This template is for non-Exempt Social, Behavioral, and Educational Research

Informed Consent Form Template Instructions

1. This template is intended to assist the Principal Investigator and study teams in the design of their informed consent form (ICF). It is important that study teams adapt their own ICFs to the outline and requirements of their particular study.

2. This form is not to be used for exempt studies. If your study falls within an Exempt category of IRB review, please utilize our Information Sheet Template provided on our website or within IRBNet Forms and Templates.

3. **Delete this instruction page prior to IRB submission**.

4. In this template:
   - Standard lettering is used for explanations to researchers only and **must not be included in your consent form**.
   - Examples are provided in blue. Some language in blue is mandatory. Instructions for mandatory language is listed in the black standard lettering.

5. When writing the consent form, remember the following:
   - The consent document is an invitation to participate in a research study that should be composed using second person language with complete, grammatically correct sentences. Scientific jargon and legalese are not appropriate. The PRISM Readability Toolkit can assist in improving the readability of research materials.
   - Language used throughout this form should not be written above an 8th grade level.
   - Use reader-friendly formatting so your document *looks* easy to read. Use 1" margins and include sufficient white space between headings and paragraphs. Use subheadings, bulleted lists, tables, etc. to improve readability. Use clean, black, minimum 12 point font (preferably times new roman).
   - Use page numbers and a version number and/or date within the header or footer.

6. There may be other elements you need to include in the consent form depending on the design of your study. Review our Institutional Boilerplate Language for additional elements that may be required.
Pay special attention to:
   - HIPAA language (required if you will be collecting PHI in a covered entity)
   - Research-related injury (required if your study is greater than minimal risk)
   - Debriefing (deception studies)

7. There are additional requirements when minor participants are involved. Refer to the Office of Research Compliance and Assurance's website for additional information on the use of minors in research.

UNIVERSITY OF SOUTH ALABAMA
CONSENT FORM FOR RESEARCH

Title of Study: [Insert title of the research study]

Principal Investigator: [Insert PI name]

Contact Information:

Advisor: [Student studies ONLY – Include faculty advisor name and department]

Collaborating Institution: [If applicable]

Key Information

This section is **NOT** required for:

- Exempt studies
- Consent documents that are **less than four (4) pages**

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding why one might or might not want to participate in the research. This part of the consent form must be organized and presented in a way that facilitates comprehension. The following list of topics should be included in the **key information** section, though this may not be all-inclusive depending on the complexity of the study:

- The fact that consent is being sought for research and that participation is voluntary
- Purposes of the research, expected duration of the prospective participant's participation, and the procedures to be followed
- Reasonably foreseeable risks or discomforts to the prospective subject
- The benefits to the prospective subject or to others that may be reasonably expected.

All of the information in this section should be described in further detail in the body of the consent document - think of it like an abstract for your consent document. Depending on the complexity of the research study and procedures involved, this section may be brief (a few sentences) or lengthier (more than one paragraph).

Example:
Here you will find a brief summary of key points to inform you about this research study. You can find more detailed information throughout this document. Please read the entire consent form or have someone read it with you. If there is anything you do not understand, please talk to the study team to have your questions answered before signing the consent form.

You are being asked to participate in a voluntary research study. The purpose of this study is to [briefly insert purpose in lay language]. Participating in this study will involve [briefly insert procedures in lay language] and your participation will last [duration].

Risks related to this research include [briefly describe risks and/or reasons a person may decide not to participate]. Potential benefits include [briefly describe benefits].

Note: If your research includes an optional sub-study, briefly summarize here.

Voluntary Participation

Indicate clearly that participants can choose to participate or not. Explain that they can stop the study at any time and provide instructions on how to notify the research team on their desire to discontinue.

Example:
This is an invitation to participate in a research study. Your participation is completely voluntary. It is your choice to participate or not. If you agree to participate, you can withdraw at any time without penalty or consequences.

