







## Guidelines for completing the project registration form

The Research Project Registration form serves to collect all the information necessary to evaluate your project for ethical approval and/or institutional authorization. This document includes instructions on how to answer certain questions on the Research Project form, as well as informative notes to explain or justify certain questions; it also identifies, when necessary, the documents you must attach. To view this information, please place the pointer of your mouse over the relevant icons. The content of the icons is presented below in case you have difficulty seeing it appear on your computer. The procedure for completing the form depends on your answers; thus, it is important to follow the guidelines listed in the boxes in sections 1, 4, and 9.




### Rules to follow

- Read the instructions and supplementary information, by hovering over the icons, carefully and ensure they are respected.
- Answer all the questions except when it is indicated that answering is optional or when the instructions direct you to skip the question.
- Include all the documents that you are asked to submit. If you are unable to attach all the required documents, explain the reason in your introduction letter.
- Keep in mind that evaluators may question some of your responses (e.g., your project cost estimate, the rate of participant loss, or reasons to exclude certain participants). It is up to you to present arguments that can convince the evaluators of the relevance and accuracy of your answers.
- Please do not hesitate to contact us at [recherche.comtl@ssss.gouv.qc.ca](mailto:recherche.comtl@ssss.gouv.qc.ca) if you have any questions.

### Procedure to follow to complete this form

-  Click on the space and write your answer. The requested information is usually provided in the gray highlighted space.
- Choose**  Position your mouse over the space and click on the triangle. A drop-down menu of answers will appear. Your answer is limited to one of these answers.
-  (or **choose**)  You can write your answer in the space on the left and/or or select one of the choices provided in the drop-down menu on the right.
- Click on the box to add an X.
- Date**  Position your mouse over the space and click on the triangle. A calendar will appear in which you must choose a date.
- Name**  Write the complete name of one person.
- +** This symbol means you may copy and paste the response line so as to duplicate it and give more than one answer to the same question.

### Explanatory list of symbols

   Hold your mouse over the icon and a text bubble will appear.

 = Additional information, details regarding the instructions.

 = Directions to follow.

 = Documents to attach.

## Acronyms

MWI IUHSSC = Montréal West Island and Integrated University Health Social Services Centre

REB = Research Ethics Board

RSSS = Réseau de la santé et des services sociaux

MSSS = Ministère de la Santé et des Services sociaux

## Contents of the icons in the project registration form

### FRAME

Project title in English: ⚠ Use the exact title as in the consent forms and letters from other institutions (if the project is multicentric).

Project title in French: ⚠ A French version of the title is only necessary if the title is used in French documents such as the consent form or an advertisement used to recruit participants.

Project number: ⚠ If the project is multicentric, write the number of the multicentric project and not the number of the local REB reviewer.

Brief summary (200 words maximum): ⚠ Briefly summarize the project objective, the methods, and the description of the participants. The project description written in the consent form may be used in this summary, in 200 words or less.

Type of project: ⚠ You can choose more than one answer.

Experimental project: ❓ Participants are subjected to the experimental manipulations, usually with a control group, to measure the effect of the independent variables versus dependant variables (measurable). ⚠ In Section 9, the hypotheses are mandatory, and the dependent and independent variables must be clearly presented.

Data collection: ❓ Data is collected from participants (e.g., through questionnaires), without being subjected to experimental manipulations. ⚠ TBD

Data extraction: ❓ No direct contact with participants is required. The data comes from preexisting files or databases. ⚠ The guidelines for data extractions presented in question 4.1 must be followed.

Evaluation of a tool, a document, a technique, or an intervention: ❓ The documents include questionnaires, forms, and informational documents, among others. ⚠ The tool and documents must be attached; techniques and interventions should be described in detail in the protocol.

Evaluation of medication treatments: ❓ TBD ⚠ TBD 📄 TBD

Health Canada clinical trials: ? Clinical Trial Project registered with Health Canada and registered in their registry. ⚠ TBD 📎 Attach Health Canada letters, including the "No objection letter", if applicable.

Pilot project: ? Project aimed at collecting preliminary data that will be used exclusively for the preparation of a complete project. ⚠ It is not necessary to justify the number of participants. The results of this type of study cannot be published unless you make a request with the REB.

