Federal regulations require that a PI cannot implement any changes to IRB-approved research, during the period for which approval has already been given, without prior IRB review and approval (except where necessary to eliminate apparent immediate hazards to human participants).

Prior to implementation, the TCU IRB must approve modifications/amendments to an IRB approved research protocol. Some modification submissions may not technically be changing any aspect of the study (such as notes to file, Memoranda from the sponsor, letters from the FDA, etc.), but the PI is still required to submit a Modification Request form to the IRB and wait for approval by the IRB to implement changes.

Complete this form and submit it by email to [IRBSubmit@tcu.edu](mailto:IRBSubmit@tcu.edu). As part of your Modification/Amendment request, include in this email a **revised/updated protocol application and revised appendix materials** (consent forms, recruitment flyers, etc.), which should reflect the changes summarized in the Modification/Amendment request form.

As part of the amendment request all changes to the protocol and consent documents should be made on the previously IRB approved protocol and consent. For example, if this is the first amendment then you will revise the initially approved protocol. If this is the second amendment you will revise the protocol and consent approved with the first amendment. **PIs should use the Track Changes in Word to show the changes they wish to make in their previously approved materials. Please submit revised documents separately. Do not copy and paste other documents into this form.**

**Date:**

1. **Project Title:**

**IRB Initial Approval Number and Date:**

1. **List the name and Faculty/Students/Staff status of the person(s) conducting the research.**
   1. **Principal Investigator:**
   2. **Department:**
   3. **Others:**
2. **Project Period:**
3. **Funding**
   1. **Agency:**
   2. **Amount Awarded:**
4. **Summarize the amendment/modifications.**

1. **Does this amendment/ modification impact the level of risk? Yes / No  
   If yes, how?**

**By signing this form, the Principal Investigator and the preparer of this form (if other than the Principal Investigator) certify that he/she has disclosed to the TCU IRB all relevant information that might impact the risk to benefit analysis of this study.**

**Preparer’s Name**       **Date:**

Printed

**Preparer’s signature** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator’s signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**