

**Changes and/or Project Termination
Approved Research Involving Human Subjects**

**Research Compliance Services
Office of Research, Grants, and Contracts
The University of Tennessee-Martin
100 Hall Moody Administration
Martin, TN 38238**

INSTRUCTIONS FOR USE

A Change/Termination Form is used to report completion of a project, request another years approval, and to report minor changes in a previously IRB-approved research project which was prepared under a IRB Application. Such changes may include, but are not limited to: change of project title, minor grammatical changes to an informed consent and/or child's assent form, addition or deletion of collaborators and/or co-PI's, change in student advisor, additional sites for the performance of the research (include a letter from the authorized individual for a new location), minor project changes which do not change the original goal, and reporting unexpected risks encountered in carrying out the project.

The IRB has directed the Research Compliance Services employ an expedited review procedure to determine if approval can be granted outright, if further information is required, whether the change must be reviewed by the full IRB, or if a new application must be submitted for review and approval. When a Change/Termination Form is approved, it does not affect the renewal date of the overall project.

DO NOT USE THIS FORM FOR MAJOR CHANGES WHICH CHANGE THE ORIGINAL GOAL OF THE RESEARCH - A NEW IRB APPLICATION MUST BE SUBMITTED!!!

INSTRUCTIONS FOR Change/Termination FORM COMPLETION - (This form must be typed.)

1. Insert the 13 digit IRB number in accordance with the number assigned on your initial approval letter.
2. Enter the name of the Principal Investigator and Department.
3. Enter your mailing address (if not UTM, be sure to include your zip code).
4. Enter the Project Title (exactly as shown on the last approval letter received). If the Project Title has changed, enter the new title and check box 5 below.
5. Check this box if the project title in item 4 is different form your last approval letter.
6. Check this box if there is a change of principal or co-principal investigators, other collaborators or a change in student advisor. Attach a memo delineating the changes in investigators.
7. Check this box if there are minor changes to the project. Revise and amend any relevant sections of the IRB Form and submit these changes with Change/Termination Form. There is no change too small to report.
8. Check this box if there are changes to informed consent forms and/or assent form(s). Submit the new consent/assent forms with Change/Termination Form.
9. Check this box if there are additional locations or organizations where the research involving human subjects will be conducted. Submit a copy of the letter(s) from those organizations, which

have given permission for you to conduct your research in their institution. The letters should be on the institution's own letterhead.

10. Check this box if you have encountered unexpected risks to research subjects (e.g., breaches of confidentiality) or to yourself (e.g., angry parents, threats of violence). Submit a copy of the incident(s) with Change/Termination Form and describe how you have or will resolve the problem.

11. Check this box if you are asking for UTM-IRB approval for another year.

12. Check this box if the project is now completed or if the project will not be conducted at all. For dissertation research: IRB-approved projects should NOT be terminated until the dissertation committee has accepted the dissertation.

13. The primary principal investigator must sign this Change/Termination Form. If the PI is a student, the student's advisor must also sign. Some departments require that the Change/Termination Form and its associated changes also be reviewed and approved by the Chair of the Departmental Review Committee. Please consult with your department for requirements.