University of North Alabama

Human Subject Committee (HSC)

Special Populations: *If your project requires the use of minors or other special populations, then implied consent MAY NOT be used. Any research involving minors must have informed consent addressed to the parent or guardian and include a signature line for them. For minors (under 18 years of age), the HSC may require Child Assent.*

Informed Consent Form

- *Prepare your informed consent form(s) by editing this document. Instructions for each section are italicized and blue.* ***Delete the beginning statements and instructions in red and blue when you are finished drafting your form.***
- *Before editing the document, save it with a name appropriate for the form you are preparing.*
- *Enter the date the form was prepared, study title, and principal investigator's name in the header. (In MS Word, click on View, and then select Header and Footer.)*
- ***Use nontechnical language.*** *It is essential that the form be understandable to participants and should be written at approximately an* ***8th grade reading level.***
- *Most sections are required for all consent forms. A few of the sections — Circumstances That Could Lead Us To End Your Participation, Alternatives To Participation, Costs, and If You Are Harmed By Participating In The Study — should be included only if appropriate for your particular study, as specified in the instructions.*

Title: Click here to enter text. *[Title of the research study, as it appears on the HSC application. If multiple consent forms will be used, add subtitles to clarify the target population.]*

Application Number: Click here to enter text.

Principal Investigator: Click here to enter text.*[Name and Department affiliation]*

Date: Click here to enter a date.*[Date the form was prepared]*

PURPOSE OF RESEARCH STUDY:

- Click here to enter text.*Begin as follows:*

  The purpose of this research study is *[describe the purpose in a way that makes the potential value of the study clear]*.

- *Include the following statement or an appropriate paraphrase:*

  We anticipate that approximately *[insert number]* people will participate in this study.

PROCEDURES:

- *Click here to enter text.Briefly describe what the participant will be asked to do, and identify any procedures that are experimental (e.g., non-standard instructional methods).*

- *Click here to enter text.Give the expected duration of the participant's participation, indicating the expected number and duration of each session.*

RISKS/DISCOMFORTS:

- *Click here to enter text.Describe any reasonably foreseeable risks and discomforts to the participant.*
- *If appropriate, include the following statement:*

  Participation in this study may involve risks that cannot be foreseen at this time.

- *For studies involving minimal risk, include the following statement, including or excluding the material in brackets as appropriate:*

  The risks associated with participation in this study are no greater than those encountered in daily life [or during the performance of routine physical or psychological examinations or tests].

BENEFITS:

- *Click here to enter text.Describe any benefits to the participant that may be reasonably expected from the research. The description should be clear and not overstated.*
- *If there are no benefits to the participant, include the following statement:*

  There are no direct benefits to you from participating in this study.

- *Click here to enter text.Describe benefits to others that may be reasonably expected from the research, such as benefits to other people suffering from a disorder being studied or benefits to the general public or society. For example, in the case of general benefits accruing from advances in knowledge about the topic under investigation, a statement such as the following might be included:*

  This study may benefit society if the results lead to a better understanding of *[insert topic]*.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW:

- *Click here to enter text.Begin with the following statements:*

  Your participation in this study is entirely voluntary: You choose whether to participate. If you decide not to participate, there are no penalties, and you will not lose any benefits to which you would otherwise be entitled.

  If you choose to participate in the study, you can stop your participation at any time, without any penalty or loss of benefits. If you want to withdraw from the study, please *[explain what the participant should do to withdraw]*.

- *Click here to enter text.If a decision to withdraw from the study would have any significant consequences for the participant, explain these consequences.*
- *Click here to enter text.If any special procedures are required for the participant's safe withdrawal from the study, describe these procedures.*
- *Include this statement if appropriate:*

  If we learn any new information during the study that could affect whether you want to continue participating, we will discuss this information with you.

Title: PI: Date:

CIRCUMSTANCES THAT COULD LEAD US TO END YOUR PARTICIPATION:

Click here to enter text.Include this section if there are specific circumstances that could lead to the participant being taken out of the study.

- *Begin with these statements:*

  Under certain circumstances we may decide to end your participation before you have completed the study. Specifically, we may stop your participation if *[describe possible reasons for terminating the participant's participation (e.g., we determine that it would be unsafe for you to continue in the study)]*.

