c\* **Instructions**: All annotations in red must be deleted before sending your document to CER en réadaptation et en déficience physique. The purpose of this outline is to guide you in writing the consent form for your project. Some headings of this outline may not be applicable for the type of research project you are conducting. If so, you do not have to include them in your consent form. You are invited to adapt the content of the headings to your research project. It is strongly recommended that you consult the “Guidelines for Investigators: Consent Forms” to write your consent form according to our REB’s requirements and comply with the ethical principles in force.

**\*\* Important:** Special attention must be paid to the **quality of English** and the **language used** in writing the consent form to ensure that the participant really understands the content. Also, it is highly recommended to refrain from using such phrasing as “You are being asked”.

\*\*\*The suggested text examples are not copyrighted. You may use the phrases in their entirety within the examples without fear of plagiarism.

#

#  When only one CISSS / CIUSSS is involved, insert its logo

**IF THERE ARE MORE THAN TWO INSTITUTIONS,**

 **INSERT THE « Québec-Drapeau » LOGO**

**And add a section below “Institutional Partners”**

**The size of the logos should be standardized**

#

# informed consent form

(if there is more than one form, specify the clientele for whom they are intended)

1. **Study title**

Write the title of the project

1. **Principal Investigators**

First name and last name

Status/Occupation

Affiliation (university or institution)

Phone number

Email

If there is more than one investigator, enter the information for each of them.

Also, if the principal investigator is not an MD, please refrain from using the acronym “Dr” before his name. In Quebec, the title “Dr” is restricted to those with an MD degree.

The REB strongly recommends avoiding the use of personal telephone numbers in order to preserve the privacy of those responsible for the project. Institutional contact should be prioritized if possible.

In the case of a student project, be sure to include the name of the responsible researcher and the name of the students involved in this section.

1. **Collaborators**

First name and last name

Status/Occupation

Affiliation (university or institution)

Phone number

Email

If there is more than one collaborator, enter the information for each of them. If, there is none, omit this section. Also, if the principal investigator is not an MD, please refrain from using the acronym “Dr” before his name. In Quebec, the title “Dr” is restricted to those with an MD degree.

The REB strongly recommends avoiding the use of personal telephone numbers in order to preserve the privacy of those responsible for the project. Institutional contact should be prioritized if possible.

1. **Institutional Partners**

When several establishments are involved, please mention them here and put the “Québec-Drapeau” logo on the first page.

If only one establishment is involved, please delete this section.

1. **Funding agency**

This study is funded by:

OR

This research project is not funded.

1. **Commercialization**

In the case of a project involving product marketing or involving a private company marketing products, the suggested text is:

Your participation could contribute to the creation of commercial products or to the wider commercialization of existing products. However, you will not be entitled to share in any economic benefits.

If this does not apply to your project, please delete this section.

1. **Introduction**

Suggested text:

We are inviting you to participate in a research project. Before agreeing to participate in this project, please take the time to read and carefully consider the following information.

This consent form explains the aim of this study, the procedures, advantages, risks and inconveniences, as well as the persons to contact, if necessary.

This consent form may contain words that you do not understand. We invite you to ask any question that you consider useful to the investigator and the other staff members assigned to the research project and ask them to explain any word or information that is not clear to you.

1. **Description of the project and its objectives**

Suggested text:

The purpose of this project is to study, evaluate (Brief description of the study, of its nature and its scope, and targeted clientele):

The objectives of this research project are:

* describe the specific goals. Please note that mentioning the hypothesis should be avoided as it could introduce a bias in the participant.
1. **Nature of participation**

This section must describe to the participants the range of steps they must follow if they decide to participate in the research. After reading this section, the participants must understand what is expected of them in terms of participation in the research. The following information should also appear:

* Use of preliminary tests to evaluate a future participant’s eligibility;
* Mention of the number of meetings (duration of each meeting and projected time for breaks) with the research participant and summary description of each task the participant will have to perform;
* The place where the experimental tasks will be conducted (including the address);
* The follow-up period, if applicable (particularly during a longitudinal study);
* Use of video or audio recording, if applicable;
* Mention of the presence, if applicable, of a double blind or a control group (explanation of the impact and the consequences for the subject);
* If the investigator is also a practitioner working with the subject, a distinction must be established to this effect, especially if the subject has a dependent relationship with the investigator.
* If the participant is an employee, specify whether the participation will be during working hours or on personal time (make sure this information matches what is written in the institutional suitability response).
1. **Personal benefits of participating in the study**

Suggested text:

You will not benefit personally from taking part in this study. However, you might contribute to the advancement of science in the field of (specify your field of research).

