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 Expedited Review
Form C

Project Title: _____

Directions: Submit this form if you believe that your project qualifies for expedited review. Generally speaking, projects that are eligible for Expedited Review status are those that do not involve vulnerable populations and present no more than minimal risk to the participants. Projects eligible for expedited review must meet ALL the criteria in Part A and at least one of the criteria in Part B.

Part A: Check the items that apply. (All must apply for expedited review.)

☐ The research does not involve prisoners, fetuses, pregnant women, and the seriously ill, or mentally or cognitively compromised adults as participants.

☐ The research is completely anonymous (the participant cannot be identified, directly or identifiers linked to the subjects) OR the research does not involve the collection or 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 research is completely anonymous OR the research does not involve the collection of information regarding sensitive aspects of the subjects' behavior. (e.g., drug or alcohol use, illegal conduct, sexual behavior)

☐ 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).

Part B: Check the items that apply.

☐ Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected or will be collected solely for non-research purposes (for example, secondary data analysis of academic performance or student conduct records). [These sources are not publicly available and although confidentiality will be strictly maintained, information will not be recorded, even if they are not directly associated with the data.]

☐ Research involving the use of survey or interview procedures, observation of public behavior or educational tests (cognitive, diagnostic, aptitude, achievement). [Although confidentiality will be strictly maintained, information will not be recorded anonymously e.g., use will be made of audio or videotapes or names will be recorded, even if they are not directly associated with the data.]

☐ Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, or research employing surveys, interviews, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies.)

☐ Collection of data from voice, video, digital or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability, be stigmatizing, or be damaging to the subjects' financial standing, employability, insurability, or reputation.

☐ Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practices excluding procedures involving x-rays or microwaves; b) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ Prospective collection for research purposes of biological specimens; research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; and collection of blood samples by finger stick or venipuncture.

☐ Research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow up of subjects; or (b) where the research remains active only for the purposes of data analysis; or (c) where the IRB has determined at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified; (d) where no subjects have been enrolled and no additional risks have been identified.

☐ Research that involves deception that is scientifically justified and involves a debriefing procedure.

If you meet the above required conditions for expedited review, complete the following items:

Part C: Please provide the following information.

1. **Provide an abstract that describes your study.** This information will be distributed to the review committee and other interested parties and will be used to assess whether your research meets the general conditions for exempt review. 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 ask them to 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? 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.

3. **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 expedited or 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. 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.

4. **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 should *at least* include the name and phone number of the IRB chair and the name of your project. It is recommended that students also provide contact information for their advisor and that faculty and staff provide their phone numbers. If you provide a written consent form to your participants, contact information can be included at the bottom.
5. **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.

6. **Describe how the participants' identities will be protected**. If the information is anonymous or confidential, 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.

7. **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.

8. **Justify any deception used in the study**. If deception is to be employed, provide a scientific justification for its use and describe debriefing procedures. [If the research is such that debriefing cannot be carried out, the project must be submitted for full committee review.]

9. **Describe you 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?

10. **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. If the research presents more than minimal risk to subjects, discuss benefits to the subjects, to science, and/or to society that will result from this work in relationship to those risks. **You must be able to show that he overall benefits to be gained from the research justify whatever risks subjects are asked to take**.