 **Institutional Review Board (IRB)**

**Instructions for Informed Consent Form (ICF) Template**

**You should use this consent form template only if:**

1. You are conducting research on adults (18 years of age or older) **and**
2. Your research poses no greater than minimal risk to participants**.**

If you are conducting research that poses **greater than minimal risk**, you will need to specify this in the section on **Risks** and include the section on **Policies and Procedures for Research-related Injuries.**

**You should not use this consent form template if:** you are doing research with minors.

Risk level is assessed in view of potential harms to participants – these include social, legal, emotional, psychological etc. harms, not just physical harms. Depending on the subject matter with which the research deals and the specific way in which the research is carried out, a study may be considered greater than minimal risk even when using survey or interview (including focus group) methodologies.

**Note:** According to DHHS Regulations “minimal risk” means: “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

This template is intended to serve as a **GUIDE**. You may need to provide more information and details than are stated in the template. You will most likely need to re-word sentences and/or add your own sentences. You may also need to add information or details that are not directly asked for in the template. Again, this template is intended to serve as a **GUIDE** and is not exhaustive.

**Remember: the Consent Form should contain only information that is applicable and relevant to your study.**

**IMPORTANT:** You should remove the red guidance text as you go through this document, by filling out information specific to your study and/or deleting irrelevant and unnecessary text. The red sentences indicate sections that must be completed by the author of the Consent Form, or serve as guidance and suggestions about what should be included. There should be **no** red sentences left anywhere in the completed Consent Form.

**PLEASE PROOF READ** your completed Consent Form before submitting it. Seemingly minor spelling, grammar, and formatting errors may require you to revise and re-submit, causing unnecessary delays.

**PLEASE DO NOT INCLUDE** these instructions in your completed Consent Form.

 **Department of (**Name)

**Informed Consent Form**

**FOR PARTICIPATION IN A RESEARCH PROJECT**

**Project Title:** (Title)

**Principal investigator:** (PI’s name)

**Mentor:** (Mentor’s name) *Include only* *if PI is a student.*

**SPU Sponsor:** (Sponsor’s name) *Include only* *if PI is not directly affiliated with SPU.*

**Introduction**

You are invited to consider participating in this research project. Please take as much time as you need to make your decision. Feel free to discuss your decision with whomever you wish, but remember that the decision to participate, or not to participate, is yours. If you decide to participate, please sign and date where indicated at the end of this form.

**Purpose**

The purpose of this research is to (the reason(s) the research is being conducted, including what the results will be used for).

**Project Plan**

You are being asked to take part in this research because you are (who? or hold what position? or have what expertise? *Identify the target population of the study*). About (how many) subjects will take part in this research.

If you decide to participate in this research, you will (*Describe fully* what participant will be expected to do or take part in. *Explain the procedures and schedule, focusing on what the subject will be expected to do, e.g. complete surveys, questionnaires, interview, etc.*).

The research will be looking at (the research topic/subject as well as the general types of questions. *Do not list specific questions. However, be sure to mention whether the research deals with issues that might be considered sensitive or controversial, e.g. sexual behavior, drug or alcohol use, other illegal activities etc.*).

The (research session or sessions) will take place (when and where?).

*If one session:*

You will be in the project for about (anticipated duration of the session).

*If multiple sessions:*

You will be in the project for about (anticipated duration of subject involvement from start to finish). Each session should last (anticipated duration of one session).

*If applicable:* You will also be contacted for follow-up (at what point? *State when in the future participants will be contacted* *and how*).

(If the research involves videotaping or audio recording, mention this here. *If so, indicate whether being recorded is a requirement for participation; in the next paragraph, please provide specific, separate information about recording storage & destruction*)

*If there are additional components to the research plan, please be sure to include them in this section.*

**Risks**

There are (amount*, e.g. no, minimal, very few, few, a number of*) risks associated with participating in this research.

*If there are any risks whatsoever, include the following:*

It is possible, but (probability*, e.g. unlikely*), that this research could cause (harm*, e.g. embarrassment, distress, employer problems*) if (circumstance that could cause risk*, e.g. others learn of your responses, you have a strong emotional reaction to* [topic]*, your employer finds out and is unhappy*).

Make sure to consider all types of risks, including physical, psychological, emotional, social, economic, and legal risks. *(Possible examples: embarrassment if private information about you is accidentally disclosed to others, emotional distress from having to answer personal questions, criminal or civil liability, etc.)*

*(For each risk, include:* The researcher will try to reduce this risk by (state steps taken to mitigate specific risk).)

**Benefits**

If you agree to take part in this research, there will be no direct benefit to you. However, information gathered in this research may (reasonable result*, e.g. provide insight into* [topic] *or help us understand* [topic]).