\*\*\*In some projects, participants may receive concrete personal benefits (Example: additional training sessions, \*\*\*etc.). If that is the case, it must be mentioned in this section.

1. **Risks and inconveniences associated with participating in the study**

**RISKS**

If the study involves minimal risks, the suggested text is as follows (it must be adapted to your project):

Your participation in this research project involves minimal risks for you.

For participants who are patients, add the following sentence (when applicable):

It is understood that your participation in the study will not affect the care and services you receive or will receive from your rehabilitation institution.

For participants who are employees, add the following sentence (when applicable):

It is understood that your participation in the study will not affect your roles and your responsibilities in your workplace or your employment status.

If the project involves specific risks, they all must be mentioned, and the means implemented to limit their occurrence must be specified. Also, risks should be presented in order from most serious to least serious, taking into account the likelihood of them occurring.

**Example:**

* Risk of Falling: The risk of loss of balance during the performance of the experimental task cannot be eliminated completely. To limit the falling risks, you will wear a harness. In addition, a person will be at your side to ensure your safety.
* Emotions: Some questions may cause you to experience negative emotions. If this occurs, you may discuss it with a research team member, who will be able to direct you to health care professionals or can provide you with a list of resources who can help you.

**INCONVENIENCES**

This section must mention all inconveniences or disadvantages that the research participant might encounter by participating in the project, such as: stress, fatigue, participation time, etc.). Unlike risks which have a certain probability of occurring, the inconveniences are direct consequences of participating to the study. If there are few inconveniences, specify that as well.

**Examples:**

Travel / participation time: The travel time from your home to the research site as well as the participation time in the research project may represent an inconvenience for some people.

Use of markers: Some areas of skin may have to be shaved before positioning electrodes/markers. As such, the strictest rules of hygiene (single-use razors and collars, hypoallergenic adhesive tape, cleaning skin with alcohol) will be applied. Moreover, despite the application of these hygiene measures, there is a possibility of skin irritation where electrodes/markers are attached. In these cases, a soothing lotion will be applied to your skin.

Fatigue

Sweating

1. Access to the results at the end of the research

Suggested text:

At the end of the study, do you want to have access to the general results of this research project.

Yes [ ]  email or address : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No [ ]

OR

A report on the general results of the study will be sent to you when it is completed.

1. **access to your medical record**

Suggested text:

You authorize the research team to consult your rehabilitation record in order to collect information in relation to (example: your stroke, your CCT, etc.) necessary to conduct the research project.

It is important to clearly specify the information sought in the record, in order to limit the search to what is necessary.

If you do not need to access the medical chart of the participant, you do not have to have this specific section in your consent form.

1. **Confidentiality**

Suggested text:

All personal information collected concerning you during the study will be coded to ensure its confidentiality. Only the members of the research team will have access to it. However, for research project control purposes, your research record could be consulted by a person mandated by the CER en réadaptation et en déficience physique or by the Direction de l’éthique et de la qualité du ministère de la Santé et des Services sociaux du Québec This person adheres to a policy of strict confidentiality. The research data (paper and recordings) will be kept under lock and key at (site) by the person in charge of the study for a period of (number according to the retention policy of the university or the institution) following the end of the project, after which it will be destroyed. In the event that the results of this study are presented or published, no information that can identify you will be included.

In focus group situations, confidentiality must also be requested from each subject. This information must be mentioned in the consent form. Here is the suggested text:

We request that you remain discreet regarding the identity of the focus group participants and the comments made there.

1. **Video recording and/or taking photographs**

Suggested text:

It is possible that certain sessions will be recorded via audio or video or that photographs will be taken of you. We would like to use these recordings or photographs, with your permission, for the purpose of training and/or scientific presentation purposes. However, it is unnecessary to consent to this in order to participate in this project. If you refuse, the recordings and photographs concerning you will be destroyed at the end of the project to respect your confidentiality.

Do you authorize us to use your photographs or recordings for the purpose of training or scientific presentations and to keep these recordings with your research data?

