



UNITED TRIBES
TECHNICAL COLLEGE

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Bismarck, North Dakota 58504
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**UTTC Institutional Review Board (IRB) for
Protection of Human Subjects
Continuing Review Application Form**

Federal regulation requires that research protocols be reviewed by the IRB on a regular basis for continued approval. This form must be submitted one month prior to the IRB approval expiration date. No research may be conducted past the expiration date unless the study has been reviewed and renewed by the IRB.

Project Title: _____

IRB Protocol # _____ Approval Date: _____

Principal Investigator (PI): _____

Email: _____ Phone: _____

Co-Investigator (if applicable) _____

Email: _____ Phone: _____

UTTC Sponsor (if applicable) _____

Current Protocol Status:

- Research not started.
- Open to accrual of new participants/Collecting data about new participants.
- Closed temporarily to accrual of new participants.
- Closed permanently to accrual of new participants.
- Closed to accrual of new participants, but intervention, surveys, or participant interactions continuing or collection of new data about participants is ongoing.
- Closed to accrual of new participants, remaining activities limited to analysis of identifiable data that have been already collected.

Provide explanation for protocol status and/or summary of progress:

Protocol Assurances:

| Yes | No | Since the <i>last</i> review, please indicate the following: |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Have subjects experienced any harms (unexpected or increased frequency or severity of expected) likely related to the research procedure? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have subjects experienced any benefits? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have there been any unanticipated problems involving risks to subjects or others? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have any subjects withdrawn, been discontinued or terminated early from the study? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have any subjects complained about the protocol? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have there been any publications in the literature relevant to the risks or potential benefits? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have there been any interim findings? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have there been any data safety monitoring board reports? |
| <input type="checkbox"/> | <input type="checkbox"/> | In the opinion of the principal investigator, have the risks or potential benefits changed? |
| <input type="checkbox"/> | <input type="checkbox"/> | Are there any problems that required prompt reporting that have NOT been submitted? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have there been any regulatory actions that could affect safety and risk assessment? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have there been any other relevant information regarding this protocol, especially information about risks? |
| <input type="checkbox"/> | <input type="checkbox"/> | Have there been any written reports from the study monitors or evaluators? |

Provide an explanation for any “Yes” responses above. Type “NA” if not applicable or “See Attached” if attaching a separate document that provides a summary of the data collected or results to date, if applicable.

I certify that the statements herein are accurate and complete. I agree to protect the rights and welfare of the human subjects participating in my research, to abide by College guidelines for securing informed consent, to safeguard the confidentiality of my research data, and to inform the IRB Chairperson/Committee Member should any changes in the research protocol or issues arise with human subjects during the course of this research. I will keep a copy submitted to the IRB Committee. I will provide a copy of the de-identified data and the research results to the Office of Institutional Research upon completion of the research.

Signature of Principal Investigator

Date

I have reviewed this application and will continue to oversee this research in its entirety.

Signature of UTTC Sponsor (if applicable)

Date

Email form to irb@uttc.edu