*(If applicable: State any alternative procedures or treatments that may be of greater benefit to the participant).*

**Confidentiality**

*Please revise this entire section to make it applicable to your project.*

Every effort will be made to keep any information collected about you confidential. However, it is impossible to guarantee absolute confidentiality.

In order to keep information about you safe, (steps that will be taken to protect data*, e.g. data will be kept in a password-protected file on the researcher’s personal computer which only the researcher can access, study data will be kept in a locked box at the researcher’s office etc.*).

Include additional information, as listed below, on how different types of data will be kept secure.

This section should include a description of:

a) What data will be kept and in what form *(e.g. digital, paper – each type of data should have its own distinct safety plan),*

b) Whether the data will be identifiable *(e.g. linked through a code, directly linked to participant names etc.),*

c) Where and how data will be securely stored *(e.g. password-protected computer, locked filing cabinet etc.),*

d) Who will have access to the data,

e) Whether identifiable data will be shared outside the researcher team *(if so, with whom, how and why)*,

f) Whether *(and if so, how and when)* identifiers will be destroyed.

*Revise or delete as applicable to this project:*

We would like to include your name in the (final goal*, e.g. thesis, publication, essay, presentation*) that result(s) from this research project. We want to (level of identification*, e.g. identify, describe*) you for attribution and explanatory purposes. However, you have the option not to have your name used when data from this research are published; if this is the case, please (procedure*, e.g. indicate so on the last page of this form, etc.*). Please note that, even if your name is not used in publication, the researcher *(if applicable:* and the research team*)* will still be able to connect you to the information gathered about you in this research.

*If there are any psychological or physical risks to participants, include this section.* ***If there are no such risks, do not include this section:***

**Policies and Procedures for research-related injuries**

Researchers will make every effort to prevent research-related injuries and illnesses. If you are injured or become ill while you are in the study, you will receive emergency medical care. The costs of this care will be charged to you or to your health insurer. No funds have been made available by Saint Peter’s University or its affiliates, or any government agency, to compensate you for a research-related injury or illness.

**Your Rights As A Research Participant**

Participation in this research is entirely voluntary. You can choose not to participate at all, or to withdraw at any point. If you decide not to participate, or to withdraw, there will be no penalty or loss of benefits to which you are otherwise entitled, or any effect on your relationship with the researcher(s), or any other negative consequences. *To be used for SPU student participants only:* Your participation or refusal to participate will have no effect on the grade you receive in any course or your standing at Saint Peter’s University.

If you decide that you no longer want to take part in this research, you are encouraged to inform the researcher of your decision. *Please include/revise the following as applicable to your project:* The information already obtained through your participation (will/will not) be included in the data analysis and final report for this research.

**Questions or concerns**

If you have questions about this research project, you may contact (PI’s Name) at (phone number) or (email address). *(If applicable:* You may also contact the researcher’s faculty mentor, (Mentor’s Name) at (phone number) or (email address). Please contact the Saint Peter’s University IRB at 201 761-6300 or jfeinberg@saintpeters.edu if you have any questions about your rights as a research participant.

**Statement of Person Obtaining Informed Consent**

I have fully explained this research to the participant. I have discussed the purpose and procedures, the possible risks and benefits, and that participation in this research is completely voluntary. I have invited the participant to ask questions and I have given complete answers to all of the participant’s questions.

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Signature of Person Obtaining Informed Consent Date

**Statement of Consent**

I understand all of the information in this Consent Form. I have gotten complete answers for all of my questions. I freely and voluntarily agree to participate in this research project. I understand that I can withdraw at any time. My signature also indicates that I am 18 years of age or older and that I have received a copy of this consent form.

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Participant Signature Date

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Printed Name of Participant

**Once you sign this form, you will receive a copy of it to keep and the researcher will keep another copy.**

NOTE ADDITIONAL CONSENT REQUIREMENTS.

PLEASE ADD IF APPLICABLE TO YOUR RESEARCH PROJECT

*If subjects will be photographed/videotaped/audio recorded/etc. include (otherwise delete):*

I understand that I will be (photographed/videotaped/audio recorded/etc.) as a part of this research.

Please indicate whether you agree to be (photographed/videotaped/audio recorded/etc.) as a part of this research.

* **YES** *(If you change your mind about this at any point, please let the researcher know)*
* **NO**

*If participants have the option to choose whether or not their names are used when data from this study are published, include (revising as necessary) otherwise delete:*

Please indicate whether you agree to have your full name *If applicable:* as well as your (organization’s name/ job title/etc.)used alongside your comments in the final (publication/presentation/essay/etc.) that result from this research.

* **YES** *(If you change your mind about this at any point, please let the researcher know)*
* **NO**
* **ALTERATION:**

 ***Name or pseudonym to be used:*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Participant Signature Date

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Printed Name of Participant