



INSTITUTIONAL REVIEW BOARD

ADDENDUM AND AMENDMENT FORM FOR IRB RESEARCH PROPOSAL AND APPLICATION

FOR INTERNAL USE ONLY

TU IRB APPLICATION NUMBER: _____

Please note: Handwritten applications will *not* be accepted.

A NOTE FROM THE IRB: The Thomas University Institutional Review Board is committed to working with researchers to facilitate research conducted in an ethical and safe manner. Should any changes outside of the original IRB proposal application occur, it is the responsibility of the *principal investigator* of the *original proposal and application* to submit all changes to the IRB through the use of the “Addendum and Amendment Form for IRB Research Proposal and Application.” If the changes in the proposal will not alter the scope of the original proposal, leading to a contradiction of the approved methods of the research, or cause the research methods to come into question in such matters as policy violations, the IRB will accept the change presented herein as an addendum or amendment to the original research proposal and application without further inquiry. However, should concerns arise, the IRB or its Chairperson may, after a good faith effort to resolve concerns related to the safety or ethics of a research activity or project determine that some or all of the research cannot be approved, or requires further inquiry by the IRB. All decisions with regard to research that is presented to the IRB will be rendered to the principal investigator of the original IRB application proposal in writing.

Application Type Originally Submitted to the Thomas University IRB:

Research Involving Human Subjects Research Involving Vertebrate Animal Subjects
 Research Involving Recombinant DNA Research for Academic Teaching Purposes Only (*Faculty*)

Title of Project: _____

The proposal status requested in the original proposal:

a. Exempt from full review b. Expedited review c. Full committee review

Original IRB Proposal Application Principal Investigator: _____

Department:
Address:
Phone:
Fax:
Email:

Original IRB Proposal Documented Faculty Sponsor: _____

Department:
Phone:
Email:

A. Please indicate below, the grounds for which you are submitting the ADDENDUM AND AMENDMENT FORM FOR IRB RESEARCH PROPOSAL AND APPLICATION to the IRB:

_____ As principal investigator, I am submitting a change in the research method, research activity, or project that is an **addition to** the research proposal that has received prior approval by the IRB. This change **is not already included or described within the original proposal and application, but is a new, independent element to the research activity or project that was previously approved.**

_____ As principal investigator, I am submitting a change in the research method, research activity, or project that is an **alteration to the existing method already included within the** research proposal that has received prior approval by the IRB. This change will affect *previously described methods of the original proposal and application*, and is **not a new, independent element to the research activity or project that has not been previously addressed within the original proposal and application.**

Provide a description of the addition or alteration that is intended for implementation within the space provided below and indicate any change in risk to participants or methods that will occur as a result of the change:

PRINCIPAL INVESTIGATOR'S SIGNATURE SECTION:

Please note: Signature of this form by the Principal Investigator provides written assurance that all abovementioned statements are written with the intent of supplying the required information of changes to the original research method, research activity or project to the IRB, so that a decision of continued approval of the research can be issued with consideration of the changes, by the Thomas University

Institutional Review Board's Chairperson or the IRB members, where applicable. The Principal Investigator understands that all information contained within this document may be forwarded to external parties when applicable to provide further scrutiny when reviewing the changes noted herein and to assist in governing the final decision of the IRB Chairperson.

Principal Investigator's Signature (SEAL)

Date

INSTRUCTIONS:

1. Complete this "**ADDENDUM AND AMENDMENT FORM FOR IRB RESEARCH PROPOSAL AND APPLICATION**" and return it to the Thomas University Institutional Review Board's Chairperson, 1501 Millpond Road Building F (Forbes) #203, Thomasville, Georgia 31792.
2. **NOTE:** We will not accept handwritten forms, incomplete forms, or forms printed on both sides of the paper. Use 10-point type or larger throughout application. The contents of this addendum/amendment and any attachments will be kept confidential within the limits of the law.

The IRB Chairperson will review your addendum/amendment at the next appointed time and notify the principal investigator in writing, of the decision to accept the change without further investigation, or the decision for the need for further inquiry. **The principal investigator may be required to attend the IRB Chairperson's review for further inquiry. If this is required, the principal investigator will be notified accordingly.**

**RESPONSE TO ADDENDUM AND AMENDMENT FORM FOR IRB RESEARCH
PROPOSAL AND APPLICATION**

All responses to addendums/amendments will be provided to the **principal investigator** in writing from the Thomas University Institutional Review Board's Chairperson. According to the complexity of the research coupled with the changes under review, a response from the Chairperson may take up to, **but not exceed**, two weeks. Should further, appropriate review by other Institutional Review Board members or officials of the institution be deemed necessary in this review process, it could delay a response from the Institutional Review Board Chairperson for an additional two week period beyond the initial two week period. The Institutional Review Board Chairperson will work to provide a response and final determination on the matter under review in a timely manner.

For questions, please contact the Thomas University IRB at irb@thomasu.edu.