Protocol Title:

Principal Investigator:

Co-Investigator(s) (if applicable):

Faculty advisor (if applicable):

Study Title:

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| **INSTRUCTIONS FOR INVESTIGATORS:** Many sections of this document include brief instructions to provide the user with a general overview of the information required in the section. The instructions are shaded so that you can tell the difference between the instructions and the required information. While preparing your form, be cognizant of the reading level. The IRB advises that consent forms not exceed an eighth-grade reading level. If you have questions about this or need assistance please contact irbprotocols@simmons.edu. Detailed instructions for preparing consent forms are available at:[**https://www.simmons.edu/**](https://www.simmons.edu/)**irb****Please delete all shaded instruction boxes before submitting this form to the** **Institutional Review Board for review.** To delete, select a shaded box and click the cut button on the Word toolbar. |

**About this form**

This form will tell you important information about a research study. If you decide to participate in this study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

**INSTRUCTIONS:** Include the following paragraph **only** if some or all of the adult subjects are incapable of providing consent and permission for their participation will be obtained from their authorized representative. Delete the following paragraph when all subjects are adults capable of providing consent.

Some of the people who are eligible to take part in this study may not be able to give consent to participate because of their medical conditions. Instead, we will ask a guardian or an official representative to give consent. Throughout the consent form, “you” always refers to the person who takes part in the study.

**INSTRUCTIONS:** Include the following paragraph **only** when some of the subjects are minors (less than 18 years of age) and permission for their participation will be obtained from their parent(s)/guardian. Delete the following paragraph when all subjects are adults.

**Note: For studies that include minors or adults who cannot consent legally, use the Parent Consent Form, and if the participant is less than 18 years old and more than 7 years old or is an adult with a legal guardian, also prepare an Assent Form.**

Some people who can take part in this study may not be able to give consent because they are less than 18 years old. Instead, we will ask their parent(s) to give consent for them and ask the minor to agree (give their assent) to take part.

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| **KEY INFORMATION**This section is designed to meet the regulatory requirement that consent documents begin with a concise and focused presentation of key study information. The Key Information section should be no longer than 1-2 pages. Consent forms 5 pages or less do not require a key information section. The key information, along with the rest of the informed consent form should be written so that it is easily understood by someone with an 8th-grade education.This section aims to help potential participants understand why they might or might not want to participate in the research. This section should address: |
| * The information you hope to learn from the study.
* How long the participants will be in the study.
* What type of procedures/activities subjects will be asked to complete.
* Potential benefits to subjects or others that may be important in deciding whether to join the study.
* Important risks or reasons why a potential subject would not want to join the research study. For treatment studies, this might include side effects that are different from those associated with standard treatment. It could be those risks a clinician would consider essential to discuss with a patient.
* Appropriate alternative procedures or courses of treatment that might be advantageous to the subject.
* Contact information for the research team and IRB.
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**Introduction**

We are [faculty/students] from Simmons University in [course] and are doing a study to learn more about\_\_\_\_\_\_\_ We are inviting you to be part of the study to \_\_\_\_\_\_\_\_\_ because \_\_\_\_\_.

**Why is this research study being done?**

In this study, we want to learn more about \_\_\_\_\_.

**What will you have to do [explain what is involved]?**

During this study, we will ask you to be part of **[X visits, X interviews, or complete survey]**

If you decide to join this research study, you will be asked to\_\_\_\_\_\_\_ [indicate how their responses will be recorded, where, how their response will be saved/recorded]

and this is not expected to take more than \_\_\_\_\_ [**X minutes/ days/weeks/months/years]** [indicate how their responses will be recorded, where, how their response will be saved/recorded

**How long will the study last?**

We will be asking XX people to join the study, which will last for XXX months/years \_\_\_\_\_\_\_\_\_\_.

**Why might you choose to take part in this study?**

**[Include any potential direct benefits including any incentives.]**We hope to learn more about \_\_\_\_\_\_\_ to [help others in the future]. We cannot promise you will benefit in any way from being part of this research study. However, possible benefits may include \_\_\_\_\_.We will provide [$XXX for the time you are taking to be part of this study.]

**Why might you choose NOT to take part in this study?**

We do not believe there will be any harm to you as a result of this study. You may find some questions are hard to answer. There is a chance you may not want to answer some questions because they make you feel uncomfortable. You may refuse to answer questions at any time during the interview.

We do not expect you to bear any costs to be part of this study other than spending some of your time on it.

**How will my privacy be protected?**

[Please edit as necessary] Any information about you will be confidential to the extent possible by law. Each person who is part of the study will have a code number to keep your personal information private. This code will be known only to the researchers. Your name and personal information will never be shared with anyone outside of this research project. No one will be able to identify your personal information when the project is finished and when we share what we found.

[If recorded interviews, add: Any voice recordings will be destroyed within XXXX (6 months) after the study reports are completed.]

**Who can I call if I have questions or concerns about this study?**

Please feel free to ask any questions you may have about the study or your rights in the research project.

[Insert name and academic degrees] is the person in charge of this study. You can call him/her at [Insert phone number] [insert when the person is available M-F 9-5 or 24/7].

You can also call [Insert the name(s)] at [Insert phone number(s)] [insert when each person is available M-F 9-5 or 24/7] with questions about this research study.

If at any time during or after the study, you would like to talk about any questions or concerns about the study, you may contact our Simmons IRB Team at irbprotocols@simmons.edu or any faculty advisor at name@simmons.edu if applicable.

You can talk to them about:

* Your rights as a research subject
* Your concerns about the research
* A complaint about the research
* Any pressure to take part in, or to stay in the research study

**What should you do if you want to stop taking part in the study?**

If you take part in this research study and want to stop, you may tell us at any time and we will ensure that you will leave the study without penalty.

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| **INSTRUCTIONS:** At the end of the Key Information section, leave the remainder of the page blank and add a page break if needed. The next section of the consent form should start on a new page.  |

The purpose of the study has been explained to me. I understand my role and my rights as a part of this study and have had all my questions answered.

* I agree to be part of this study.
* I understand that I may quit at any time without any problems.
* I have been given a copy of this form

**Signature of Subject:**

I consent to participate in this research study and agree to allow my information to be used and shared as described above.

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_

I give my consent to be recorded via audio/video [specify if it is audio or video or both] for the purposes of this research project.

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_