Yes [ ]  No [ ]

You can also consider the possibility of “blurring” the faces of the participants in this context, in which case please add this mention in the text above.

If you do not intend to take photographs or recording for the purpose of training or scientific presentations, please remove this section.

If the recordings and photographs are research data, this section does not apply.cFor this situation, please refer to the “Nature of Participation” and “Confidentiality” sections.

1. **Voluntary participation and right of withdrawal**

Suggested texts:

You are free to accept or refuse to participate in this research project. You may withdraw from this study at any time, without having to give a reason and without suffering prejudice of any kind. You simply have to notify the resource person of the research team. In case of withdrawal on your part, the audiovisual and written documents concerning you will be destroyed at your request.

Focus group version:

It is understood that your participation in this research project is completely voluntary and that you remain free to terminate your participation at any time without having to give a reason and without suffering any prejudice of any kind.

However, given that this is a focus group, total destruction of the recordings and transcriptions will be impossible. The dialogues will be kept to maintain the coherence of the discussion.

Anonymous questionnaire version:

It is understood that your participation in this research project is completely voluntary and that you remain free to terminate your participation at any time without having to give a reason and without suffering any prejudice of any kind. However, when you have completed and returned the questionnaire, it will be impossible to destroy the data, because no information is collected that allows identification of the respondents.

1. **Secondary use of information for research purposes**

Suggested text:

The information you provide may be used, before the expected date of its destruction, in other research projects that will focus on the different facets of the topic for which you are solicited today. These possible projects will be the responsibility of the principal investigator and will be authorized by the CER en réadaptation et en déficience physique (or indicate the name of another REB). The research team is committed to maintaining and protecting the confidentiality of your data under the same conditions as for this project. Do you agree that your data can be used in this context:

[ ]  Yes [ ]  No \*

1. **Subsequent studies**

Suggested text:

It is possible that the results of this study will give rise to another research project. In this context, do you authorize the persons in charge of this project to contact you again and ask if you would like to participate in this new project?

[ ]  no

[ ]  yes, for one year \*

[ ]  yes, for two years \*

[ ]  yes, for three years \*

\* Note, if you check off one of these three options, your personal contact information will be kept by the Lead Investigator for the period which you have selected.

1. **Responsibility of the research team**

Suggested text:

By accepting to participate in this study, you do not renounce any of your rights nor do you release the investigators (the sponsor: to be added if there is one) or the institution(s) involved from their civil or professional responsibilities.

1. **Compensatory indemnity**

Suggested texts (Choose the one appropriate to your research project) :

* You will receive an amount of $\_ to cover your travel expenses, upon presentation of receipts;

OR

* You will receive $\_\_ in consideration of the constraints and inconveniences resulting from your participation in the research project;

OR

* No compensatory indemnity is offered to participants taking part in this research project.
1. **Resource persons**

Suggested text:

If you have any questions regarding the research project, if you wish to withdraw from this study or if you wish to inform the research team regarding an incident, you may contact: (enter the name, profession and complete institutional contact information: telephone and email) Please make sure that this contact person is fluent in English.

For a student project, please include the name of the responsible researcher as the contact person.

If you have any questions regarding your rights and responsibilities or your participation in this research project, you may contact the CER en réadaptation et en déficience physique, by email at the following email address: cercrir@ssss.gouv.qc.ca.

For these questions, you may also contact the Local Complaints Commissioner of your institution (provide her/his phone number and email address) or (if there is more than one institution, provide an attachment and enter the contact information for each Commissioner) in a document annexed to the consent form (SEE ATTACHED LIST)

1. **Consent**

Suggested text:

I declare that I have read and understood this project, the nature and the scope of my participation, as well as the risks and inconveniences to which I may be exposed, as presented in this document. I have had the opportunity to ask all my questions regarding the different aspects of the study and to receive answers to these questions. A signed copy of this information and consent form must be provided to me.

I, undersigned, voluntarily accept to participate in this study. I can withdraw my participation in this study at any time without prejudice of any kind. I certify that I was allowed all the time necessary to make my decision.

\*\*\*Add the following sentence in case participation in the project may have an impact on the participant’s rehabilitation treatments: A copy of the consent form will be placed in my medical record. If applicable, the research team must deposit the consent form in the participant’s medical record.

