

This template is for Social, Behavioral, and Educational research (This is NOT for exempt studies)

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 forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study.
2. This form is not to be used for exempt studies. Review the Office of Research Compliance and Assurance's [website](#) for additional information on the appropriate consent form.
3. Delete this instruction page prior to IRB submission.
4. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
5. 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 forms**.
 - examples are provided in *blue italics*. Some language in blue italics is mandatory. Instructions for mandatory language is listed in the black standard lettering.
6. When writing the consent form, remember the following:
 - The consent document is an invitation to participate in a research study that should be composed in second person with complete grammatically correct sentences. Additionally, scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
 - Language used throughout form should be at the level of a local student of class 6th/8th
 - Use reader-friendly formatting so that your document *looks* easy to read (i.e. wide margins and bullet points).
 - Make sure that a version number and/or date is used

7. 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:

- ClinicalTrials.gov language
- HIPAA language
- ICF Checklist
- Debriefing (deception studies)

8. There are additional requirements when minors 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**

[Insert title of the study]

Principal Investigator: [Include contact information]

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

KEY INFORMATION

Consent forms that are >4 pages must provide a concise overview of key information that may influence a potential participant's decision to participate in the research. This information is **NOT** required for (i) exempt studies or (ii) consent documents that are four or less pages in length. **If your consent document is ≤ 4 pages in length, then you can delete this section.**

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 here]. Participating in this study will involve [briefly describe procedures here] and your participation will last [duration].

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

IS MY PARTICIPATION VOLUNTARY AND CAN I WITHDRAW?

Indicate clearly that they 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 is entirely 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.)

WHAT IS THIS STUDY ABOUT?

State that you are inviting them 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 consider participating 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.)

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Briefly describe all procedures participants will perform, and their locations. State approximate time required for each procedure.

(Example: If you decide to participate in this study, you will need 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. Additionally, you will complete a questionnaire before and after the interview. The interviewer may ask you questions that are uncomfortable to answer. You do not have to answer any question that makes you uncomfortable.)

Audio / Video Taping: If your study involves the use of audio 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: Please initial one of the following:

 I agree to be audio/video taped

 I do not wish to be audio/video taped

WHAT RISKS CAN I EXPECT FROM BEING IN THE STUDY?

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

(Example: 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. It is unlikely that this study will cause physical harm.)

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Describe the potential direct or indirect benefits to participants from participating in the research. If none, state there are none.

(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.)

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

This section may not apply because there may not be an alternative to participate. If the research includes USA students (i.e., 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.

(Example: You do not have to participate in this or any other study to earn additional credit. Extra credit may be obtained by writing a two-page summary of chapter 12 in the textbook. Additional information is outlined in the syllabus.)

HOW WILL MY INFORMATION BE PROTECTED?

Explain how the research team will maintain the confidentiality of data or if the data will be anonymous. You also need to 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 how long the data and 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.)

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Clearly list what the patient or their insurance will be responsible for. List what, if anything, will be paid for by the study.

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

WILL I BE PAID FOR BEING APART OF THIS STUDY?

Describe any payment or 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. Incentives must be minor and may not constitute undue influence to participate. If the incentive involves entering a 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.**

If a drawing is being offered for participation, this paragraph **must** be completed and inserted into the information sheet or consent:

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) 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.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?

Explain the use of the IRB as well as provide the contact information.

(Example: You have rights as a research participant. All research with human participants is reviewed by a committee called the Institutional Review Board (IRB) which works to protect your rights and welfare. If you have questions about your rights, an unresolved question, a concern or complaint about this research you may contact the IRB office at 251-460-6308, toll-free at 866-511-6509 or via email at irb@southalabama.edu.)

HOW DO I INDICATE MY 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 _____

Name of Person Obtaining Informed Consent (printed) _____ Date _____

Signature of Person Obtaining Informed Consent _____ Date _____