Purpose

State that you are inviting the individual to participate in the research study. Explain **in lay terms** why you are doing the research. The language used should clarify rather than confuse. Avoid using terms like indicators, determinants, equitable, etc.

Example:
This study is being done in order to note how well a person's memory works when under stress. We hope to learn how stress affects memory under different situations. This information can help create tools that people can use to increase their memory.

How Participants Will Be Selected

Explain how participants will be selected for this research study. Include the basis of selection for the study and the basis for exclusion from the study, if any.

Example:
You are being invited to participate in this study because you are a psychology student at USA and are 18 years of age or older.

Procedures

Briefly describe all procedures participants will perform and locations where they will be performed. Identify any procedures which are experimental. State approximate time required for each procedure. If more than one procedure, also state the entire length of time / total duration. Specify all costs to participants, if any. If none, state there are no costs to the participant.

Example:
If you decide to participate in this study, you will be asked to come into the behavioral clinic twice within a 30 day period. At each visit you will be interviewed by someone from the research team. You will also be asked to complete a questionnaire before and after each interview. There are no costs for you to participate in this study.

Audio / Video Taping

If your study involves the use of audio and/or video recording, you must include a place for the participant to opt out of being recorded. If the participant must be recorded for the study, then it will need to be clearly stated that they cannot participate if they do not wish to be recorded.

Example 1:
This study involves audio recording. By participating in this study and signing this consent, you agree to be audio recorded. If you do not wish to be recorded, please decline to participate in this study.

Example 2:
This study involves the use of audio/video recording. Please initial one of the following:

____I agree to be audio/video recorded

____I do not wish to be audio/video recorded

If you do not wish to be audio or video recorded, your answers will be documented by handwritten notes.

Risks

Describe the known risks to participants from participating in the research itself, if any. Potential risks can include physical, psychological, and social risks/discomforts; potential breach of confidentiality; and/or placing a participant at risk of criminal or civil liability if information is released outside of the research. If the research involves psychologically sensitive information, resources should be included for participants experiencing a crisis. If you will be collecting identifying information, it should be disclosed that there is a risk of loss of confidentiality.

Example 1:
As part of this study, we will be recording your identifying information. Any time information is collected there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

Example 2:
It is unlikely that this study will cause physical harm. Some of the answers you provide may be very personal or indicate behavior which you do not want made public. You may experience embarrassment or distress at sharing your answers. The interviewer may ask you questions that are uncomfortable to answer. You do not have to answer any question that makes you

uncomfortable. If you are experiencing a psychological crisis at any point in the study, we encourage you to contact the National Suicide Prevention Hotline by calling or texting 9-8-8.

Example 3:
To the best of our knowledge, the risk of harm and discomfort from participation is no more than you would experience in daily life.

Disclaimer: Sensitive Survey Topics

The following disclaimer must be included in an information sheet/consent form for any survey of **USA faculty/staff** that includes sensitive topics:

Mandatory, if applicable:
Study results will not be reported to the University of South Alabama Human Resources. The individual subject is responsible for reporting any violation of University policies to Human Resources.

Potential Benefits

Describe the potential direct or indirect benefits to participants from participating in the research. If none, state there are none. State potential benefits, if any, to science or society that can be expected from the research.

NOTE: Compensation/incentives associated with research participation is not considered a benefit and must not be included within this section.

Example:
If you participate in this research there will be no direct benefit to you. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Alternatives to Participation

This section may not apply to your study as there may not be an alternative to participation.

If the participant population includes USA students and the research is being offered as **extra credit**, **an alternative must be included**. A description and explanation of the procedures that will be employed to provide alternative yet equal activities/extra credit for those who do not wish to participate in the research must be included in the consent. If this applies to your study, the below statement is mandatory based on your population:

Mandatory if enrolling SONA Students:
You do not have to participate in this or any other studies to receive subject pool credits. Credits may also be obtained by writing summary papers as described in the class syllabus.

