**Informed Consent Checklist**

You must create your own informed consent document ensuring all required elements are present. There are required elements for all projects and additional required elements based on your specific project. Below are the requirements listed with sample language for each. Edit the sample language to include specific information about your project and upload your informed consent document into your Kuali protocol for IRB approval

Remember to read through the **Additional Elements** section to determine if any of those are applicable to your study.

This Informed Consent Checklist is applicable to all non-exempt projects using subjects over the age of 18. If you are using children or have an exempt project, please follow the links below to access the appropriate documents you need.

* [**Exempt Research Participation Notification**](https://www.siue.edu/graduate/pdf/IRB-Research-Participant-Notification.pdf)
* [**Child Assent**](https://www.siue.edu/graduate/pdf/IRB_Child%20Assent%20Form.docx)
* [**Parental Consent**](https://www.siue.edu/graduate/forms/IRBParentalAcknowledgmentofInformedConsentunder18parent-guardian.doc)
* [**Audio/Visual Consent**](https://www.siue.edu/graduate/pdf/Audio%20Video%20Digital%20Recording%20Release%20Consent%20Form.docx)

Please see our [Informed Consent FAQ](https://www.siue.edu/graduate/faqs/pages/Informed-Consent-Options.shtml) for more information.

# Does the consent information begin with a “concise and focused presentation of key information?”

Discussion

Informed Consent must begin with a “concise and focused presentation of key information” that would assist subjects in deciding why they may or may not want to participate in the research. Organize and present it in a way that facilitates comprehension by your target audience.

Sample Language

* "You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is unclear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study."

# Is there a statement that the study involves research and an explanation of the purposes of the research?

Discussion

An explanation that the study involves research and the purpose of the research must be included. Briefly tell the participant why this research is being done, why the individual is being invited to participate and how this study will address the problem. Identify yourself, your affiliation to SIUE, and any other researchers involved and their affiliations.

Sample Language

* "[Name(s) and rank(s) of Investigator(s)] is/are inviting you to participate in this **research study**. The purpose of the study is <<explain purpose of the research using simple, accurate language>>. This study is being conducted by <<insert sponsor, granting agency, investigator, etc.>>."

# Is the expected duration of participation stated?

Discussion

The expected duration of participation must be stated. If applicable, include the total length of time that the participants will be involved in all activities. If your study involves multiple activities (such as an interview, survey, and focus group), it must be clear if:

* participants have the option to consent to individual activities and
* you must make it clear to the IRB how you are capturing that information during your consent process.

Sample Language

* "The anticipated time for your participation in this research is approximately <<insert time, e.g. 1 hour, 3 hours, 1 day>>."
* “Your participation in this study will involve [describe the subject’s participation and duration in the research].”

# Is there a description of any foreseeable risks or discomforts to the participant?

Discussion

Describe any reasonably foreseeable risks, discomforts or side-effects the participant may experience AND the steps you are taking to mitigate those risks.

Sample Language

* "The risks of this study are minimal. You may feel upset thinking about or talking about personal information related to <<insert topic>>. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience, you can tell the researcher, and he/she will tell you about resources available to help."
* “Almost all students who are learning about public speaking will feel some nervousness about having to talk in front of a group. If you seem to be feeling more than a normal amount of nervousness, we will help you feel at ease, take you out of our study, and get you the same kind of individual tutoring that is always offered during the public speaking unit. We do not think that either the hands-on training in relaxation techniques or the video tapes about relaxation will increase your nervousness. If that would happen, we would see that you got the individual tutoring that was necessary

# Is there a description of any benefits to the participants or others?

Discussion

A description of any benefits to the participants or to others that may be reasonably expected from the research must be included. Do not state or imply that compensation to be offered to participants is a benefit. The description of benefits to the participant must be clear and not overstated to avoid coercion. If no direct benefit is anticipated, **it must be stated that there is no direct benefit anticipated.**

Sample Language

* "There are no direct benefits for taking part in this study. However, we hope the information we get from this study may help develop a greater understanding of <<insert topic>> in the future."

