**Institutional Review Board**

**Consent Form**

Protocol Title: Insert the title of the study

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| --- | --- |
| Primary Contact Information | Institutional Contact  |
| Name of Researcher: Phone Number: Email Address: Research Advisor:  | Saint Mary’s University of MinnesotaInstitutional Review BoardDr. Molly O’Connor, IRB Chairirb@smumn.edu |

You are invited to participate in a research study about < insert the title of the research study >. This study is being conducted by < insert the researcher’s name > under the supervision of <insert name of the Faculty Advisor>. The study will be used to fulfill a requirement for completion of a < insert degree / name of program> degree at Saint Mary’s University of Minnesota. If the study is being funded or supported, list those here.

Please read the form carefully and ask any questions you may have before agreeing to participate in the study.

**Key Information about the Study**

The study involves research. Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” This means that the investigator (or researcher) is going to use information provided by participants such as yourself to come to conclusions that can help people. Please use this information and the information on this consent to decide whether or not you wish to participate in this study.

Things to know about your participation in the study:

* Your participation is completely voluntary
* You will not be penalized for refusing to participate
* You can agree to participate then change your mind without penalization
* *The <treatment/procedure> may involve risks to <you/the embryo/the fetus (if pregnant)> that are currently unforeseeable Delete if not applicable.*
* *Any significant new findings developed during the course of the study that may be related will be shared with you to consider whether or not you want to continue to participate Delete if not applicable.*
* *Your biospecimens, even if the identifiers are removed, may be used for commercial profit, in which you <will/will not> share. Delete if not applicable.*

**What is the purpose of this study?**

Explain the purpose of the study in language understandable to the participant. Suggested beginning statements include: The purpose of this research study is . . . or We are conducting this research study to . . .

**Why am I being asked to participate?**

Describe why the participant is eligible for the study, including:

* Inclusion and exclusion criteria. If participants are screened, describe what they are being screened for.
* How the participant was identified.
* The approximate total number of participants

**How long will I be expected to participate?**

Describe how long the research will last, including a timeline of activities that participants will participate in, the length/duration of visits, activities, and procedures, and how often the activities will be performed.

**What will I be asked to do?**

Address the following sections in a way that the participant can understand, as appropriate:

* Describe the procedures to be used in the study in sequential order. If participants will be screened, describe the screening procedures.
* If any of the procedures are experimental, you must identify and describe them.
* Describe the study design. For example, if the research involves questionnaires, surveys, or interviews, describe the type of questions that will be asked or what topics will be covered.
* Anyone with whom the participant will interact
* Describe where the research will be conducted
* Describe when the research will be conducted
* Describe any responsibilities of the participant (e.g., returning a computer or device lent to them for the study)
* What is being performed as part of the research study and what is part of standard care (if the study involves any type of clinical care)
* If the research involves use of deception or incomplete disclosure, insert the following suggested statement. Otherwise, delete: Some research requires that the full purpose of the study not be explained before you participate. You will be given a full explanation at the end of the study. Please note: the last sentence can be further customized to say, You will be given a full explanation as soon as you complete the study.

**Are there any risks to participating in the study?**

Accurately describe any risks involved in participation in the study.

* Risks may include any of the following:
	+ Physical
	+ Side effects of drugs/devices
	+ Psychological
	+ Privacy and/or confidentiality risks
	+ Legal
	+ Social
	+ Economic
	+ Group or community risks
* Each procedure should be identified and then the associated risks described.
* Identify steps taken to minimize risks.
* Indicate if there may be unforeseen risks.
* If there are no risks associated with the study, you may use the following suggested statement:Participation in this study does not involve risks beyond those associated with normal day to day living.

**Are there any benefits to participating in the study?**

Generally, there are no benefits to participating in a research study. Unless there are concrete and identifiable benefits to participating, either delete this entire section or insert: There are no benefits to you for participation in this study. Monetary compensation is not a benefit.

### Is there any compensation for participating in this study? Are there any costs to participate?

Describe any compensation the participant will receive. Compensation might include money, gift cards, donations to a charity, class points, gifts, food, and so forth. Explain when payment will occur and the conditions of payment. Describe conditions for partial payment or no payment if the participant withdraws from the study before it is completed.

Describe any additional costs to the participant (including transportation costs).

If participants will not receive payment and there are no costs, you may use the following suggested statement: Participation in this study will not cost you anything, and you will not be paid to be in this study.

**Are there any alternative procedures or courses of treatment that might help me?**

Describe if there are any alternative procedures or courses of treatment outside of this research study that might help the participant. *Delete if not applicable.*

**What kind of information about me will be collected, and what will happen to that information?**

Describe the data you will gather about the participant (responses to tasks, observations of behavior, interview transcripts, completed surveys/tests, e.g.).

You must also describe the extent to which confidentiality of the information identifying the participant will be maintained. Provide detail about how information will be kept confidential (both in the storing of information and in the dissemination of results from their research) and how information will be destroyed or discarded once the data are no longer needed. Please refer to your discipline's standards of practice regarding both storage of information (including length of storage required) and methods of discarding data. Note that some disciplines require data retention for up to five years after the study has been publicly disseminated. A statement like the following could be used for this purpose: The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant. Research records will be stored securely and only researchers will have access to the records. The original data will be destroyed five years after the study is completed.