Participant’s Name: SIGNATURE

Signed at \_\_\_\_\_\_\_\_\_ on \_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_\_

Name of the legal representative Compulsory signature of the

of the participant in case the participant legal representative

is a minor or legally incapable

Signed at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, on \_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_\_

**THE RESEARCHER MUST GIVE A SIGNED COPY OF THE CONSENT FORM TO THE PARTICIPANT AND KEEP ANOTHER ONE IN THE RECORD**

In the case of an anonymous online survey, you could use the wording: "I understand that by answering the questions and clicking 'send' at the end of the survey, I am expressing my consent to participate. ".

1. **Assent**

Assent can be defined as the agreement of an incapable person or a minor to participate in a research project.

Some legally incapable persons or some minors, about 8 years of age or older, nonetheless may be able to indicate whether nor not they wish to participate in a research project, despite the fact they are incapable of giving free and enlightened consent. In such circumstances, the investigator must obtain the participant’s assent. This assent alone is insufficient to allow participation in a research project. Moreover, if the minor or the incapable person refuses, he or she may not participate in the project.

Suggested text

I understand that I may terminate my participation in this study at any time and I understand what my participation in this study involves. I accept to participate in this study.

PARTICIPANT’S NAME SIGNATURE

Signed at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, on \_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_\_

Minor: I, ……………., hereby confirm that I have explained to the above-mentioned child the nature of the research project and the known risks involved in participation in this research and that the parent(s) and child have the option of withdrawing from this study at any time. We have assured the child/the parents that despite the publication of the results of the study, the child’s identity will be kept confidential.

Incapacitated adult: I, ……………., hereby confirm that I have explained to the above-mentioned participant the nature of the research project and the known risks involved in participation in this research and that the participant and his legal representative have the option of withdrawing from this study at any time. We have assured them that despite the publication of the results of the study, the participant’s identity will be kept confidential.

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Signature of the person in charge of the project

of her/his representative

 Signed at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_\_\_.

1. **Commitment of the investigator or her/his representative**

I, undersigned, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, certify:

1. that I have explained to the signatory the terms of the present form;
2. that I have answered any questions that she/he asked me in this regard;
3. that I have clearly indicated that she/he remains, at any time, free to terminate her/his participation in the research project described above;
4. that I will provide her/him a signed and dated copy of this form.

**In the case of an incapable subject (to be added, if applicable):**

1. that I have ensured that the subject understood, the maximum of her/his capacities, all the aspects of her/his participation in the study described in this form.

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Signature of the Lead Investigator or his representative

 Signed on \_\_\_\_\_\_\_\_\_ of \_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_\_

**APPENDIX**

**LOCAL COMPLAINTS COMMISSIONNER**

**OF THE CRIR INSTITUTIONS AND THEIR PARTNERS**

**Centre de réadaptation Lethbridge-Layton-Mackay**

* **Centre de réadaptation Constance-Lethbridge**
* **Centre de réadaptation MAB-Mackay**

CIUSSS du Centre-Ouest-de-l’Île-de-Montréal

Phone : 514-340-8222, extension 24222

Email : ombudsman.ccomtl@ssss.gouv.qc.ca

**Institut universitaire sur la réadaptation en déficience physique de Montréal**

* **Centre de réadaptation Lucie-Bruneau**
* **Institut Raymond-Dewar**
* **Institut de réadaptation Gingras-Lindsay de Montréal**

CIUSSS du Centre-Sud-de-l’Île-de-Montréal

Phone : 514-593-3600

Email : commissaireauxplaintes.ccsmtl@ssss.gouv.qc.ca

**Hôpital juif de réadaptation**

CISSS de Laval

Phone : 450-668-1010, extension 23628

Email : plaintes.csssl@ssss.gouv.qc.ca

**Institut Nazareth et Louis-Braille**

CISSS de la Montérégie-Centre

Phone : 450-466-5434 of toll free 1-866-967-4825, extension 8884

Email : commissaire.cisssmc16@ssss.gouv.qc.ca

**Centre de réadaptation en déficience physique des Laurentides**

CISSS des Laurentides

Phone : 450-432-8708

Email : info-plaintes@ssss.gouv.qc.ca

**Centre de réadaptation en déficience physique de Lanaudière**

CISSS de Lanaudière

Phone : 450-759-5333, extension 2133 or toll-free 1-800-229-1152, extension 2133

Email : plaintes.cissslan@ssss.gouv.qc.ca