{NOTE: The informed consent document should be presented in a language appropriate to the projected subject population. For the lay subject, use clear, concise language readable at the 8th grade level. Remove all template instructions *(in italics)* prior to submission.}

**Saint Francis University**

**[Department name] Department**

*{You may insert your department logo if you wish}*

**CONSENT TO PARTICIPATE IN RESEARCH**

**PROJECT TITLE**: *Insert Title Here*

You are being invited to take part in a research project conducted by [*insert name(s) of investigator(s)*] from the [*insert departmental affiliation*] at Saint Francis University. [*If student, indicate that project is part of thesis, dissertation, etc. Indicate that the project is being conducted under the supervision of (faculty sponsor’s name).*]

# NON-PARTICIPATION STATEMENT

Taking part in the research project is voluntary and you may refuse to take part or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. You may also refuse to answer any research-related questions that makes you uncomfortable. *[If you are a student, a decision to participate or not or to withdraw your participation will have no effect on your course or academic standing.]*

# PURPOSE OF THE STUDY

State the purpose/objective of the project. Include the duration of the entire study (i.e., 6 months, 1 year, etc., as well as the length of time the subject’s participation will last)

# PROCEDURES

*(Single location study)*

You will be one of approximately \_\_\_\_\_ subjects invited to take part in this project. OR

*(Multi-location study)*

A total of \_\_\_\_\_ subjects at \_\_\_\_\_locations will be invited to take part in this project. You will be one of approximately \_\_\_\_\_ subjects invited to take part at this location.

Describe the research project in clear, concise language appropriate to the targeted subject population (for a non-scientific subject, language should be readable at an 8th grade level). This should include, but not be limited to:

* Procedures to be performed, including frequency and follow-up (if applicable). Indicate any procedures that are experimental in nature.
* Number, frequency and duration of interactions. If multiple visits and procedures are to be conducted, a timeline or chart of visits is helpful
* Specimens to be collected, including frequency and size/amount (if applicable)
* Specific requirements of the research subject, including follow-ups, journals, questionnaires, interviews, etc.
* An example of any sensitive questions or information they will be asked to answer/provide

# CONFIDENTIALITY

Describe if a subject’s identity will be held in confidence or remain anonymous.

If confidential: Every effort will be made to maintain the confidentiality of your participation in this project. Each subject’s name will be paired with a code number by the principal investigator. This code number will appear on all written materials. The list pairing the subject’s name to the assigned code number will be kept separate from all research materials and will be available only to the principal investigator. Confidentiality will be maintained within legal limits.

# RISKS/DISCOMFORTS

Describe any reasonable foreseeable risks, discomforts, or inconveniences, and how they will be managed. (Please consider physical, psychological, social, or legal risks.) If necessary, appropriate referrals should be offered.

For research involving more than minimal risk, an explanation must be provided regarding whether any compensation or medical treatment is available in case of research-related injury.

If there are no foreseeable risks, state that this is the case.

**INJURY CLAUSE**

*If there is a risk of injury, this statement must be included verbatim*

In the unlikely event that you become injured as a result of your participation in this study, Saint Francis University will make every effort to assist you in obtaining medical care. Saint Francis University will also assist you in the cost of your medical expenses limited to any applicable insurance coverage available through the University. If you want more information about this, please contact Jeffrey Savino, Vice President for Finance at 814-472-3261.

# BENEFITS

Describe any direct benefits to the individual subject participating in this project. (Please remember that extra credit, coupons, or any other form of remuneration are incentives rather than benefits.)

If no direct benefits, you may include wording such as:

While you will not directly benefit from participation, your participation may help investigators better understand [*insert project specific information*].

# ALTERNATIVES

The following alternative procedures are available if you choose not to participate in this project:

OR

Participation in this project is voluntary and the only alternative to this project is non-participation.

# COSTS *(to be used only if applicable)*

# If subjects will be expected to incur any costs related to this project (ex: parking), describe in detail.

# INCENTIVES/REMUNERATION *(to be used only if applicable)*

Also, if the subject is to receive any type of remuneration include both what the subject will receive (for example, type and amount of gift certificates) as well as any parameters required to receive the remuneration (i.e., indicate whether remuneration will be pro-rated for subjects who enroll in but do not complete all parts of the project.)

# PUBLICATION STATEMENT

The results of this study may be published in scientific journals, professional publications, or educational presentations; however, no individual subject will be identified.

# AGREEMENT FOR THE USE OF AUDIO/VIDEO TAPES *(to be used only if applicable. If only audiotaping, remove all references to video, and vice versa)*

If you consent to take part in this study, please indicate whether you agree to be audio/video taped during the study by checking the appropriate box below. If you agree, please also indicate whether the audio/video tapes can be used for publication/presentations.

* I agree to be audio/video taped during the interview.
  + I agree that the audio/ video tape(s) can be used in publication/presentations.
  + I do not agree that the audio/ video tape(s) can be used in publication/presentations.
* I do not agree to be audio/video taped during the interview.

# *Include a statement regarding whether a subject can still take part in the research if they do not agree to the audio/videotaping.*

# CIRCUMSTANCES FOR DISMISSAL FROM PROJECT *(to be used only if applicable)*

Your participation in this project may be terminated by the principal investigator *(select only those that* *are appropriate based on the considerations of the study*):

* if you do not follow the instructions you are given;
* if the principal investigator determines that staying in the project is harmful to your health or is not in your best interest *(typically only used in clinical or physical exertion studies, with some exceptions);*
* if the study sponsor decides to stop or cancel the project *(applies only to sponsored research)*

**SUBJECT RIGHTS**

1. I understand that informed consent is required of all persons participating in this project.
2. I have been told that I may refuse to participate or to stop my participation in this project at any time before or during the project. I may also refuse to answer any question.
3. Any risks and/or discomforts have been explained to me, as have any potential benefits.
4. I understand the protections in place to safeguard any personally identifiable information related to my participation.
5. I understand that, if I have any questions, I may contact [*insert principal investigator’s name*] at [*insert work or SFU telephone number*]. I may also contact [*insert faculty sponsor’s name*], faculty sponsor, at [*insert SFU telephone number*].
6. **Any questions regarding my rights as a research subject may be addressed to the Saint Francis University Institutional Review Board (**[*irb@francis.edu*](mailto:irb@francis.edu)**). All research projects that are carried out by Investigators at Saint Francis University are governed by requirements of the University and the federal government**.

**SIGNATURES**

{NOTE: Please ensure all signatures are on the same page. Delete this note section for your final informed consent document.}

***I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions to my satisfaction. I give my consent to participate in this study, and have been provided with a copy of this form for my records and in case I have questions as the research progresses.***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Subject (print name)

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Subject Signature Date

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***I have read this form to the subject and/or the subject has read this form. An explanation of the research was provided and questions from the subject were solicited and answered to the subject’s satisfaction. In my judgment, the subject has demonstrated comprehension of the information****.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent Role in Research Study

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Signature of Person Obtaining Consent Date