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## 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.”

**Abuse/Neglect/Sexual Misconduct/Title IX****In the event that research procedures may elicit information relating to harassment, discrimination, or retaliation occurring on a Purdue campus, the following statement must be included in “Who will see information about me collected in this study?”**

“Under federal law, Purdue researchers must report all incidents of discrimination, harassment, and/or retaliation in the Purdue workplace and/or educational environment to the Title IX Coordinator or Equal Opportunity/Affirmative Action Officer. “Harassment” includes sexual harassment, sexual violence, rape, and any non-consensual sexual act. “If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.”

**If conducting research in areas that may trigger mandatory reporting requirements (e.g., child abuse and/or neglect), this must be disclosed** with the following statement in *“***Who will see information about me collected in this study?”**

“Under Indiana law, Purdue researchers must report any suspected child abuse or neglect to law enforcement or to the Department of Child Services hotline.”

Include one of the following statements in studies in which researchers are probing for or likely to elicit information about child abuse or neglect. All Purdue University employees (including faculty, staff, and student employees) are required by Indiana law and by Purdue policy to report suspected cases of child abuse and/or neglect.

If we learn about current or ongoing child abuse or neglect, under Indiana law, Purdue researchers must report any suspected child abuse or neglect to law enforcement or to the Department of Child Services hotline

or

We will not ask you about child abuse, but if you tell us about child abuse or neglect, under Indiana law, Purdue researchers must report any suspected child abuse or neglect to law enforcement or to the Department of Child Services hotline.

## Certificate of Confidentiality

If the study either has NIH funding or will apply for a Certificate of Confidentiality (without NIH funding), add the following to the section titled, **“How will the researchers protect my information?”**

**Certificate of Confidentiality:**

“This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. For additional information about CoCs see <http://grants.nih.gov/grants/policy/coc/faqs.htm>.”

## Conflict of Interest Disclosure

**Required only if one or more research team members have a conflict or proprietary interest in the study and the IRB determines that your study requires disclosure of this fact. Otherwise, you may omit this section. Note this language will be reviewed by Purdue’s FCOI team prior to IRB approval. Please review your Management Plan and contact** [**fcoi@purdue.edu**](mailto:fcoi@purdue.edu) **with any questions on the language to include in your consent.**

Identify those with a financial interest and the use of any data for potential commercial relationships.

***Example:*** *The following disclosure(s) is(are) made to give you an opportunity to decide if this(these) relationship(s) will affect your willingness to participate in the research study.*

## Greater Than Minimal Risk

**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.*

### 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 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.*

# Research-Related Injury Language:

**Please use the following language verbatim in the section “What happens if I become injured or ill because I took part in this study?”**

“If you feel you have been injured due to participation in this study, please contact [provide the name, phone number and any other contact information of an individual associated with the research study who can be reached at all times.]

Purdue University will not provide medical treatment or financial compensation if you are injured or become ill as a result of participating in this research project. This does not waive any of your legal rights nor release any claim you might have based on negligence.”

### Number of Participants

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

***Example****: We expect to enroll <<enter number>> participants at Purdue University.*

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

## Clinical Trials

**Required only if the study is an NIH-funded clinical trial, is FDA-regulated, or you will register the study on ClinicalTrials.gov. Otherwise, you may omit this section.**

“A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.”

## Genomic Data Sharing

If your study requires you to share the genomic information into a database (e.g., NIH dbGAP) or similar, add this language under the heading “**Genomic Data Sharing**”:

“If you agree to take part in this study, some of your genetic and health information will be placed into a scientific database called “dbGaP” that is maintained by the National Institutes of Health. Other researchers may be able to see and use your genetic information, but your name and other information that could directly identify you will not be used. Your genetic information is unique to you, however, there is a small chance that someone someday could trace it back to you. In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance and employment discrimination based on genetic information obtained about you. In general, this law makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long-term care insurance.”

## What alternatives are available?

**This section is not required unless this is a treatment study.**

If this is a treatment study, list any and all currently available alternative procedure(s) that might be available to participants.

If there are no alternatives to participation, simply state that individuals may choose not to participate in this research study.

## 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.

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Name of Authorized Personal Representative

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Signature of Authorized Personal Representative Date