[Focus Groups 1](#_Toc132321464)

[ClinicalTrials.gov 1](#_Toc132321465)

[Certificate of Confidentiality 1](#_Toc132321466)

[Prisoners 2](#_Toc132321467)

[Incomplete Disclosure/Deception 2](#_Toc132321468)

[Sexual Misconduct/Title IX 3](#_Toc132321469)

[Greater Than Minimal Risk Requirements 3](#_Toc132321470)

[Unforeseeable Risks 3](#_Toc132321471)

[Research-Related Injury Language 3](#_Toc132321472)

[Right of Investigator to Withdraw Participants 3](#_Toc132321473)

[New Information 3](#_Toc132321474)

[Number of Participants 4](#_Toc132321475)

[Reproductive Risks 4](#_Toc132321476)

[Optional Element(s) 4](#_Toc132321477)

[Legally Authorized Representative Signature Block 5](#_Toc132321478)

## Focus Groups

**In the section titled “How will the researchers protect my information?” add the following:**

“Although we ask everyone in the group to respect the privacy and confidentiality of participants, and to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting.”

## ClinicalTrials.gov

**If the study is a clinical trial that will register and report results on ClinicalTrials.gov:**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## Certificate of Confidentiality

**If the study either has NIH funding or will apply for a Certificate of Confidentiality (without NIH funding):**

**In the section titled “How will the researchers protect my information?“, add the following:**

**Certificate of Confidentiality:**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed.  This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.  
   
Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.  The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).  The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.  
   
Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.  The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

## Prisoners

**If the study will enroll prisoners:**

**In the section titled “Will being in this study help me in any way?” include the following:**

Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

## Incomplete Disclosure/Deception

**If the study will use incomplete disclosure and/or deception as research techniques:**

**If you intend to withhold information about the real purpose of the study or purposely give participants false information about some aspect of the research (i.e., incomplete disclosure or deception), include one of the following statements in the “Key Information” section of the consent. There are occasionally situations where the potential harms to participants from debriefing may outweigh the benefits of disclosure – those situations will be rare; if you plan not to debrief participants regarding the use of deception/incomplete disclosure, you must explain in the protocol document why you think the harms of debriefing could outweigh the benefits. For further guidance on the use of deception and incomplete disclosure in research, see the NU IRB’s guidance document at:**

For scientific reasons, this consent form does not include complete information about the research questions or topics being tested. You will be fully debriefed following your participation in the research, and you will have the right to withdraw your consent at that time. If you withdraw your consent, your personal information will be deleted.

**OR**

We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these conditions, we will explain the procedure to you fully after your participation, and you will have the right to withdraw your consent at that time. If you withdraw your consent, your personal information will be deleted.

## Sexual Misconduct/Title IX

**If your study may lead to disclosure of information relating to sexual misconduct that involves at least one member of the NU community (including sexual harassment and violence):**

I (or the Principal Investigator on this study) may be required by law to report to appropriate UIUC authorities any information you provide to me that indicates sexual misconduct, including sexual assault, sexual exploitation, dating violence, domestic violence, stalking, and sexual harassment. Therefore, I cannot promise you complete confidentiality of any information you share with me about experiences of sexual misconduct.

## Greater Than Minimal Risk Requirements

Add each of these sections to the consent document(s) for greater than minimal risk research.

### Unforeseeable Risks

State that participation in the study may involve risks that are currently unforeseeable.

*Example: In addition to the risks listed above, you may experience a previously unknown risk or side effect.*

### Research-Related Injury Language

To be updated

### Right of Investigator to Withdraw Participants

Describe foreseeable circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent. **This section may be omitted if there are no anticipated circumstances under which the subject’s participation may be terminated.** If withdrawal of a participant by the investigator can occur, possible reasons should be listed. Describe any procedures required for an orderly termination of participation.

*Example: The investigator can withdraw you without your approval. Possible reasons for withdrawal include <<list reason(s) why the participant may be withdrawn>>.*

Include a description of any adverse effects on the participant’s health or welfare, or follow-up that may be requested if the participant is withdrawn from the study.

### New Information

State that new findings developed during the course of the research that may affect to the participant’s willingness to continue participation will be provided to the subject. **This section may be omitted if new information could not reasonably used to alter participation (e.g. one-time interventions).**

*Example: Sometimes during the course of a research project, new information becomes available about the <<treatment/drug>> that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study.*

*Example (additional text if applicable): If you decide to withdraw at that time, your research doctor will make arrangements for your medical care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your medical care to continue.*

*Example: During the course of this study, you will you be informed of any significant new research findings (either good or bad), such as changes in the risks and benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.*

### Number of Participants

State the approximate number of participants to be enrolled. Indicate whether this study is part of a national study.

***Example****: We expect to enroll <<enter number>> participants at the University of Illinois Urbana-Champaign.*

***Example****: We also expect to enroll <<enter number>> participants* *at <<enter number>> other other centers.*

## Reproductive Risks

For studies involving possible reproductive risks, please include a section that includes the following:

1. State any known risks in pregnancy, either to mother or child.
2. State that there may be unforeseeable risks to the participant (or to the embryo or fetus) if the participant is pregnant or becomes pregnant during the study.
3. List the acceptable methods of birth control for this research project.
4. Describe what action will occur in the event of pregnancy (i.e. follow-up of pregnancy outcome, immediate withdrawal from the study, etc.)

***Example****: It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not take part in this study, nor should women who plan to become pregnant during the study. Women who are at risk of pregnancy will be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. If you could become pregnant must use an effective contraceptive during the course of this study. Acceptable methods of birth control include <<list acceptable methods>>. If you become pregnant while taking part in the study, you must immediately tell your research doctor. Options will be discussed with you at that time. Whether or not you remain on study treatment, we will follow the outcome of your pregnancy and we will continue to follow you according to the study plan.*

## Optional Element(s)

[Include for any optional elements of the research approved by the IRB. Otherwise, delete.]The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

| **I agree** | **I disagree** | | |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_ | The researcher may [Describe the optional procedure or activity.] . | |

[Example: The research may take photographs. Although efforts will be made to protect your identity, your identifiable image(s) from this study may be viewable indefinitely in electronic media (such as the internet) and in print media (such as books and journals). In addition, your identifiable image(s) will not be used for advertising or promotional purposes]

## Legally Authorized Representative Signature Block

Include the entire section below:

**If the participant is unable to give consent and authorization, consent and authorization is given by the authorized personal representative of the individual:**

**LEGALLY AUTHORIZED REPRESENTATIVE CONSENT STATEMENT:**

I confirm that I have read this consent and authorization document. I have had the opportunity to ask questions and those questions have been answered to my satisfaction. I am willing and authorized to serve as a surrogate decision maker for

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Participant’s Name

I have been informed of my role and my obligation to protect the rights and welfare of the participant. I understand that my obligation as a surrogate decision maker is to try to determine what the participant would decide if the participant were able to make such decisions or, if the participant’s wishes cannot be determined, what is in the participant’s best interests. I will be given a signed copy of the consent and authorization form to keep.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Authorized Personal Representative

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Authorized Personal Representative Date