* If the participant’s responses will be recorded using an audio or video recording device, the participant must give explicit consent for this recording to be done. Include a place in this section of the consent form for the participant to sign his or her name giving consent for audio or video recording of the interview or other research activity.

**What will happen to the data or biospecimens collected from me?**

If identifiable private information or identifiable biospecimens are being collected and may be retained for future research, explain where the data/specimens will be stored, who will have access to them, and for how long. Include one of the following statements:

* This study involves the collection of <identifiable private information/identifiable biospecimens>. If the identifiers are removed from the <identifiable private information/identifiable biospecimens>, the <information/biospecimens> could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.
* This study involves the collection of <identifiable private information/identifiable biospecimens>. The <information/biospecimens> collected will not be used or distributed for future research studies, even if all the identifiers are removed from the <information/biospecimens>.

Include this statement if applicable: Your <identifiable private information/identifiable biospecimens>, identifiable or de-identified, may be used in the future to create products or to deliver services for commercial profit. In this instance, it <is/is not> anticipated that you will be notified of this use or receive any compensation or profit from it.

**Will I ever be asked to leave the study?**

Describe any anticipated circumstances under which the participant may be terminated or withdrawn from the study without regard to the participant’s consent. Describe in detail what those reasons are and what the termination or withdrawal procedures will be, and emphasize that there will be no penalizations if they are asked to leave. The following statement may be used: There will be no consequences if you are asked to leave the study.

**What if I do not want to participate in this study?**

Clearly state that participation in this research study is voluntary, and that there are no negative consequences for declining to participate. Clearly indicate that the individual can discontinue participation in the study at any time, and that there will be no adverse consequences for stopping participation. The following suggested statement may be used: You are under no obligation to take part in this study. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

* If there are any consequences for when a subject decides to withdraw from the study before it is completed, e.g., \_\_\_\_\_, describe what those consequences are and what the procedures for orderly termination are.
* For interviews, focus groups and surveys, it may be appropriate to inform participants that they are not required to answer each question. You may use the following suggested statement: You do not have to answer any question that you do not want to answer.

For certain vulnerable populations it may be necessary to expand upon the “no penalty” statement. If you are enrolling patients in a clinic, include a statement indicating that the services they receive through the clinic will not be taken away or changed if they decline to participate.

**Who can I talk to about questions I have about the research and my rights?**

Provide the name, phone number and email address of the PI/Researcher, the Faculty Advisor, and the email address for the IRB (irb@smumn.edu). A statement such as the following may be used: We will be happy to answer any questions you have about this study. If you have any further questions or if you have a research-related problem, you may contact the researcher, <name, phone number, email> or the Faculty Advisor, <name, phone number, email>. If you have any questions concerning your rights as a research participant, you may contact the Saint Mary’s University of Minnesota Institutional Review Board (IRB) at irb@smumn.edu.

**Who can I talk to if something happens to me during the study?**

Provide the name and contact details of anyone who may provide support to the participant in the event that something happens (such as a research-related injury or adverse event) to the participant. This will depend on the nature of the study. For example, if the study is taking place in a school, you may refer the participant to their teacher or guidance counselor. If the study is taking place at a corporation, you may refer the participant to their HR staff. This may require that you contact these individuals beforehand to ensure that they are the right person to contact and how the participant may contact them.

(If the research is more than minimal risk and the next two questions apply, include them here. If not, delete the next two questions)

**Is there any compensation if something happens to me, and if so, what is it and how can I find out more?**

Describe what the compensation would be and where they can find out more. *Delete if not applicable.*

**Are any medical treatments available if something happens to me, and if so, what are they and how can I find out more?**

Describe any medical treatments available and where they can find out more. *Delete if not applicable.*

**Will I find out about the results of this study?**

It is almost always appropriate to offer to share a summary of the main findings of a research study with the participants in the study. Specify in the consent form if results will be shared and, if so, how they will be shared (e-mail to participant, letter to participants, posting on a website, handout to a class, presentation to a class, etc.) If participation in the study is anonymous, provide a means to share the results with participants while maintaining the anonymity of the responses of the individual participant.

**Statement of Consent:**

I have read this form and decided that I will participate in the project described. Its general purposes, the particulars of involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

For Adults able to Consent. Delete this line.

Participant’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Researcher: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Include if Participant Requires a Witness. Delete if not applicable.

**Witness Statement**

The participant was unable to read or sign this consent form because of the following reason:

[ ]  The participant is unable to read the information

[ ]  The participant is visually impaired

[ ]  The participant is a non-English speaking individual

[ ]  The participant is physically unable to sign the consent form. Describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Other (describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Include if the Participant Requires an Interpreter. Delete if not applicable.

As an interpreter for the participant, I declare that the English version of the consent form was orally presented to the participant in the participant’s own language, and that the participant was given the opportunity to ask questions about the study to make an informed decision.

Interpreter’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Interpreter’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For Adults Unable to Consent. Delete this line. Delete this section if not applicable.

As the Legally Authorized Representative (LAR) of the participant, your signature documents your permission for the named individual to participate in this study.

Participant’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of LAR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

LAR’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Add 2nd LAR’s signature, if applicable. Delete if not applicable.

Name of 2nd LAR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2nd LAR’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_