Guidelines
Consent for Participation in Research

The elements that are required to be in the consent form has been inserted in the template and must remain in the document. Items that must be included in the form are:

- A statement that the study involves research and participation is voluntary.
- An explanation of the purposes of the research.
- An explanation of the expected duration of the participant’s participation and the approximate number of participants expected to be involved in the study.
- A description of the procedures to be followed.
- Identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant or to others which may reasonably be expected from the research.
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights.
- A statement that refusal to participate or deciding to discontinue participation at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled.

The following must be included for studies which are greater than minimal risk:

- Alternative procedures or courses of treatment that might be advantageous in lieu of participation in the research.
- A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable.
- An explanation of whom to contact in the event of a research related injury.
- Whether any compensation is available if injury occurs, and if compensation is available, an explanation of what it consists of, or where further information may be obtained.
- Whether any medical treatments are available if injury occurs and if medical treatments are available, an explanation of what it consists of, or where further information may be obtained.

The following must be included if:

- **The research is FDA-regulated:** Provide a statement that there is a possibility that the Food and Drug Administration may inspect the records.
- **The research includes women of child bearing potential or pregnant women, and the effects of any research procedures on embryos and fetuses is not well known:** Provides a statement that, if the participant is or may become pregnant, the particular treatment or procedure may involve risks to the embryo or fetus which are currently
unforeseeable and if applicable, an explanation that measures must be taken to prevent pregnancy.

- **There are anticipated circumstances under which the participant’s participation will be terminated by the investigator without regard to the participant’s consent:** Describe circumstances under which participation may be terminated by the investigator without the participant’s consent.

- **There are costs to the participant that may result from participation in the research:** Describe additional costs associated with study participation.

- **There are adverse consequences (e.g., physical, social, economic, legal, or psychological) of a participant’s decision to withdraw from the research:** Describe consequences of a participant’s decision to withdraw from the research and procedures for an orderly termination of participation.

- **Significant new findings during the course of the research that may relate to the participant’s willingness to continue participation are possible:** Provide a statement that new findings developed during the course of the research that may relate to the participant’s willingness to continue in the research study will be provided to the participant.

The following must be included for studies involving:

- **Blood samples:** A statement naming and describing the method through which blood will be sampled, the frequency with which this method is used, any possible side-effects of the method, who will obtain the sample and how much they will obtain, and how the blood will be used.

- **Blood tissue or body fluid for possible genetic research:** A statement explaining the fact that the specimens will be maintained without identifiers, the risk level to the subject if they agree to participate, where the specimens will be stored, who owns the specimens, how the specimens will be used in the future, and the limited protections afforded by the Genetic Information Nondiscrimination Act.

- **Physical risk:** A statement that includes the following: The University does not have a plan to provide facilities or insurance to cover research-related injuries. Only UT student participants will be afforded access to the designated services available through The University of Texas Student Health Center. If emergency treatment for research-related injuries is arranged, that should be stated, but a disclaimer for extended care should be added.

- **Drugs:** A statement including: known side effects, possible drug interactions (including interactions with alcohol), and a warning about activities that may be dangerous (such as driving with a drug that has a sedative effect).

- **Psychological risk:** A statement informing the participants of the risk and indicating that UT does not have a plan for providing treatment; a list of names and telephone numbers of agencies that may alleviate mental concerns, such as a crisis hot line. If the principal investigator or the faculty sponsor of a student investigator is qualified to treat mental health problems, that person may be listed as a resource. Only UT student participants will be afforded access to the designated services available through The University of Texas Student Health Center.

- **Sensitive topics:** A statement that some of the questions maybe of a personal or sensitive nature and examples of the topics or questions; a statement that they can
skip a question if they do not wish to answer it; if questionnaires or interviews may generate reports of child physical or sexual abuse, a statement that the researcher may be legally required to report this information to Child Protective Services; if the questionnaires or interviews may generate reports that the participant plans to harm him or herself or others, a statement that the investigator is ethically required to report that information to the local police department. Information about the legal obligations to report abuse and threats of harm to oneself or others may be omitted if the responses are anonymous. In the event that the Privacy rule is more restrictive than the procedures described in the consent requirements, the more restrictive rule must be followed.

• **Audio or video recordings**: A statement that the interviews or sessions will be audio or videotaped, the cassettes will be coded so that no personally identifying information is visible on them, the recordings will be kept in a secure place, and the recordings will be heard or viewed only for research purposes by the investigator and his or her associates. A statement that either recordings will be erased after they are transcribed or coded or they will be retained for possible future analysis. If the researcher wishes to present the recordings at a convention or to use them for other educational purposes, the statement (after the signature lines), “We may wish to present some of the tapes from this study at scientific conventions or as demonstrations in classrooms. Please sign below if you are willing to allow us to do so.” Additionally, a second signature line should be added with the preface, “I hereby give permission for the video (audio) tape made for this research study to be used for educational purposes”.

• **Monetary or other compensation**: A statement describing the amount and types of compensation and clearly specifying the requirements to earn them. In addition, the following statement must be included when monetary gifts or gift cards are provided: “You will be responsible for any taxes assessed on the compensation.”

• **Deception**: If deception is a necessary part of the experiment, a preliminary consent, in which the investigator informs the subject of the research, should be obtained. After the experiment, the subject should be informed of the deception and its purpose. In rare instances, the IRB may approve a study even if no consent can be obtained or debriefing done. Deception requires a waiver of informed consent.