

Institutional Review Board Modification Request Form

Complete IRB Form #6 if requesting approval of a modification / change to a previously approved research study. DO NOT IMPLEMENT MODIFICATIONS UNTIL APPROVED.

Principal Investigator: _____

Faculty Advisor (if PI is a student): _____

IRB No.: _____

Study Title: _____

Please describe the requested modifications and rationale below and supply requested information on page 2. If applicable, attach and send a revised research proposal, informed consent form(s), interview / survey / questionnaire questions, and other study documents to the IRB by e-mail.

1. Will the modifications / amendments change the scope or objectives of the study? The following examples of actions are considered to change the scope or research objectives: A change in the specific purpose approved at the time of IRB approval; a change from the previously approved use of human subjects; a change in data collection method.

Yes

No

N/A

If Yes, describe how and provide sufficient information / documentation to allow the IRB to review and approve prior to implementation.

2. Will the modifications / amendments change the risks to subjects?

Yes

No

N/A

If Yes, provide sufficient information / documentation to allow the IRB to review and approve prior to implementation. In particular, describe how risks are minimized and reasonable in relation to expected benefits.

Investigator's Statement:

As Principal Investigator, I acknowledge that I am responsible for reporting any unanticipated problems or serious effects or reactions; that I will submit any proposed procedural modifications to the IRB for its review and approval and, except where necessary to eliminate apparent immediate risks, no such modifications will be put into effect without prior Institutional Review Board (IRB) approval; that unless otherwise directed by the IRB, I will renew this application with the IRB no less than annually; that the research project is being conducted in compliance with the IRB's guidelines and recommendations; that the IRB is provided all information on the research project necessary for its complete review; and that this research project will not continue until final IRB approval is received.

Principal Investigator – Typed name is acceptable if e-mailing form

Date

Faculty Advisor (if applicable) – Typed name is acceptable if e-mailing form

Date

For electronic submissions, a check in this box will constitute a written signature:

Instructions

When form is completed, please attach all revised documents (e.g., consent form, questionnaires and/or survey forms, interview questions, and recruitment materials) and submit via e-mail, or fax, to the IRB Coordinator.