This template is for <u>non-Exempt</u> Social, Behavioral, and Educational Research

Informed Consent Form Template Instructions

1. Please note that this is a template to assist the Principal Investigator in the design of their informed consent form (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.

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

3. **<u>Delete this instruction page prior to IRB submission</u>**.

4. In this template:
- Square brackets indicate where specific information is to be inserted
- Bold lettering indicates sections or wording which should be included
- Standard lettering is used for explanations to researchers only and **must not be included in your consent form**.
- Examples are provided in *blue italics*. Some language in blue italics 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. Additionally, scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool and not as a legal instrument.
- Language used throughout this form should be written at an 8th grade level.
- Use reader-friendly formatting so that 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, 12 point font (preferable times new roman).
- Make sure that a version number and/or date is used within the header/footer.

6. Remember that there may be other elements that you need to include in the consent form depending on the design of your study. Review the Office of Research Compliance and Assurance's website for a full list of elements. Pay special attention to:
- <u>HIPAA language</u>
- ICF Checklist
- Debriefing (deception studies)

7. There are additional requirements when minor participants are involved. Refer to the Office of Research Compliance and Assurance's <u>website</u> 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]

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

Key Information

45 CFR 46.116 General Requirements for Informed Consent:

"Informed consent must begin with concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension."

Key Information is **NOT** required for:

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

Here you will find a brief summary of key points to inform you about the research study you are being invited to participate in. You can find more detailed information throughout this document.

You are being asked to participate in a voluntary research study. Even if you decide to join the study, you are free to leave at any time if you change your mind. The purpose of this study is to [briefly insert purpose in lay language here]. Participating in this study will involve [briefly describe procedures in lay language here] 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]; and benefits related to this research include [briefly describe the benefits]. The alternative to participating in this study is to [provide alternative procedure or treatment, if any].

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

Purpose

State that you are inviting the individual to participate in the research being conducted. 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. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

(Example: You are invited to participate in this research study. 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 their locations. 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: 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, [include option of how to proceed] *please decline to participate OR 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; information to be collected could place a

participant at risk of criminal or civil liability if information is released outside of the research; potential breach of confidentiality.

(Example 1: To the best of our knowledge, the risk of harm and discomfort from participation is no more than you would experience in daily life.

Example 2: 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 your uncomfortable. It is unlikely that this study will cause physical harm.

Example 3: Due to the nature of this study, there is a possible risk for loss of confidentiality.)

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 subject population includes USA students (e.g., students in a classroom or 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 must be included in the consent. If this applies to your study, the below statement is mandatory based on your population:

(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.

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: This study is anonymous. No identifying information is being collected as part of the research study. The data is 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.

OR

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.)

Payment

Describe any payment or incentives for participating in the research study that will be offered to <u>all</u> participants. This may be as compensation for time and effort or as an incentive to participate. Incentives must be minor and may not constitute undue influence to participate. If the incentive involves entering a raffle or drawing for a prize, describe the drawing, prizes, and approximate likelihood of winning. The contact information of the participant must be separate from the project. **If there is no payment, provide a statement that they will not be compensated or offered any incentives for their participation.**

(Example: You will be compensated for time and travel. You will receive $20 at the end of each completed visit.)

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

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 _____ (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.

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: Your participation in this research study is completely voluntary. It is your choice whether to participate or not. You can withdraw from the study at any time without penalty or consequences. Tell the study team if you are thinking about stopping or decide to stop.)

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 IRBNet Forms and Templates.

NOTE: If your research project does not fall under the HIPAA regulations/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, the purpose and procedures of this research. 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.)

_____

Participant Name (printed) Date

_____

Signature of Participant Date

_____

Signature of Person Obtaining Informed Consent Date