis
Surname: Prud'homme
Organisation: Institut de recherche de l'Hôpital Montfort, Institut du savoir Montfort,
Address: 202-745A Montreal Road
City: Ottawa
Province/State: ON
Postcode/ZIP: K1K 0T1
Telephone: (613) 746-4621 ext. 6023
Fax: (613) 288-1337
Email: denisprudhomme@montfort.on.ca

The Secondary Institution Representative must be indicated as follows in the applications within CTO Stream:

Title: Mrs.
First Name: Johanne
Surname: Pomerleau
Organization: Hôpital Montfort
Address: 745-A ch. Montréal Rd, suite 102
City: Ottawa
Province/State: ON
Postcode/Zip: K1K 0T1
Telephone: (613) 746-4621 ext. 2221
Fax: (613) 746-4111
Email: jpomerleau@montfort.on.ca

Requesting Institutional Representative signature

The research team must first send an email (outside of CTO Stream) to Mrs. Johanne Pomerleau (jpomerleau@montfort.on.ca), who will review the application for aspects related to institutional authorization (such

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as linguistic requirements). If applicable, Mrs. Pomerleau will communicate any changes directly to the research team, outside of CTO Stream. Once Mrs. Pomerleau has accepted the application, she will request Dr. Prud'homme's signature in CTO Stream. The research team is not permitted to request Dr. Prud'homme's signature on the form; the application must first be reviewed and accepted by Mrs. Pomerleau.

REB of Record Study Agreement

CTO will send the REB of Record Study Agreement to the PI for signature with cc to Johanne Pomerleau. The PI/delegate will send a scanned copy of the Agreement (signed by the PI and witness) to CTO (streamline@ctontario.ca), who will obtain the signature from the institutional signing authority and the REB Host Institution. Fully executed Agreements will be circulated via the correspondence feature in CTO Stream and by email.