CONSENT FORM

The Full Study Title Should Be Placed Here.

Principal Investigator: Dr. John Smith
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60 Riverside Drive
Charlottetown, PE C1A 8T5
Tel: 1-902-XXX-XXXX

Sub-Investigator: Dr. Jane Smith
Queen Elizabeth Hospital
60 Riverside Drive
Charlottetown, PE C1A 8T5
Tel: 1-902-XXX-XXXX

Study Sponsor: [Where applicable; do not include if the study is unfunded.]

INTRODUCTION

Suggested Wording:
You are invited to join a research study. The study is being offered at *(insert location)*. We are doing this study to find out more about _____ . This information will help you decide if you want to be part of the study or not.

WHY IS THIS STUDY BEING DONE?

Required Elements: Provide background information, in lay terms, about the research and why it is being undertaken.

WHY AM I BEING ASKED TO JOIN THIS STUDY?

Required Elements: Include a statement indicating why any particular person was flagged as a possible candidate for inclusion in the study.

Suggested Wording:
You are being asked to join this study either because you were identified by ____ as _____ and expressed an interest when told about the study, or because you contacted us after seeing our advertisement, expressing interest in the study. It is your choice whether you wish to participate or not. If you do decide to take part, you can still change your mind and stop participating at any time.

WHO CAN TAKE PART IN THIS STUDY?

The REB requires that potential participants be informed of the criteria relevant to their inclusion or exclusion in a particular research study. However, please note that only those criteria that potential participants would understand and would be able to deliberate about should be included.

IMPORTANT: Remember that the inclusion and exclusion criteria in the consent form should match those in the protocol. Remember to simplify these criteria so that potential participants can understand them.

Suggested Wording:
You may take part in this study if the answer is YES to all of the following:
- List Inclusion Criteria

BUT, if the answer to any of the following is YES, you should not take part in this study:
- List the Exclusion Criteria

All of these will be discussed in more detail with you. You will also be told the reasons why they are important.

WHAT HAPPENS IN THIS STUDY?

Required Elements: In this section, please provide an overview of the basic research design, in lay terms (e.g. – how is the study going to answer the research question[s] which it aims to answer?). Will participants be randomized? Will participants be asked to complete questionnaires, or be expected to keep diaries? Please consult our Consent Form Guidelines for requested wording related to the use of randomization and blinding.

State how long participants will be involved with the study (e.g. – the length of time over which the study visit[s] will occur) and the approximate overall amount of time that the study activities will require of participants (if possible).

Describe where the study is being done. If the study is being done only at the Queen Elizabeth Hospital or only in Prince Edward Island, please state "This study is taking place only in Prince Edward Island." If the study is being done in multiple provinces but only in Canada, please state "This study is taking place throughout Canada." [and list provinces taking part] Finally, if the study is being done in countries other than Canada, please state "This study is taking place throughout Canada, as well as in [list participating countries]."

Please include the number of people expected to participate worldwide (globally) and the number of people planned to participate locally (at this study centre/site).

Describe the research procedures or activities that participants will undergo or participate in as part of the screening process and study.

Whenever possible, please use a table to describe the study procedures in regard to timelines. This is more efficient and is much easier for the participant to follow along with, and understand. This is especially true for studies that require a number of study visits. [If the study only involves one study visit and only a couple of procedures or activities take place at the study visit, a table is not required.]

Describe any activities the participant will be asked to follow or undergo if he/she withdraws from the research study. Distinguish between those procedures that will be recommended for the participant's benefit as well as those requested for the benefit of the research.

ARE THERE RISKS TO THE STUDY?

Required Elements: Provide information about the risks of the study, especially addressing the issues listed below:

- List the possible adverse effects of the intervention or procedures.
- Explain whether potential harms are reversible.
- Include a statement acknowledging the possibility of unforeseen harms.
- The risks of questionnaires/surveys and blood sampling need to be stated (our requested wording for these risks are cited below; include these subsections only if applicable to your study).

WILL IT COST ME ANYTHING?

Required Elements: Provide information about the costs of the study, especially addressing the issues listed below:

- Are there any costs to participants?
- Will participants be paid?
- State whether, and how much the participants out-of-pocket expenses (e.g travel) will be reimbursed.
- Indicate how, if at all, reimbursement will be handled if participants withdraw or is withdrawn prior to study conclusion

WHAT ABOUT MY RIGHT TO PRIVACY?

