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
Amendments to Previously Approved Research Application Form

All amendments to currently approved research must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the human subjects. Researchers should allow approximately one month for modifications that require Full Committee review and approval of a major amendment and approximately one week for modifications that meet the criteria for expedited review and approval of a minor amendment. The IRB will determine the appropriate review level.

Project Title: _____

IRB Protocol # _____ Approval Date: _____

Principal Investigator (PI): _____

Email: _____ Phone: _____

Co-Investigator (if applicable) _____

Email: _____ Phone: _____

Protocol Change Requested:

Minor Changes	Major Changes
☐ Administrative change	☐ Changes that adversely affect the risk/benefit ratio or the study or specifically increase risk to subjects
☐ Minor changes to consent form	☐ Changes in inclusion/exclusion criteria that impact the risk/benefit ratio of the study.
☐ Minor changes to recuritment procedures or materials, or new recruitment materials	☐ Significant changes in study design, such as addition of a new population or eliminiation of study arm
☐ Minor changes to study documents such as surveys	☐ New risk information that is substantial or adversely affects the risk/benefit ratio of the study
☐ Editorial changes that clarify but do not alter the existing meaning of a document	☐ Significant changes to the study documents to be distributed to or seen by subjects
☐ New study documents to be distributed to or seen by subjects that are similar in substance to those previsious approved	☐ New study documents to be distributed to or seen by subjects that include information/questions substantively different from previously approved
☐ Addition of or changes in study personnel or site	☐ New/revised financial conflictof interest management plans (e.g. change in PI or study design)
☐ Decrease in the number/volume of the sample but does not affect the risk/benefit of the study	

Provide rationale for protocol modification or change:

Include the relevant modified study documents, recruitment materials, consent forms, and other pertinent documentation as applicable with this request.

Approval of the change in protocol will not change the approval period of the study.

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