IRB Research Modifications Request

Modifications to research studies approved by an Institutional Review Board (IRB) require prior review and approval, unless there is an immediate need to eliminate a hazard to subjects. Modifications can range from minor changes like updating contact information to major changes like altering the study protocol or adding new procedures. Any change that affects the study protocol, consent forms, or participant risk must be submitted to the IRB for review and approval before implementation.

Categories of Amendments/Modifications

A. Minor Changes – Do not significantly alter risk/benefit assessment or study aims/design. Examples include:
   1. Add/remove study team members.
   2. Add procedures with no increased risk.
   3. Remove procedures to reduce risk.
   4. Add nonsensitive questions to surveys/interviews.
   5. Revise recruitment materials/strategies.
   6. Administrative edits (e.g., typos).

B. Significant Changes – Affect risk/benefit assessment or substantially alter study aims/design. Examples include**:**
   1. Add new subject population (e.g., control group, vulnerable population).
   2. Add high-risk procedure.
   3. Add sensitive questions that may impact participants' welfare.
   4. Remove necessary follow-up for participant safety.

C. Level of Review
   1. Significant changes require the same review level as initial approval (screening committee or full IRB).
   2. If risk increases, the screening committee refers to the full IRB.
   3. Minor changes may receive administrative approval and are noted at the next IRB/screening committee meeting.

D. Sponsor Agency Modifications
   1. Only IRB approved studies may be modified.
   2. If the sponsor modifies a proposal, wait for IRB approval before implementing.
   3. All sponsor changes require IRB or screening committee review. The PI must submit sponsor documents and summarize impacts on the study.

Tarrant County College District

IRB Research Modification Request Form

Research Proposal Title: _____

Principal Investigator: _____

Campus: _____ **Department:** _____

Phone: _____ **Email Address:** _____

The submission of a modification form is required whenever **any changes** are made to an approved project. This includes, but is not limited to, changes in: (a) title, (b) investigators, (c) funding source, (d) data collection methods, (e) recruitment materials, (f) confidentiality measures or (g) test instruments.

Please note: All changes must be submitted and approved by the IRB **prior to** their implementation unless the change is necessary to protect the safety of participants. Email forms and supporting documentation to: irb@tccd.edu.

Materials revised/amended/added:

☐ **Proposal** – if checked, attach one copy of last approved proposal, with any deletions highlighted, and one copy of revised/amended proposal with any revisions or amendments highlighted.

☐ **Consent Form(s)** – if checked, attach one copy of last approved consent form(s) with any deletions highlighted and one copy of revised/amended consent form(s) with any revisions or amendments highlighted.

☐ **Other (Identify):**

Provide a descriptive summary of the changes and a reason for each change:

Will the revision/amendment/addition change the scope or research objectives of the project?

☐ No ☐ Yes

If yes, please describe:

Signature of Principal Investigator : _____ **Date:** _____

Email forms and supporting documentation to: irb@tccd.edu.