THE CONSENT FORM

Free and informed consent is a process in itself and not simply a form to be signed. It is at the heart of the ethics governing research involving human subjects and implies dialogue and information sharing, with the entire process allowing potential participants to agree or refuse to participate in research projects.

The consent form is a tool that protects and promotes human dignity. A copy of the consent form must be given to the participants for them to retain and to serve as the basis for future discussions with the research team.

This guide is designed to assist in the development of consent forms for research projects. **However, some sections may not apply to your research project.** If this is the case, please omit these sections on your form. Explanations are provided under each section to help the investigator write the form.

GENERAL INSTRUCTIONS

As many forms as necessary must be written, i.e. a consent form is required for each target group **for which participation differs within a given protocol** (e.g. control group, treatment group).

A form must be **easy to read and simple to understand**. Avoid language that is too scientific or complex.

Font

The font used as well as the layout of the information must be such that these documents can be easily read and understood. The use of "Arial" or "Times New Roman" 12 point font is therefore recommended, along with clear headings (in bold) and ample space within the text. Furthermore, all text must be aligned to the left to facilitate reading of the documents.

Letterhead

The first page of a consent form must be printed on the letterhead of the organization responsible for the study (e.g. *Université de Moncton*).

Form identifier

The dated version must be indicated at the bottom left of each page.

The page numbering must appear at the bottom right, with the total number of pages also being indicated (e.g. page 1 of 7)

A section at the bottom left must be reserved for participants to initial each page. This procedure allows them to ask questions and to assimilate information as each page is read.

Use of the pronoun "you"

It is recommended that the word "you" (second person) be used throughout the text, except for the section of the form where the participant must give his or her consent.

SECTIONS OF A CONSENT FORM

PROJECT TEAM AND SPONSOR

- **Title of the research project**
- **Principal investigator (address, telephone number, email and professional title)**
- **Co-investigators**
- **Project sponsor**

Prospective participants should know who is asking them to participate in a study and why.

The consent form should identify the principal investigator and the other members of the research team that the participants will be dealing with. The names of all these people should be provided along with their affiliations (professional titles). In addition, the organization that is sponsoring the project and all the other organizations involved should be identified.

DECLARATION OF RESPONSIBILITY

After the section with information on the research team members, a statement of responsibility for the project must be signed by the investigator in charge. Copies of the consent form must be signed ahead of time.

A. INTRODUCTION

The investigator must indicate the reasons for recruiting a participant into the study, i.e. the specific reasons for asking him or her to participate rather than someone else.

B. OBJECTIVE OF THE RESEARCH PROJECT

The information given to prospective participants should explain, in layman's terms: the **goal of the research, the subject being studied, and hypothesis and/or objectives of the proposed research.**

C. NATURE OF MY PARTICIPATION

This section must be very clear and detailed and provide enough information for participants to be able to understand and visualize what they will have to do. Rather than providing a scientific description of the procedures, this section must explain the practical implications for participants. If needed, use a table. It is necessary to:

- Describe everything that participants will have to do in simple terms, illustrating with examples if necessary;
- Indicate whether participants must change or cease a current treatment or medication in order to be included in the study, and explain how this change or cessation will affect their health status;
- Explain the specific restrictions associated with the treatment, such as diets or exercises;
- Indicate the routine examinations and tests that participants will have to undergo in order to be included and participate in the study (physical examinations, vital signs, medical history, blood tests [with the amounts of blood drawn each time indicated, if applicable], urinalysis, X-rays, frequency of tests, etc.);
- Indicate the specialized examinations that participants will have to undergo in order to be included and participate in the study, and provide clear explanations;
- Indicate the questionnaires or logbooks that participants will have to complete and specify the amount of time they will have to devote to doing so and at what frequency; Specify the number of sessions, the length of each session, and the planned breaks;
- Specify the follow-up (if applicable), especially in the case of longitudinal studies;
- Indicate where the experimentation will take place;
- Specify whether the sessions will be recorded on audio or video tape;
- Make a distinction between the standard treatment and the treatments or interventions related to the research project.

D. POSSIBLE BENEFITS OF MY PARTICIPATION

Describe the benefits that participants are entitled to expect, even if these cannot be guaranteed. If no benefits are expected to accrue to the participants themselves, indicate this also. If there are no direct benefits, it is appropriate to indicate the contribution that participants will make to the advancement of scientific knowledge or to the understanding of a condition or illness, etc.

“Closer follow-up” (medical, nursing, dietary or other) is not to be mentioned among the benefits, since this would amount to saying that regular patients do not receive good services, and may have the effect of inciting, not to say coercing, potential participants in their decision-making process. As well, this “closer follow-up” is determined by the research protocol and could, in some cases, even constitute a genuine inconvenience, depending on the number and length of the visits.

The reimbursement of expenses incurred during visits is not a benefit, since it is quite normal to reimburse expenses that participants would not have incurred had they not been participating in the study.

E. RISKS AND INCONVENIENCES POTENTIALLY RESULTING FROM MY PARTICIPATION

Prospective participants must understand the risks to which they will be exposed and must, in particular, be informed about the possible harm they might suffer from their participation in the study.

The information supplied to prospective participants seeking their consent should describe all foreseeable harm, including physical, emotional or psychological harm as well as any other potential inconveniences.

- Some examples could include:
- Loss of self-confidence after receiving a poor result on a memory test;
- Regret at revealing personal information to an interviewer;
- Interruption of family routines;
- Long waits;
- Boredom;
- Disclosure of personal information;
- Fatigue;
- Stress related to the experimentation;
- Pain related to the type of samples taken;
- Transportation;
- Emotional reactions;
- Other.