Genetic, biological or non-biological databank: ? Genetic, biological materials (e.g., human tissue, brains, blood or saliva sample, etc.) or other data to be stored in a bank for analysis in future projects. ⚠ TBD 📎 TBD

## 1. RESEARCH TEAM AND LOCATION

1.1. Main investigator: ? The principal investigator is responsible for the actualization of the entire project. The students, including postdoctoral fellows and medical residents, cannot act as the principal investigator. 📎 Attach the declaration of interests signed.

1.1... Academic or university affiliation: ? The researcher is affiliated if he has a professorial position. This excludes teaching positions as well as students, including postdoctoral fellows and medical residents.

1.1... RSSS Affiliation: ? The researcher is affiliated if he is an employee of a health facility / hospital center or an affiliated research center. Consult <https://m02.pub.msss.rtss.qc.ca/M02ListeInstLoc.asp> to see which establishments belong to which facilities. ⚠ A local researcher must preferably collaborate on the project if the principal investigator is not affiliated with the CIUSSS ODIM. You must register the site to which the researcher is affiliated and the position he/she occupies there.

1.1... Research Privilege at the MWI IUHSSC: ? The research privilege is granted by the institution following an evaluation of the researcher's file. It recognizes the researcher's ability to conduct research projects in the institution. ⚠ The procedure to obtain a research privilege is in progress. For now, CV must be submitted. 📎 Attach a completed CV in the researcher's preferred format.

1.2. Local researcher or manager of the MWI IUHSSC: ? The local researcher is responsible for aspects of the project taking place at the MWI IUHSSC. It is mandatory, only, if the project is a clinical trial. 📎 Attach a completed CV in the researcher's preferred format.

1.2... Research Privilege at the MWI IUHSSC: ? The research privilege is granted by the institution following an evaluation of the researcher's file. It recognizes the researcher's ability to

conduct research projects in the institution. ⚠ The procedure to obtain a research privilege is in progress and will be given if necessary.

1.3. Co-researcher: ⓘ A co-investigator is a member of the research team of the principal investigator who shares responsibility for the direction of the proposed project.

1.3... Contribution: ⓘ The contribution allows us to understand how the expertise of each co-investigator and collaborator facilitate the success of the project. This information is important if the project requires a particular expertise the principal investigator does not have.

1.4. Collaborator: ⓘ A collaborator participates in the project by offering a special service (e.g. access to equipment, statistical analysis, access to a group of patients, etc.) but does not share the responsibility of the project management.

1.4... Contribution: ⓘ The contribution allows us to understand how the expertise of each co-investigator and collaborator facilitate the success of the project. This information is important if the project requires a particular expertise the principal investigator does not have.

1.7. Is your project multicentric? ⓘ The institutions (CISSS and CIUSSS) are made up of several facilities (hospitals, CLSCs, CHSDL, etc.). See <https://m02.pub.msss.rtss.qc.ca/M02ListeInstLoc.asp> for more information on the structure of the RSSS and institutions.

1.7... Yes: ⚠ The project is multicentric under the MSSS Framework if more than one RSSS institution participates in the project. A REB of one of the institutions must be appointed to take charge of the ethics review for all institutions.

1.7... No: ⚠ The project is not multicentric if only **one** institution of the RSSS (i.e. the MWI IUHSSC) participates in the project. Centres outside the RSSS institutions (e.g. universities or hospitals outside Québec) are not taken into consideration.

1.8... Yes, list all the participating sites: ⚠ Add as many rows to the table below as there are participating sites.

1.8... No, indicate who is acting or will act as the REB evaluator (...): ⓘ Attach the ethical approval letter and the latest renewal issued by the reviewers.

1.9... Indicate all participating sites not part (...): ⚠ You must address all possible issues related to cultural differences and language in the project description (section 9). Explain how the documents will be translated and who will be your point of contact.

## 2. FINANCIAL INFORMATION

2.1... The project does not incur any expense (...): 🚫 An expense record seems necessary when it comes to compensating, staffing, using paid services, publishing, traveling, etc.

2.1... Help from funds provided by (...): ⚠️ If the beneficiary is not part of the research team, you must attach a letter from them stating their financial commitment. 📎 Attach the proof of funds or indicate in the checklist that the letter will follow when funds are obtained. In addition, attach the letter of commitment of the recipient of funds, if applicable (see instructions).