Suggested Wording:

We will do everything possible to keep your personal information confidential. Although your name may be used in the study records, no identifying information (such as your name, or hospital number) will be sent outside of _____. Instead we will use special numbers (which may include your initials and date of birth) on any information sent outside of _____. If the results of this study are presented at a meeting, or published, nobody will be able to tell that you were in the study.

Your records will be kept in a secure area such as a locked file cabinet and office during the study, and after the study ends they will be kept for ___ years in a secure area owned or leased by _____.

Some other people or groups may need to check or see your study records to make sure all of the information is correct. All of these people have a professional responsibility to protect your privacy.

These groups and people are:

- **_____, the study sponsor and their assigned representatives**
- **The PEI Research Ethics Board which is responsible for the protection of people in research here**
- ***[List others as appropriate.]***

The information they check may include _____.

You also allow the collection, reporting and transfer of data collected from this study, including limited personal data such as your date of birth, to _____ for the purposes of this study and further analyses related to it.

You may also be contacted personally by the PEI Research Ethics Board for quality assurance purposes.

WHAT IF I WANT TO QUIT THE STUDY?

Required Elements: Please ensure that this section includes all applicable information requested below:

- Reiterate any procedures the participant will be asked to follow or undergo if he/she withdraws from the research. Distinguish between those procedures that will be recommended for the participant's benefit and those requested for the benefit of the research.

- Disclose whether withdrawal from study participation cannot include withdrawal of personal data collected up until that point, or whether data collected up until that point will be included in the study analyses. *[If data may be withdrawn, please amend the last sentence of our requested wording to reflect this fact.]*

Suggested Wording:
If you choose to participate and later decide to change your mind, you can say no and stop the study at any time. If you wish to withdraw your consent please inform the Principal Investigator. All data collected up to the date you withdraw your consent will remain in the study records, to be included in study related analyses.

WHO DO I CONTACT IF I HAVE QUESTIONS OR PROBLEMS?

Required Elements:
For further information about the study call _____. _____ is in charge of his study at _____(site)(he/she is the "Principal Investigator"). _____ work telephone number is (902) XXX-XXXX.

The Principal Investigator is _____.
Telephone: (902) XXX-XXXX

Your Research Coordinator is _____.
Telephone: (902) XXX-XXXX

If you have any questions about your rights as a research participant, contact the PEI Research Ethics Board Office at 902-569-0576.

CONSENT FORM SIGNATURE PAGE

Required Element:
After you have signed this consent form you will be given a signed copy.

IMPORTANT:

- No new information regarding the study, or limitations on the rights of participants should appear on the consent form signature page.
- Please note that checkboxes for optional sub studies should only be contained on the consent form signature page, and not anywhere else throughout the consent form document.
- The consent form signature page should be contained on a single, separate page. Consent forms with signature pages spanning more than one page will be returned for revision.

Requested Wording:
I have reviewed all of the information in this consent form related to the study called:
[Provide Full Study Title]

I have been given the opportunity to discuss this study. All of my questions have been answered to my satisfaction.

My signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time.

_____	_____	____ / ____ / ____
Signature of Participant	**Name (Printed)**	**Year Month Day***
_____	_____	____ / ____ / ____
Witness to Participant's Signature	**Name (Printed)**	**Year Month Day***
_____	_____	____ / ____ / ____
Signature of Investigator	**Name (Printed)**	**Year Month Day***
_____	_____	____ / ____ / ____
Signature of Person Conducting Consent Discussion	**Name (Printed)**	**Year Month Day***
_____	_____	____ / ____ / ____
Signature of Participant's Legally Accepted Representative	**Name (Printed)**	**Year Month Day***

If the consent discussion has been conducted in a language other than English, please indicate: _____ (Language)

_____	_____	____ / ____ / ____
Signature of Translator	**Name (Printed)**	**Year Month Day***

Note: Please fill in the dates personally

I Will Be Given a Signed Copy of This Consent Form

Thank you for your time and patience!

Witness:
Whenever possible, the witness to the participant's signature should be a person who is independent of the research team (e.g. – a relative or family member of the potential participant). When this is not possible, the witness to the participant's signature may be a member of the research team that is present when the participant's signature is obtained. The signature of this individual indicates only that they were present to witness the signature of the participant; not the entire consent process.

Legally Accepted Representative:
Legally Accepted Representative field should be included only if required. You must have informed the REB as to why it is necessary to use the Legally Accepted Representative in the consenting process.

Translator:
If the consent discussion for all potential participants will be conducted in English, the subsection related to translation is not required. If some potential participants may have the consent discussion conducted in a language other than English, include the relevant subsection, and consult our Consent Form Guidelines for further guidance regarding the use of translation.