

Indiana University East Institutional Review Board

INSTRUCTIONS FOR COMPLETING A STUDY AMENDMENT FORM

This **STUDY AMENDMENT FORM** should be used to report any changes whatsoever, regardless of the level of the original review and regardless of the investigator's assessment of the importance of the change. Changes must be approved by the Committee **BEFORE** they are implemented by the investigator.

Please use the one page form as a cover sheet (**keeping it on a single sheet of paper**) and provide the information requested in 1 and 2 on separate sheet(s). Reference the original title of the study and the principal investigator. Any changes to the title, the principal investigator, or the sponsor should be described in item 1. Changes to the project start and/or end dates should also be described in item 1.

Amendments involving minor changes that pose no more than minimal risk to subjects will be reviewed on an expedited basis. Amendments involving more than minor changes or involving changes that pose more than minimal risk will be reviewed by the full Committee, at their next scheduled meeting. Investigators will be notified when this is necessary, so that they can provide the required number of copies in a timely manner.

If you have questions or problems you may contact the IRB chair(s) or Academic Affairs.

INDIANA UNIVERSITY
EAST CAMPUS INSTITUTIONAL REVIEW BOARD

_____ Study Amendment _____
of
Research Project Utilizing Human Subjects

NOTE TO INVESTIGATORS: Study amendments may not be instituted until written approval from the IUE Institutional Review Board has been given. Return this form to: IRB c/o Academic Affairs, Whitewater 263. Please complete in a legible manner! This entire page **MUST be on a single sheet of paper. Use this as a cover page and attach pages with the information requested in items 1 and 2.**

TITLE OF PROJECT _____

PRIN. INVESTIGATOR _____ DIVISION/DEPARTMENT _____

BUILDING/ROOM # _____ E-MAIL _____ TELEPHONE _____

FUNDING AGENCY: _____

**PLEASE USE THIS AS A COVER PAGE.
ATTACH PAGES with the INFORMATION REQUESTED in items 1 and 2.**

1. Describe the proposed change(s) and rationale for the change(s). Include any changes to project start and end dates. If submitting a revised questionnaire or survey, please include a copy **with** changes highlighted.
2. Describe how the amendment will affect the risk/benefit ratio for subjects.
3. Does the proposed amendment require changes in the Informed Consent Statement? _____. If the answer is yes, check the appropriate line and attach a copy of the revised Informed Consent Statement, **with** changes highlighted.

- _____ The new Informed Consent Statement is in addition to the current one.
- _____ The new Informed Consent Statement is to replace the current one.

Principal Investigator (typed/printed name) (signature) (date)

Faculty Advisor/Sponsor (typed/printed name) (signature) (date)

CAMPUS LEVEL REVIEW

_____ The Amendment of this protocol for use of human subjects has been reviewed and approved by the IUE Institutional Review Board.

_____ Exempt review

_____ Expedited review _____ Full Committee review

Chairperson/Agent IUE IRB Date