- *If the list of reasons is not exhaustive, add this sentence:*

  There may also be other circumstances that would lead us to end your participation.

- *If appropriate, include this sentence at the end:*

  If we end your participation before you have completed the study, we will provide compensation for your participation up to that time.

ALTERNATIVES TO PARTICIPATION:

Click here to enter text.Include this section when (a) the participant may benefit from participating in the study and (b) the same or similar benefits may be obtained in some other way. For example, in the case of an educational study that provides special tutoring to participants, include this section if the same or similar tutoring is also available to students not taking part in the study.

- *Click here to enter text.Describe the alternatives to participation that may confer the same or similar benefits.*

CONFIDENTIALITY:

- *Click here to enter text.Describe to what extent the confidentiality of records identifying the participant will be maintained. For most studies, the following statement will be appropriate:*

  Any study records that identify you will be kept confidential to the extent possible by law. The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the University of North Alabama Institutional Review Board and officials from government agencies such as the National Institutes of Health and the Office of Grants and Sponsored Programs. (All of these people are required to keep your identity confidential.) Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

- *Click here to enter text.Some studies may require disclosure of information to other parties. For such studies, explain what information will (or may) be disclosed and to whom.*

- *Click here to enter text.Describe how the study records will be created, stored, and maintained to protect confidential information (e.g., use of code numbers rather than participants' names on data sheets, keeping records in a locked file cabinet).*

COSTS

Include this section if there are, or may be, any costs to the participant.

- *Click here to enter text.Describe the costs to the participant.*

Title: PI: Date:

COMPENSATION:

- *Click here to enter text.Describe all payments or other compensation (e.g., extra credit in a course, transportation reimbursement) the participant will receive. Include details of payment methods or bonuses. For example:*

  If you satisfactorily complete the study, you will receive $000.00 to compensate you for your participation. $000.00 of this amount is a bonus for completing all of the sessions. If you end your participation before completing the study, you will be paid for your participation up to that time, at a rate of $000.00 per session. Payments are made by check at the end of the study.

- *If no compensation is provided, include the following statement:*

  You will not receive any payment or other compensation for participating in this study.

IF YOU HAVE QUESTIONS OR CONCERNS:

- *Click here to enter text.Begin with the following statement, inserting the name and phone number of the investigator or other appropriate contact. More than one contact may be provided if appropriate. For each contact, give his/her role in the study (e.g., Dr. John Smith, the director of the study).*

  You can ask questions about this research study now or at any time during the study, by talking to the researcher(s) working with you or by calling *[insert name and role]* at *[insert phone number]*.

- *Also include this statement:*

  If you have questions about your rights as a research participant or feel that you have not been treated fairly, please call the Office of Grants and Sponsored Programs (256) 765-4607.

IF YOU ARE HARMED BY PARTICIPATING IN THE STUDY:

Include this section if the research is of greater than minimal risk and research-related harm (physical, psychological, social, financial, or other) to the participant is possible.

- *Click here to enter text.Begin with the following statement, inserting the name, role, and phone number of the principal investigator or other appropriate contact:*

  If you feel that you have been harmed in any way by participating in this study, please call *[insert name and role]* at *[insert phone number]*. Please also notify the Office of Grants and Sponsored Programs (256) 765-4607.

- *tClick here to enter text.Then state whether any compensation and/or treatment is available to participants who have been harmed and, if so, describe the compensation/treatment or indicate where further information may be obtained. Make clear whether treatment will be provided without cost to the participant or, instead, the participant will be required to pay.*

- *If no compensation or treatment is available, include the following statement:*

  This study does not have any program for compensating or treating you for harm you may suffer as a result of your participation.

SIGNATURES

WHAT YOUR SIGNATURE MEANS:

Title: PI: Date:

Your signature below means that you understand the information in this consent form. Your signature also means that you agree to participate in the study.
By signing this consent form, you have not waived any legal rights you otherwise would have as a participant in a research study.

Participant's Signature Click here to enter text.
Date Click here to enter a date.

Signature of Person Obtaining Consent
(Investigator or HSC Approved Designee)

Date Click here to enter a date.