**Texas State University**

**Consent Form Requirements**

**Implemented 5/15/2014**

**The Consent Form submitted to the IRB for approval MUST address/include information according to the following eight items:**

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
   * Include details about the length of time assessment/participation required, number of questions included in a survey, etc. that will be used to collect data in easily understandable terms and language.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
   * For questionnaires/surveys/instruments that may be sensitive in nature, include a sample question(s) from the questionnaire/survey/instrument so that each participant is fully informed prior to giving consent.
   * Clearly identify any procedures that are experimental.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
   * Include details of any compensation offered to participants (e.g., the amount of money on a gift card, the amount of extra credit, etc.). If extra credit is provided to students who choose to participate, it must be stated that an alternative form of extra credit will be made available to students who choose not to participate. This alternative form of extra credit must be clearly described. Researcher should ensure that the alternative form of extra credit is comparable to the requirements of the study.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
   * Be specific, including details about the storage location, length of time, and persons who will have access.
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
   * For studies that have the potential of being psychologically/emotionally distressful, a resource list of at least three mental health providers must be given to all participants. It must be stated who is responsible for covering expenses incurred in the event that the participant requires attention from a mental health provider. If the Texas State University Counseling Center is listed as a referral, and if your participants are registered Texas State students, please state that mental health services at the Counseling Center are free to registered students, although the number of sessions allowed may be limited.
   * A protocol for the implementation of medical procedures must be listed for studies with any risk of physical harm/medical complications to participants. It must be stated who is responsible for covering medical expenses incurred in the event that the participant requires medical attention.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
   * Give the researcher(s)’ name(s), contact information and affiliation(s) in the very first paragraph.
   * This statement MUST appear in the consent form:   
       
     **This project [insert IRB Reference Number] was approved by the Texas State IRB on [insert IRB approval date]. Pertinent questions or concerns about the research, research participants' rights, and/or research-related injuries to participants should be directed to the IRB chair, Dr. Jon Lasser (512-245-3413 -** [**lasser@txstate.edu**](mailto:lasser@txstate.edu)**) and to Becky Northcut, Director, Research Integrity & Compliance (512-245-2314 -** [**bnorthcut@txstate.edu**](mailto:bnorthcut@txstate.edu)**).**
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
   * For surveys/interviews, include a statement that participants may choose not to answer any question(s) for any reason.

**The following suggestions for consent forms are not required by the IRB but instead are presented as best practices to be adopted when applicable to the research study:**

The Consent Form should be written in language that is easily understood by prospective subjects. Many consider it most appropriate to write the Consent Form between 5th and 8th grade reading levels. There are [numerous online tools](http://www.google.com/search?q=How+to+determine+reading+level+of+documents&ie=utf-8&oe=utf-8&aq=t&rls) for assessing reading levels.

Depending on the target population, the Consent Form (and other relevant documents) may be required to be written in a language other than English.

The Consent Form should include the reason(s) why the participant has been chosen/asked to participate.

The Consent Form should state that a summary of the findings will be provided to participants upon completion of the study, if requested. The researcher should include instructions for accessing results of the study.