2.3. How are the actual expenses allotted towards the completion of the project? ⚠️ Include expenses related to salaries, compensations granted to participants, use of specialized equipment, publication and convention fees, etc. 📎 Attach the project budget or describe it here.

2.4... Yes (...): 📎 Attach the contract or indicate in the checklist that the contract will follow later if it is not ready.

### **3. PREVIOUS EVALUATIONS**

3.1... Yes (...): 📎 Attach the result of the ethics evaluation(s).

3.2... Yes (...): 📎 Attach the result of the scientific evaluation(s).

3.3... Yes (...): ⚠️ Comments raised in previous assessments should have been addressed; otherwise, they must be stated here. 📎 Attach responses to comments made in ethical and scientific assessments where appropriate.

### **4. NATURE OF THE DATA**

4.1. Your data will be: ⚠️ You can check more than one answer.

4.1... The values obtained directly from human participants (...): ⚠️ Attach the information and consent forms used to obtain the consent of the participants. Sections 5 to 9 of this form must be completed. 📎 Attach the information and consent forms in the languages spoken by the participants. The form must follow the guidelines presented on the "Checklist" form.

4.1... Extracts from medical records with (...): 🚫 Medical records include clinical information of patients in medical follow-up. ⚠️ Attach the information and consent forms used to obtain the consent of the participants. Sections 5 to 9 of this form must be completed. 📎 Attach the information and consent forms in the languages spoken by the participants. The form must follow the guidelines presented on the "Checklist" form.

4.1... Extracts from medical records without (...): 🚫 Only the Professional Services Directorate may authorize access to personal records without the consent of patients. The files include,

among other things, clinical information in medical follow-up kept in the CIUSSS ODIM archives. ⚠ Complete the Access to Personal Information form to receive authorization from the Professional Services Directorate. You do not need to complete sections 5 to 8 of this form unless you collect data from participants. 📎 Attach the Personal Information Access Form signed by the Principal Investigator.

4.1... Extracts from clinical-administrative databases: ⓘ Local clinical-administrative data and applications for extracting them are managed by performance and statistical services. ⚠ Complete the Access to Personal Information Form to receive permission from the Access, Quality and Performance. You do not have to complete sections 5 to 8 of this form unless you collect data from participants. 📎 Attach the Access to Personal Information form signed by the principal investigator.

4.1... Extracts from research files from another research project (...): ⓘ The data have already been collected and are confined to a database or research files set up as part of another research project. ⚠ You do not have to complete sections 5 to 8 of this form unless you collect data from participants unless you collect data from participants. 📎 Attach a copy of the sheet that participants signed to consent to their data being used for secondary analysis or attach a copy of your permission to access the databank.

## 5. NUMBER OF PARTICIPANTS

5.2. How do you justify the number of participants? ⚠ It is strongly recommended that the results of a strong analysis be used to justify the number of participants.

## 6. RECRUITMENT

6.1. Inclusion criteria: ⓘ The selection criteria must be justified because they are discriminatory and may interfere with the rights of individuals to participate in the project. In addition, some criteria can create significant biases and affect the meaning of the results.

6.1... Write a list of inclusion criteria used to select the participants of the group: ⚠ If there is more than one group of study participants, please identify the group here and repeat this section as many times as there are groups.

6.1... Age: ⓘ Consent of a minor is given by the person possessing parental authority or guardianship. A minor of 14 years and up may consent on his own if, in the opinion of the competent REC, the research carries only a minimal risk and the circumstances warrant it. ⚠  
TBD

6.1... Language: ⓘ TBD ⚠ TBD

6.2... Write a list of exclusion criteria used to select the participants: ⚠ Do not enter criteria that adds nothing more than what the inclusion criteria already indicates. For example, if French is a criterion for inclusion, it is not worth noting here that other languages are exclusion criteria.

6.3... Advertisements publicized in the following media: ? The ads advertise the project and provide information to contact the research team. They can be broadcasted in electronic and print media, on television, and on radio. ⚠ TBD 📎 Attach a copy or transcript of the ad.

6.3... Advertisements posted in the following places: ? The posters introduce the project and provide information to contact the research team. They are placed in physical places, billboards, walls, poles, etc. ⚠ TBD 📎 You must attach a copy of the ad or poster.

6.3... Leaflets placed in the following places: ? Printed leaflets normally contain more information than a poster and can be taken with participants. ⚠ TBD 📎 Attach the pamphlet.