If a risk exists, it must be accurately described by explaining the possible consequences and related probabilities. All known risks must be disclosed, even when they are rare, if knowledge of them may make a reasonable person hesitate to participate in the study. The possibility of unexpected risks, where a study involves a new intervention whose dangers are not all yet known, must be mentioned. If there are risks, mention the corresponding preventive measures that will be taken.

F. ALTERNATIVES TO PARTICIPATION

Some projects may involve treating participants who are suffering from a particular illness, syndrome or condition. In such cases, it is especially important for prospective participants to know whether other treatments or therapeutic options are available, where these exist. Where there are no other alternatives (e.g. no other possible therapies), this should be mentioned.

As well, prospective participants should be informed about the care they can expect to receive if they decline to participate in the study. If a research project is not examining a medical treatment, it must be made clear to participants that, from the medical perspective, they will obtain no benefit from the research.

G. COMPENSATION IN CASE OF HARM

The following paragraph must appear in consent forms:

If you were to suffer any harm resulting from any procedure related to the study, you will receive all necessary medical care. By agreeing to participate in this study, you waive none of your rights and do not release the investigators (where applicable: organizations, companies) or institutions involved from their legal and professional responsibilities.

H. VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

It is important to carefully explain to participants that their participation is voluntary and that they can terminate it at any time, for any reason and without prejudice, by giving a verbal notice.

It must be determined what will happen to the data collected from participants who withdraw. The investigator must clarify whether, in such cases, this data will be retained or destroyed.

I. HALTING OF THE PROJECT OR OF A PARTICIPANT'S INVOLVEMENT

Participants must know that certain grounds could lead to the halting of the project by the investigators, e.g. new data rendering the project unethical or a participant no longer meeting the selection criteria.

J. ACCESS TO MEDICAL OR OTHER RECORDS

Indicate whether the investigator, or anyone else involved in the project, will have access to certain data in participants' medical records. Clearly indicate what information will be obtained from the records and for what reason. All access to medical records must be approved by the Research Ethics Board (REB).

K. FINANCIAL COMPENSATION

The monetary, moral or material contribution offered to participants must retain a symbolic value and must at no time constitute an incentive for participants to participate in the research where it could reasonably be assumed they would have refused without the offer. The investigators and REB are responsible for evaluating the symbolic or unduly motivating nature of the compensation offered, depending on the participants involved in a research project. Financial compensation in no way signifies that participants are to be paid. The money is given on a "complimentary" basis, and the investigator will justify

doing so in the consent form. **If no financial compensation is to be provided for participation, this must also be mentioned.**

L. INFORMATION DISSEMINATION PLAN

Investigators must inform participants whether they plan to use the information collected for the purposes of scientific and professional communications (publications). Please ensure to mention that no information identifying participants will be disclosed in these communications.

M. CONFIDENTIALITY

The measures that will be taken to protect the confidentiality of data must be specified, namely the:

- Codification of nominal data;
- Location where research data will be stored and related procedures;
- Storage methods;
- Access to the data.

Specify the period during which the data will be retained. If this period is greater than **five years**, the investigator must justify this choice to the REB, which will be required to evaluate the relevance of the time period.

Explain that the data, including audiovisual materials, will be destroyed when this time period expires.

Investigators must inform research participants that the information collected will only be used in relation to the current research.

N. CONTACT PERSONS

In addition to questions resulting from emergency situations that may arise, study participants may wish to receive more information on the study itself, some terms and conditions, or their rights as research participants. For this purpose, the contact information of the resource person (principal investigator and/or one of the co-investigators) who will be able to address these issues must be provided to research participants.

The following paragraph is mandatory:

If you have questions about your rights as a research participant, or if you wish to discuss the study with someone who has no ties to the research, you may contact the Regional Ethics Office of the Vitalité Health Network, 275 Main Street, Suite 200, Bathurst, NB E2A 1A9, 506-544-2506; e-mail address: ethique.ethics@vitalitenb.ca**.**

O. DECLARATION BY THE PARTICIPANT

Except in some special cases, consent is given by the participants themselves, which means this section must be written in the first person singular, must be kept as simple as possible, and must not repeat information previously stated in the form.
Insert a sentence stating that participants have read and understood the terms of the consent form and have been satisfactorily informed about the nature of, and reasons for, their participation in the project.

Members of the REB encourage investigators to allow participants a period of reflection between the first contact, when the investigator explains the expected participation, and the second contact, when the participants sign the consent form. **A copy of the form must be given to participants** (two copies of the form are therefore required at the first meeting, with participants signing and dating both copies and keeping one).
For each signature, the name must also be printed. A witness must also sign.

P. DECLARATION BY THE PERSONS RESPONSIBLE FOR OBTAINING THE CONSENT

For research ethics follow-up, it is important to have the name of the person who obtained the participants' consent. **This person may be the principal investigator.** Indeed, some participants subsequently complain that the person did not inform them well about some elements of the research.

Furthermore, by signing, the person responsible for obtaining the consent declares having fulfilled all the conditions required to obtain free and informed consent from participants. A witness must also sign.

Q. DECLARATION BY THE LEGAL REPRESENTATIVE OR PROXY

Signature by the proxy or legal representative will **only** be requested in cases of incompetency, of a participant who is a minor, of a reading or writing difficulty, or of a need for an interpreter. A witness must also sign.

The following paragraph is mandatory:

I certify that under the provincial and federal applicable laws, I am the legally authorized representative of the participant named above and I am authorized to sign this consent to his/her participation in the registry described above.

This section must be contained within **one separate page**.