****

**St. John Fisher University Institutional Review Board**

|  |
| --- |
| **Statement of Informed Consent for Adult Participants** |

**[INSERT TITLE]**

|  |
| --- |
| **SUMMARY OF KEY INFORMATION:*** You are being asked to be in a research study of [insert general statement about study]. As with all research studies, participation is voluntary.

The purpose of this study is [explain research question and purpose in clear, concise language to help participant fully understand research].* Approximately [number] people will take part in this study. The results will be used for [describe what the results will be used for, including a master’s thesis or other course requirement, if applicable].
* If you agree to take part in this study, you will be involved in this study for [insert length of time (hours, days, week(s), month(s), or year(s)), number of sessions, duration of participant involvement, and estimated amount of time (in hours or minutes) spent participating. Include whether you intend to collect follow-up information and when this will be done. For example: “Follow-up information will be collected six months after last study visit.”]
* Briefly describe what will happen to the participant if they decide to participate, including the activities they will be asked to engage in, how long they will take, where the research will take place, and how often they will be asked to perform the research tasks. Note that you will provide more detail in the body of the consent form.
* Inform the participant of the major risks or discomforts (e.g. physical, emotional, and social) as a result of study procedures. If there are no known risks, then use the following suggested statement in this section: “We believe this study has no more than minimal risk.” Next, inform the participant of any minimal risks and/or inconveniences (e.g. the amount of time required to complete procedures, abstention from food, length of time participants may be required to sit or stand) as a result of the study procedures.
* Describe any direct benefits to the participant that may be reasonably expected as a result of the research. Describe benefits expected to accrue to the population the participant represents or to society in general (e.g. advancement of knowledge, health benefits to others). DO NOT include payments for participation or other incentives and gifts as a benefit of participation. If participants are not expected to directly benefit, then use the following suggested statement in this section: “You may not directly benefit from this research; however, we hope that your participation in the study may… (Describe societal benefits).” If no benefits, state that here].
* [Describe alternative procedures or course of treatment, if any.]
 |

**DETAILED STUDY INFORMATION (some information may be repeated from the summary above):**

You are being asked to be in a research study of [insert general statement about study]. This study is being conducted at [describe study location – refer to Section 1 Question 5 on the IRB application form]. This study is being conducted by: [Name of PI, and if student, also include name of faculty research mentor] in the [academic department or academic program] at St. John Fisher University.

You were selected as a possible participant because [explain how subject was identified].

Please read this consent form and ask any questions you have before agreeing to be in the study.

**PROCEDURES:**

If you agree to be in this study, you will be asked to do the following:

[Describe *in detail* what will happen to the subject if they decide to participate. Include a step-by-step description of the activities participants will be asked to engage in, how long they will take, where the research will take place, and how often they will be asked to perform the research tasks. If the procedures are simple and/or only happen one time, this section may be quite short.

The subject needs to know what will happen to them at each study visit. All study procedures need to be described, but do not include procedures and treatments that are established practice and not part of the study. If terminology is used, a description should be included. Bullet points, charts or tables are encouraged to increase readability of complicated procedures.

List all study visits separately, in chronological order and note what procedures are to be expected. If multiple visits or sessions will be held, provide a timeline with a detailed description of each visit or session.

If applicable (e.g., clinical trial, treatment, etc.), include a description of how participants will be assigned to groups, informed of their group assignment, the different groups involved, and any inclusion/exclusion criteria.

If audio- or video-recording will be used, the subject must be informed of recording and given the choice to agree to the recording at the end of this form. Subjects must be informed of whether they can opt out of the recording and still participate in the study. If recording/transcription is required for participation, this must be clearly stated, both here and in the signature at the end of the study.]

**COMPENSATION/INCENTIVES:**

You will/will not receive compensation/incentive. [Indicate compensation and/or incentive and when and how it will be distributed. If monetary benefits will be pro-rated due to early withdrawal, explain that.]

