Creighton UNIVERSITY

Creighton University Institutional Review Board
2500 California Plaza, Omaha, NE 68178 • Phone: 402-280-2126
Email: irb@creighton.edu

Research Information Sheet

[Insert Study Title Here]

Instructions for Completing Your Research Information Sheet:

This is a required template for exempt projects and expedited studies for which the IRB has waived documentation of consent. Use of this template will speed up the IRB review and approval of your study.

Before you submit this document to the IRB, delete these instructions – both the text box containing these instructions and all text contained herein.

If your project is online research: (a) also remove the CU header and (b) include the contents of the research information sheet in the introduction section of the online survey.

The font color of the finished consent document must be black, and it must be a complete and accurate copy of the information that you will give to any potential research subject who is contemplating participation in this study.

The purpose of a research information sheet is to improve a potential participant's understanding of the study to help them decide whether they want to participate in the research.

You (the research investigator) should use language that the average person is likely to understand. Technical and scientific terms should be explained, or common terms substituted. The research information sheet must be written using the second person writing style (i.e., participant addressed as "you" and clinical investigators as "I/we").

The font must be easy-to-read and at least a 12-point size. If enrolling older adults, consider using a larger font size.

***BLUE** text represents information that you will need to fill out or add to this information sheet.*

***BLACK** text is the IRB's mandatory template language. **Unless the instructions on the following page(s) instruct you to delete information that does not apply to your study, please do not delete template language without first speaking to the IRB.** Federal law requires that specific information be provided to individuals who are contemplating participation in a research study. The template language in this information sheet was designed to ensure that all required elements of informed consent have been included.*

***RED** text provides information about template language that can be deleted if it does not apply to your study.*

Introduction
You have been invited to participate in a research study. The purpose of this Research Information Sheet is to help you decide if you want to participate. It is up to you whether you want to take part. You should only participate if you want to. Participation in this study is voluntary. If you decide to participate after reading this letter, you can change your mind and stop participating at any time. If you decide not to participate in this research or you decide to stop participating before the end of the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

This sheet may include words that you do not understand. Please ask the researcher to explain any words or procedures with which you are unfamiliar.

Study Summary
The purpose of this study is_____. You are being asked to take part in this research because you are_____[*participant description].* This study is for research purposes only. Your alternative to participating in this study is not to participate.

If you decide to participate in this study, you will be asked to _____ *[summarize what is expected of participants. Include study location].*

We expect that your participation in this study will take _____ *[time commitment]*.

Risks and Benefits of Participation
This study is minimal risk research, which means that the risks to you by participating in this study are no greater than the risks you ordinarily encounter in your daily life or during the performance of routine physical or psychological examinations or tests. Risks of participating in this study include [*list all reasonably foreseeable risks*]. As with participation in any research study, there may be risks to your confidentiality and privacy because of your participation in this study. The following measures are in place to help guard against these risks: *[list measures to protect confidentiality such as encryption, passwords, locked offices, other data storage methods.].*

There may or may not be direct benefit to you as a result of your participation in this study. This study may help researchers learn more about _____ *[benefits to researcher and society]*

Compensation
(Include if there is compensation, otherwise include the "no compensation" language below.)
You will receive ____ *[payment form (e.g. gift card), total amount of compensation, disbursement details, Make it clear compensation is not based on completing the study]* for your participation in this study. You will still receive this compensation if you choose to end your participation early.

OR

You will not be compensated for your participation in this study.

(*Include if collecting identifiers, otherwise delete.*)
What Will Happen to My Identifiable Private Information and/or Biospecimens?

Although we are asking for *[list identifiers, other information]* it is *[unlikely/likely]* that someone could identify you because [*rationale*].

(***If you are collecting identifiers, you are also required to include of the following statements below**. If you are not collecting identifiers, delete both statements.)*
Identifiers might be removed from the identifiable private information or identifiable biospecimens collected as part of this study and, after removal, the information or biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

OR

The information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(Keep the following paragraph if you plan to enroll CU students or faculty/staff members, otherwise delete.)
CU Students, Faculty, and Staff
If you are a Creighton University (CU) student or faculty/staff member, your decision about whether to participate in this study will not affect your grades, academic status, or job status at CU. You will not be offered or receive any special consideration if you take part in this research study. *[For studies that are giving class credit to participate, list the alternative option.]*

Contact Information
If you have questions or concerns about this study, please contact *[insert study team member and contact information]*. If you have questions about research participants' rights, contact the Creighton University Institutional Review Board (CU IRB) at 402-280-2126.

By choosing to participate in this study, I acknowledge or am aware that:

- The researcher(s) discussed the study with me and answered all my questions.
- I can contact the study team or the CU IRB using the contact information provided above if I have any questions or concerns about the study.

OR

(*For online research*)
By choosing to participate in this online survey, you consent to participating in this study. Click here to read the Bill of Rights for Research Participants.

Bill of Rights for Research Participants

As a participant in a research study, you have the right:

1. To have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.

2. To refuse to be in the study at all, or to stop participating at any time after you begin the study.

3. To be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you are in the study.

4. To be told about the reasonably foreseeable risks of being in the study.

5. To be told about the possible benefits of being in the study.

6. To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.

7. To be told who will have access to information collected about you and how your confidentiality will be protected.

8. To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research participant.

9. If the study involves treatment or therapy:

    a. To be told about the other non-research treatment choices you have.

    b. To be told where treatment is available should you have a research-related injury, and who will pay for research-related treatment.