UNITED TRIBES TECHNICAL COLLEGE
3315 University Drive
Bismarck, North Dakota 58504
701-255-3285

United Tribes Technical College
Institutional Review Board for the Protection of Human Subjects
Checklist for Research Qualifying for Full Review
Form D

Project Title: _____

Directions: Submit this form if you believe that your project requires full review.

Part A: Check the items that apply.

☐ The research involves prisoners, fetuses, pregnant women, children, or the seriously ill, or mentally or cognitively compromised adults as participants. [The accompanying proposal must indicate clearly why the use of subjects in any of these categories is scientifically necessary.]

☐ The research involves the collection of recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. [The accompanying proposal must indicate clearly why the collection or recording of such behavior is scientifically necessary and what steps will be taken to preserve subjects' anonymity/protect subjects' confidentiality.]

☐ The research involves the collection of information regarding sensitive aspects of the subject's behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior). [The accompanying proposal must indicate clearly why the collection or recording of such behavior is scientifically necessary and what steps will be taken to preserve subjects' anonymity/protect subjects' confidentiality.]

☐ The procedure of this research presents no more than minimal risk to the participant (where minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests). [The accompanying proposal must identify all risks (physical, psychological, financial, social, legal, other) connected with the proposed procedures, indicate clearly how such risks to subjects are reasonable in relation to anticipated benefits, describe procedures designed to protect against or minimize such risks, and assess their likely effectiveness. The general vulnerability of the participant cannot be used to justify additional risks entailed through participation of the research. For example, failing to protect the confidentiality of illegal workers cannot be justified by saying that these people face a daily risk of deportation.]

☐ This research does not fall into any of the categories explicitly as qualifying for exempt or expedited review.

Part B: Please provide the following information:

1. **Provide an abstract that describes your study.** This information will be distributed to the review committee to provide an overall picture of your research plan. It is important that we understand the goals of the study so that we can judge whether the consent form is accurate and the data collected is clearly relevant to the project. It should contain the study's goals, description of the subjects (including expected age range, sex distribution, and basic demographic information), if the participants need to have any particular characteristics to be eligible to participate (for example, if you are interested only in studying American Indian/Alaska Native females), how the participants will be recruited or selected for participation, what you will do and how long it will take, and whether the participants' identity will by anonymous, confidential, or public.

2. **Provide a description of how you will recruit participants and who will be eligible to participate**. Describe the eligibility requirements of your participants. If you are targeting particular populations, why is this necessary to fulfill the goals of the project? Is risk distributed fairly across the population? Please include all recruitment materials, such as a sample script used when approaching subjects on the street, e-mails, to be sent to potential respondents, newspaper ads, flyers, etc. It is important that your recruitment materials and scripts provide enough information about study components and potential risks that participants can decide whether to proceed further in the research process.

3. If you are collecting data from vulnerable populations or those who may not be fully aware of the risks they are agreeing to, clearly explain why these procedures are necessary. For example, asking minors about illegal activities their families may be involved in can be particularly sensitive, especially if they are not old enough to clearly appreciate the risks. A clear justification must be provided for collecting sensitive data from a vulnerable population. When possible and appropriate, informed consent from guardians or other responsible persons (e.g., parents or guardians) should be obtained.

4. **Provide a copy of your consent form or script**. Informed consent is the central component of the protection of research participants. Written consent is standard for all projects requiring full review. A copy of the consent information should be provided to all participants. It is also recommended that the consent form be fully explained to the participants, because consent forms tend to be quite detailed and participants may feel pressured to read quickly and thus skim over important information. If participants are under 18, parents must provide written consent and children must provide at least oral assent.

   The consent form should contain a clear description of the risks and benefits of participation, including limits of confidentiality. For example, the court provides no protection against subpoena of research records and these limitations (as well as PI efforts to protect the participant) should be recognized in the consent document.

   Exceptions to these general requirements must be clearly and fully justified in the proposal and an acceptable alternative consent procedure must be proposed. Please look at the IRB website for all the required components of consent and examples of consent forms.

5. **Provide a copy of the contact information handout you will give to participants**. All researchers who interact with research participants are required to offer participants contact information so participants who have questions after the study can speak to the researcher or to the IRB. This must include the name and phone number of the IRB chair and the name of your project. Students should provide contact information for their advisor and faculty and staff provide their phone numbers. You may include contact information at the bottom of the consent form you provided to your participants.

6. **Provide copies of your research protocols**. Provide enough information for the reviewers to have a clear idea of exactly what your participants will be asked to do and they kind of information they will be asked to provide. This may differ for different types of data collection tasks:

    a. Observations: Provide a clear description of where you will be doing your observations, what will be observed and how you will record it (e.g., running record, videotape, etc.). If you will be interacting with the participants, describe your own role in the setting. Remember, participant observation requires informed consent or requires expedited review.

    b. Open-ended interviews: Describe the topics that will be raised by the interviewers. What will be done if the interview strays outside the topic covered by the consent procedure or includes unanticipated disclosure of illegal or sensitive material?

    c. Closed-form surveys or interviews: Provide a script of the interview questions or a copy of all instruments (surveys, test, etc.). What will be done if the interview strays outside the topic covered by the consent procedure or includes unanticipated disclosure of illegal or sensitive material?

    d. Existing data: Provide a description of how you will obtain the data and permission for use of the data and proof that IRB process was used prior to the data collection of the existing data.

7. **Describe how the participants' identities will be protected**. Describe how you will record and protect the identity of the participants (including in your field notes or on your computer, if applicable). This description should also include plans for protecting any recordings or videotapes made. Unless materials can be properly archived, it is recommended that they be destroyed at the end of the research period.

8. **Describe how you will maintain and secure original data.** Describe plans for maintaining and securing original data collected during the study and following completion of the study. Provide documentation stating how long you will keep the original data. Describe the process for disposing of data records.

9. **Justify any deception used in the study**. If deception is to be employed, provide a scientific justification for its use and describe debriefing procedures.

10. **Describe your relationship, if any, with participants outside the research setting**. If you are involved with the participants in a formal or informal role (tutor, instructor, resident assistant, colleague), address such issues as: how will this research impact your relationship with the participant? Will their participation be truly voluntary and free of coercion? What steps have been taken to minimize pressure or unanticipated negative consequences on the research participants?

11. **Clearly describe potential risks and benefits of participating in the study**. If participants will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.