# Is there a statement describing the confidentiality of records?

Discussion

A statement describing the extent, if any, to which confidentiality of records identifying the research participant will be maintained must be included. This must include information about storage of the records and data pertaining to the participant and how confidentiality will be protected. Include who may have access to the data or if you are required to provide data to any sponsors or third parties.

Sample Language

* "Your name <<will/will not>> be kept with your responses from <<the interview, focus group, questionnaire, etc.>>. In publications, your name will be <<used, removed, protected, etc.>>."
* We will keep a record of your scores and grades during your public speaking course at SIUE. The record will include your age, year in school, major, sex, and race. However, the record will NOT include your name, address, social security number, school ID number or any other personal information. While we are working in your class, the record will be open to your public speaking instructor. After our work with your class is done, the confidential records will be kept in a file cabinet and on computer files at our SIUE offices. They will be open to members of our research team. Data may be shared with the study sponsor, the National Science Foundation.

# Is there a statement that participation is voluntary and individuals may refuse to participate or discontinue participation?

Discussion

A statement that participation is voluntary must be included Note if there are no consequences to the participant withdrawing and that they can withdraw at any time. The informed consent process must include a statement that the refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and they may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

*If there are any possible consequences of a participant’s decision to withdraw from the research, it must be explained.*

Sample Language

* “You can choose not to participate. If you decide not to participate, there will not be a penalty to you or loss of any benefits to which you are otherwise entitled. You may withdraw from this study at any time.
* "If you want to stop being in this study, please let the research doctor know. That way you can find out what should be done about your normal medical care outside of the study."
* “If you decide to take part, you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don’t take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient."

# Is there a statement about any alternative procedures?

Discussion

This section must include a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. (If there is no alternative procedure, simply state that there are no alternative procedures for this research except for non-participation.)

Sample Language

* If you choose not to participate in the research project, the researcher will provide an alternate course of treatment or procedure for you to participate in which may be similar to the research activity or may simply be the option of nonparticipation.

**Additional Elements that may be Necessary Depending on your specific project:**

# Is there a description of any compensation given to the participant, including the anticipated prorated payment, if any?

Discussion

Explain whether participants will be compensated. Specify the overall amount, schedule of payment(s) (if applicable) and any plan for prorating payments if a participant does not complete the study or if completion is required. It must not be implied that compensation is a benefit to participants. Therefore, it is best to explain compensation separately from the description of benefits.

Depending on the amount of compensation and the method used to make the payment, tax information may need to be collected from participants and shared with SIUE Accounts Payable.

Sample Language

* "You will not receive payment for taking part in this study."
* “You will receive a $25 electronic gift card for participating in this study.
* If collecting tax information for Accounts Payable: “Since you will be paid for participating in this study, it is necessary for us to collect your Social Security Number. You will provide this information for a Federal W-9 Form that is filed with our Accounts Payable department. The amount you receive for taking part in this study will be turned into the Internal Revenue Service (IRS) as taxable income. You can choose not to provide us with your Social Security Number for this form and still participate in this study; however, we will not be able to pay you as outlined in this consent form.”

# If applicable, is there a statement about the investigators’ conflict of interest?

Discussion

A management plan may require a disclosure of conflicts of interest to all potential research participants in the informed consent document. The informed consent document must describe the financial interest in the consent form.

Sample Language

* “<<Investigator’s name>> <<describe real or apparent conflict of interest, e.g., receives payments for lecturing for, has an equity interest in, receives royalty from a patent associated with, or serves in an executive position with>> <<sponsor name>>, a sponsor of this research study. This conflict has been reviewed and managed by the SIUE Office of Research & Projects.”
* “A company called <<insert name of sponsor>>, who is the sponsor of the study, is paying for this study. The study investigators and members of the study team receive compensation from <<sponsor name>> for your participation in the study as well as for the time and materials used to track your progress in the study.”

Created with thanks to University of Utah