CONSENT FORM

PROJECT TEAM AND SPONSOR

TITLE OF PROJECT :

PRINCIPAL INVESTIGATOR(S) : Name and professional title
Address,
Téléphone number
Email

CO-INVESTIGATOR(S) : Name and professional title
Address,
Téléphone number
Email

PROJECT SPONSOR : (Name of organization, e.g., Université de Moncton)

DECLARATION OF RESPONSIBILITY

The principal investigator is responsible for the conduct of this project and agrees to fulfill the commitments contained herein.

Signature of investigator responsible for the project:

_____

A. INTRODUCTION

Sample wording:

We are inviting you to participate in a research project involving people who, like you, suffer from rheumatoid arthritis and who have never taken anti-inflammatory drugs…

You have just undergone chemotherapy for cancer of the prostate. We are inviting you to…

B. OBJECTIVE OF THE RESEARCH PROJECT

Sample wording:

This project is designed to document… or… The goal of this study is to…

C. NATURE OF MY PARTICIPATION

Sample wording:

Your participation in the study requires one (or more) meetings that will last… at most and take place at… (location). You will be asked to answer questions on… You will also have to attend sessions ….

Provide enough information for subjects to be able to understand and visualize what they will have to do.

D. POSSIBLE BENEFITS OF MY PARTICIPATION

Sample wording:

There are no direct benefits resulting from your participation in this study. However, your participation will allow research to be conducted that will advance knowledge of…

E. RISKS AND INCONVENIENCES POTENTIALLY RESULTING FROM MY PARTICIPATION

Sample wording:

The primary drawback associated with your participation is the time you will be required to devote to this research. You could also feel concern about… In this case, you can express your concern and expect to receive all necessary explanations.
It is understood that, from a medical perspective, your participation in this research project poses no risk to you whatsoever. However, from a psychological perspective, it is possible that discussions occurring during the project may cause you to relive difficult memories. If you feel the need, psychological support will be at your disposal at any time and completely free of charge. It is also understood that your participation will have no effect on any treatment you will eventually receive.

F. ALTERNATIVES TO PARTICIPATION

Sample wording:

You do not have to participate in this research project to obtain the necessary health care for your condition. There are other therapeutic options or interventions for the treatment of arthritic pain. We encourage you to discuss all possible options with the

principal investigator. He or she will discuss all the benefits and risks associated with other treatments or interventions.

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

Sample wording:
It is agreed that your participation in the aforementioned research project is entirely voluntary and that you remain free to terminate your participation at any time, without having to justify your decision or suffer any loss whatsoever.

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

Sample wording:
The researchers might have to withdraw you from the research project if you do not follow the project guidelines (e.g. no smoking or drinking) or if the researchers deem it better for your health and well-being.

J. ACCESS TO MEDICAL OR OTHER RECORDS

Sample wording:
The research team will consult your medical record in order to obtain the following information: (provide a list of the information required and the reason for its requirement).

K. FINANCIAL COMPENSATION

Sample wording:
As compensation for potential expenses incurred in the course of your participation, you will receive a lump sum of $X for the session (or each session if there are several).
OR
You will receive no compensation for your participation in this research. However, you will be reimbursed for parking and meal expenses you incur during your visits for this research project. Please supply us with the receipts.

L. INFORMATION DISSEMINATION PLAN

Sample wording:
The data collected will be used for scientific and professional communication purposes.

M. CONFIDENTIALITY AND ANONYMITY

Sample wording:

The data collected will remain confidential. Personal data will be stored in a locked filing cabinet. Only those people responsible for the project will have access. The data will be retained for a maximum of five years and will then be destroyed.

You may also explain in this section that additional precautions will be taken to keep the data confidential, such as assigning a numeric code to all documents so that no names appear.

N. CONTACT PERSONS

Sample wording:

For any questions or information requests about the project, I can contact either of the following persons:

- *Principal investigator: (telephone number)*
- *Co-investigator: (telephone number)*

Required text:

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.

DECLARATION BY THE PARTICIPANT

The entire "Declaration" section must be contained within one separate page.

Sample wording:
I declare having received sufficient explanations on the nature and conduct of this research project. I have read and understood the terms of this consent form and have received a copy. I acknowledge having been sufficiently informed about the nature and reasons for my participation in the project. I have had the opportunity to ask questions, which were answered to my satisfaction.

I accept that the acquired information from my medical records are conserved in a data base for future research purposes. *Oui* ☐ *Non* ☐

_____ _____
Signature of participant *Date*

Name printed: _____

_____ _____
Signature of witness: *Date*

Name printed: _____

DECLARATION BY THE PERSON RESPONSIBLE FOR OBTAINING THE CONSENT

I, _____, undersigned, attest having explained the terms of this form to the prospective participant, having answered the prospective participant's questions, and having clearly indicated that the prospective participant is free to terminate participation in the above project at any time.

_____ _____
Signature of person responsible for obtaining consent *Date*

Name printed: _____

_____ _____
Signature of witness *Date*

Name printed: _____

Signed in Moncton, on _____

DECLARATION BY THE LEGAL REPRESENTATIVE OR PROXY

This section must be contained within one separate page.

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.

_____ _____
Signature of the legal representative Date

Name printed: _____

_____ _____
Signature of witness Date

Name printed: _____

DECLARATION OF IMPARTIAL WITNESS

This section must be contained within one separate page.

The impartial witness is needed if the participant or the legal representative ***is incapable to read*** *this consent form.*

As impartial third party :

- *I attest that I was present during the entire discussion regarding the consent form.*
- *I attest that the consent form was entirely read and explained to the participant or to his legal representative, as named above, and was understood.*
- *I attest that the participant had sufficient time to understand the information and ask questions, and accepted voluntarily to participate in this study.*

_____ _____

Signature of the impartial witness *Date*

Name printed: _____

GENETIC CONSENT (OPTIONAL)

This section must be contained within one separate page. This section is only relevant for projects with a genetic component.

I allow the sampling of biological tissues □ for myself / □ for the person represented, _____, to be used for molecular genetic analysis for this project.
Participant

□ I want / □ I do not want / in the future, for the health professionals of the Dr-Georges-L.-Dumont University Hospital Center to communicate my results to other health professionals if this can help diagnose similar diseases in members of my family and my in-law-family.

□ I give / □ I do not give / permission to utilize, in the future, my DNA samples for other analysis regarding the same disease or a new technology

□ I want / □ I do not want / to be informed of the results.

If other information regarding these DNA samples would become accessible and could have an implication for myself or members of my family, □ I want / □ I do not want / to be informed of these results.

_____ _____
Signature (Participant or legal representative) *Date*

Name printed: _____

_____ _____
Signature of witness *Date*

Name printed: _____