This template is for

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:

³, Q I R U P H G F R Q V H Q W P X V W E H J L Q Z L W K F R Q F L V H D Q G I R F X V H G S U H
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:

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

Purpose

State that you are inviting the individual to participate in the research being conducted. Explain **in lay terms**

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 ZHOOSHUVRQ¶V RPHPRU\ZKHQ XQGHUSUHVVXUHWRSHUIRUPLQWHQVH:KRZ VWUHVVQGHDUIGHFWV 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*

(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