Instructions for Consent Form

This form must be presented to potential participants to explain all of the information necessary to consent to participate. While preparing your form, be cognizant of the reading level. The IRB requires that consent forms not exceed an eighth-grade reading level. If you have questions about this or need assistance please contact irbprotocols@simmons.edu.

We have a template that includes all required sections. However, you will need to modify the information in each section as appropriate for your study.

About this form

- A statement explaining that the potential participant is invited to participate, what participation involves, and requesting their signed consent.

Include the following paragraph in the "About this Form" section **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. 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."

Include the following paragraph in the "About this Form" section **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.

> "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."

Introduction

- This section should explain who is conducting the study and the study objective(s).
- A statement that the study involves research.

Why is this research study being done?

- Include an explanation of the purpose(s) of the research.

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

- A description of the procedures to be followed
- The expected duration of the subject's participation
- Identification of any procedures which are experimental
- Explanation of how their responses will be recorded, where, how their response will be saved, and if audio or video recording is required to participate

How long will the study last?

- The expected duration of the entire study

Why might you choose to take part in this study?

- A description of any direct benefits to the subject or to others which may reasonably be expected from the research. If no direct benefits, this should be clearly stated in the consent form.

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

- A description of any reasonably foreseeable risks or discomforts to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
- An explanation of whether participants are expected to bear any costs or not by participating other than their time
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

How will your privacy be protected?

- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- An explanation of when any audio/video recordings will be destroyed, if applicable

Will your information [and/or type of biospecimens] be used for future research or shared with others?

- A statement explaining if the data may be used for future studies or shared with others or include a statement that the study information will not be used for future studies.

Will you be paid or given anything for taking part in this study?

- A description of any compensation that participants will receive for participation or an explanation that participants will not receive any compensation for taking part in the study
- If compensation will be included, a description of the process for how compensation will be determined and distributed. Also, include a description of how or if compensation will be distributed if the participant withdraws from the research before the end of the study.
- This statement must be added if you are offering research incentives or compensation regardless of whether they are paid in cash, gift cards, or other valuable property. "This incentive is considered taxable income by the IRS and you are required to report it on your personal income tax return. It is recommended that you consult a tax professional for personalized advice regarding how this may impact your specific tax situation. You can also refuse the incentive, should you choose."

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

- A statement explaining how participants can terminate their participation if they so choose
- A statement indicating that their decision to participate or not participate will have no negative or positive impact on their relationship with the institution where the study is being conducted

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

- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
    - This must include the contact information for the PI(s), faculty advisor if applicable, and Simmons' IRB at irbprotocols@simmons.edu

What will happen if you are injured by this research?

- This language in the consent form template has been provided by the Office of General Counsel for required inclusion in consent forms.
- Revise this section of the template to include potential risks of participating in your study. NOTE: only include "death" as a possible risk if it can be a direct result from participating in your study intervention.

Acknowledgement of participation and signature of consent

- A line for the participant to list their name, date and signature
- A line for the participant to consent to audio and/or video recordings