**CONFIDENTIALITY:**

The records of this study will be kept private and your confidentiality will be protected. In any sort of report the researcher(s) might publish, no identifying information will be included. [If research methods include a focus group, add: Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others. If applicable, add: The only exception to maintaining confidentiality would be if you indicate that there is immediate and serious danger to the health or physical safety of yourself or others. In that case, a professional may have to be contacted. We would always talk to you about this first.]

Identifiable research records will be stored securely and only the researcher(s) will have access to the records. All data will be kept [describe where records will be kept, such as a locked filing cabinet in the researcher’s office or on a password-protected laptop] by the investigator(s). All study records with identifiable information, including approved IRB documents, tapes, transcripts, and consent forms, will be destroyed by shredding and/or deleting after [specify number of 3 or more] years.

 [If any recordings will be made, explain who will have access, how identifying information will be handled, whether the recordings will be used for educational purposes, and when they will be erased. If this is not relevant to your study, delete this last section.]

 [Please note some professional organizations and/or journals now require indefinite, de-identified data sharing prior to submission for publication. If this applies to your research study, you must indicate that in this section of the consent form with the following language: “The data collected in this study as well as the results of the research can be used for scientific purposes and may be published (in ways that will not reveal who I am). An anonymized version of the data from this study may be made publicly accessible, for example via the Open Science Framework (osf.io), without obtaining additional written consent. The anonymized data can be used for re-analysis but also for additional analyses, by the same or other researchers. The purpose and scope of this secondary use is not foreseeable. Any personal information that could directly identify an individual will be removed before data and results are made public. Personal information will be protected closely so no one will be able to connect individual responses and any other information that identifies an individual. All personally identifying information collected about an individual will be stored separately from all other data.”]

**VOLUNTARY NATURE OF THE STUDY:**

Participation in this study is voluntary and requires your informed consent. Your decision whether or not to participate will not affect your current or future relations with St. John Fisher University [or with name any other cooperating institutions, such as a school or agency, or omit this if not relevant to your study] . If you decide to participate, you are free to skip any question that is asked. You may also withdraw from this study at any time without penalty.

**CONTACTS, REFERRALS AND QUESTIONS:**

The researchers(s) conducting this study: [name of researcher(s)]. If you have questions, **you are encouraged** to contact the researcher(s) at [location, phone number, e-mail address. If researcher is a student, include advisor’s name, title, telephone number and e-mail address as well.]

The Institutional Review Board of St. John Fisher University has reviewed this project. For any concerns regarding this study/or if you feel that your rights as a participant (or the rights of another participant) have been violated or caused you undue distress (physical or emotional distress), please contact the SJF IRB administrator by phone during normal business hours at (585) 385-8012 or irb@sjf.edu.

[If the study has the potential to cause physical or emotional distress, then you must direct participants to seek out an appropriate provider. If participants are SJF students, then refer them to the SJF Health and Wellness Center (385-8280). If participants are not SJF students, then refer them to their healthcare provider or an appropriate agency.]

**STATEMENT OF CONSENT:**

I am 18 years of age or older. I have read and understood the above information. I consent to voluntarily participate in the study.

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Retain this section only if applicable:*

*I agree to be audiorecorded/ transcribed \_\_\_\_ Yes \_\_\_\_No If no, I understand that the researcher will [explain alternative to audiorecording, if any. If no alternative, state this clearly].*

*I agree to be videorecorded/ transcribed \_\_\_\_Yes \_\_\_\_No If I do not wish to be videotaped, I will inform the researcher, who will instead [explain alternative to videorecording, if any. If no alternative, state this clearly].*

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If this is an online study, remove the signature sections above and instead use this language: “Electronic Consent: Clicking on the “Agree” button below indicates that:

* I have read the above information.
* I voluntarily agree to participate.
* I am at least 18 years of age.

If you do not wish to participate in the study, please decline participation by clicking on the “Disagree” button below.”

***Please keep a copy of this informed consent for your records.***