

Instructions for Completing Form D

Form D is used to report completion of a project or to request minor changes in a previously IRB-approved research project that was prepared under a Form B. 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-investigators, change in student sponsor, 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 Pellissippi State IRB will 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 Form D is approved, it does not affect the renewal date of the overall project.

NOTE: DO NOT USE THIS FORM FOR MAJOR CHANGES THAT AFFECT THE ORIGINAL GOAL OF THE RESEARCH! IN THIS CASE A NEW FORM B MUST BE SUBMITTED!

INSTRUCTIONS FOR FORM D COMPLETION - (*This form may be typed or printed in ink*)

1. Insert the IRB number, followed by the letter "B" in accordance with the number and letter assigned on your initial approval letter.
2. Enter the name of the investigator and Department or Division.
3. Enter your phone number.
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 from your last approval letter.
6. CHECK this box if there is a change of investigator or co- investigators, other collaborators, or a change in student or project sponsor. **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 Form B and submit these changes with Form D. 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), and/or assent form(s). **Submit the new consent/assent forms with Form D.**
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 an adverse event 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 Form D and describe how you have or will resolve the problem.**

11. 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.

12. The primary investigator must sign this Form D.