Mandatory if enrolling USA Students:
You do not have to participate in this or any other study to earn additional credit. Extra credit

may be obtained by [describe the alternative]. Additional information is outlined in the class syllabus.

Confidentiality

Explain how the research team will maintain the confidentiality of data or if the data will be anonymous. List all efforts that will be made to protect confidentiality of data such as names being kept separated from the information and replacing names with codes/numbers. Additionally, the participant should be made aware of who will have access to the data and how long the data and potentially identifying information will be retained.

Example 1:
This study is anonymous. No identifying information is being collected as part of the research study. The data will be stored in a locked file cabinet in a locked room. Only the researchers have access to this information. Data will be stored for approximately 10 years.

Example 2:
You will be asked to provide your name and email address during this study. Your information will be kept confidential by all identifying information being replaced with a number. Data collected during this study will be stored securely on a password protected computer in a locked room. Only the PI of the study will have access to the data. Data will be stored for 7 years.

NIH Certificate of Confidentiality

If the study is funded by the NIH and collects **identifiable,** sensitive information (e.g., illegal activities, use of illegal substances, undocumented immigrant status, etc.), research subjects must be told about protections afforded by the NIH Certificate of Confidentiality and any exceptions to those protections.

Example:
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 give permission. 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.

There are some important things that you need to know. 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. This 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. This certificate does not prevent your information from being used for other research if allowed by federal regulations.

Mandated Reporting

For studies in which researchers are likely to elicit information about child abuse or neglect, it must be disclosed in the consent form that this information will be reported.

Example:
If we learn about current or ongoing child abuse or neglect, it is our ethical and legal responsibility to report such situations to the appropriate authorities.

Compensation

Describe any monetary compensation or other incentives for participating in the research study that will be offered to all participants. This may be as compensation for time and effort or as an incentive to participate. Monetary compensation should not be referred to as 'payment' or 'incentive.' Compensation must be minor and may not constitute undue influence to participate. The contact information of the participant for purposes of compensation must be kept on forms or files separate from the project data. **If there is no compensation, provide a statement that they will not be compensated or offered any incentives for their participation.**

Example 1:
You will be compensated for time and travel. You will receive a $20 gift card at the end of each completed visit.

Example 2:
You will not be compensated for your participation in this research study.

If a raffle or drawing is being offered as compensation for participation, the following paragraph **must** be completed and inserted into the consent form:

Mandatory if applicable:
You will be included in a drawing of _____(amount) by _____ (gift card / check) for the completion of _____ (questionnaire / survey / donation of samples). The likelihood of being chosen is dependent on the number of participants, and it is expected that _____ (number of questionnaires, etc.) will be completed. The drawing will be conducted at _____ (location) in the presence of _____ (advisor / staff member / faculty) on _____ (date/time). You will be contacted by / through _____(phone call / email) if you have been selected.

HIPAA

If your research falls under HIPAA regulations, please insert your completed HIPAA Template within this section. The required USA HIPAA language/template can be located in our Institutional Boilerplate Language.

NOTE: If your research project does not fall under the HIPAA regulations or take place within a USA Covered Entity please disregard this section.

Contacts and Questions

Include PI contact information as well as IRB office contact information.

Example:
For more information about this research, please contact [insert PI name and contact information]. For questions about your rights as a research participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the University of South Alabama Institutional Review Board office at 251-460-6308, toll-free at 866-511-6509, or via email at irb@southalabama.edu

Agreement to Participate

This section should have a statement similar to the one below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. This section should avoid statements that have "You understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of consent.

Example:
You have read or have had read to you this research consent form. You have had an opportunity to ask questions which have been answered to your satisfaction. You voluntarily agree to participate in this research as described. You will receive a copy of this consent form.

_____
Participant Name (printed)

_____ _____
Signature of Participant Date

_____
Name of Person Obtaining Informed Consent (printed)

_____ _____
Signature of Person Obtaining Informed Consent Date