6.3... With the help of a person(s) (...): ? Non-research team members may include teachers, health professionals, and social workers, among others. ⚠ Individuals who are not part of the research team must provide a collaboration letter to demonstrate their involvement if they are not part of a CIUSSS or CISSS. 📎 Attach the leaflet, document, or other materials made available to the person who will inform the participants. Attach a letter of support from people who are NOT part of a CIUSSS or CISSS.

6.3... By contacting potential participants (...): ? The agreement to be contacted is usually given when participating in a research project. ⚠ It is necessary to demonstrate how the authorization of the participants to be contacted was obtained. 📎 Attach a copy of the sheet that participants have signed to agree to be contacted again.

6.4... Using ... given to the participants (...): ? Triage questionnaires include all forms used to set up participants' profile. 📎 Attach the triage form or other document used to collect information about potential participants, including the script used for telephone questions and the email, if applicable.

6.4... An in-person interview: ? Interviews are used to obtain more qualitative information about participants or to assess the participant's clinical condition. ⚠ These assessments should be described in Section 9 and in the consent form. The participant must sign the consent form before taking the interview and compensation must be provided, if applicable. 📎 Attach the interview script, if possible.

6.4... Based on clinical characteristics (...): ? Medical methods include any practice to extract biological samples or use medical equipment. ⚠ These evaluations should be described in Section 9 and in the consent form. The participant must sign the consent form before being subjected to these procedures and compensation must be provided, if applicable. 📎 Attach a copy

of the sheet that participants have signed to consent to their files being accessed to ensure their eligibility for future experiments.

6.4... By consulting a list of potential participants held by: ? The list of participants contains only a limited amount of information per participant. It may come from a clinical service or a bank of participants run by a research team (including the researcher's).

## 7. CONSENT

7.1. Are the participants, within the meaning of the law (...): ? TBD

7.3. Is there a relationship between the participants (...): ? The link can be one of authority, business, clinical relationship, friendship, etc.

7.5. What consent do you ask participants? ⚠ The procedure for obtaining participants' consent must be described in the project method in Section 9.1.

7.5... Participants will be asked to consent to (...): ⚠ Repeat this line as many times as there are different consents to obtain. 📎 Attach the consent forms or sheets.

## 8. RISKS

8.1... Major risks / disadvantages: ? TBD

8.1... Minor risks / disadvantages: ? TBD

## 9. PROJECT DESCRIPTION

9.2... Magnetic resonance imaging scanner (MRI): ⚠ The project must be approved by the Magnetic Resonance Research Committee (MRRC) if it takes place at The Neuro or Douglas. 📎 Attach the letter of approval from the Magnetic Resonance Research Committee (MRRC) if the project is done at The Neuro.

9.2... Positron emission tomography (PET): ⚠ The project must be approved by the Magnetic Resonance Research Committee (MRRC) if it takes place at The Neuro or Douglas. 📎 Attach the letter of approval from the Magnetic Resonance Research Committee (MRRC) if the project is done at The Neuro.

9.2... Magnetoencephalography system (MEG): ⚠ The project must be approved by the Magnetoencephalography Research Committee (MEGRC) if it takes place at The Neuro. 📎



Attach the letter of approval from the Magnetoencephalography Research Committee (MEGRC) if the project is done at The Neuro.

9.3... Extracting data from files: ⚠ Information taken from the files must be described in the protocol. 📎 If the participant cannot consent to their file being accessed, you must attach the access to personal information form.

9.3... Interview: ⚠ Describe the interviews in the project method. 📎 Attach the interview guides, if necessary.

9.3... Focus group: ⚠ Describe how the focus groups work in the project method. 📎 Attach the guides used to lead discussions, if necessary.

9.3... Clinical assessment, neuropsychological tasks: ⚠ Describe clinical evaluations in the project method. 📎 Attach the clinical evaluations.

9.3... Questionnaire or survey: ⚠ Describe questionnaires and surveys in the project method. 📎 Attach the questionnaires and surveys.

9.3... Audio or video recording: ⚠ Registration measurements must be made known to the participant in the consent form.

9.4... Administration of the following drugs: ⚠ TBD

9.4... Taking the following samples: ⚠ TBD

9.4... Injection of the following substances: ⚠ TBD

9.7. How long will the data be retained? ? Data retention should normally be 7 years.