

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). The document has been created as a PDF file that you can fill in and print (but not save), and should print on one page. **Please complete the form this way rather than printing and filling in by hand.**

Fill in the red boxes. Reference the **original** study title and principal investigator. Any changes to the title, the principal investigator, or the sponsor should be described in section 1. Changes to the project start and/or end dates should also be described in section 1. Changes to the subject population should describe all details as requested for an original application, including numbers, inclusion criteria, and recruitment methods. If there are additions or deletions of co-investigators, provide names and e-mail addresses. New co-investigators should sign beside their name.

Amendments involving minor changes that pose no more than minimal risk to subjects will be reviewed on an expedited basis according to the weekly review schedule--deadline is Fridays at 5:00 p.m for review the following week. (There are occasional modifications due to holidays, school calendar, vacations, illness, etc. You may contact the office for current information or check the web site at <http://www.research.indiana.edu/rschcomp/operate.html>). 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 monthly 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 Senta Baker or Ryan Merckle at 855-3067, or e-mail at iub_hsc@indiana.edu.

REQUIREMENTS FOR IUB RESEARCHERS USING HUMAN SUBJECTS

1. Protection of Human Subjects Test: ALL researchers, sponsors and co-investigators have to document that they have been trained to involve humans in research by passing the IU test for using humans in research before their study will be reviewed. The tutorial and test can be found at

<http://www.indiana.edu/~rcr/index.php>

Proof of having passed the test must accompany the application at the time of submission. Failure to provide proof with the application will delay the review until everyone listed on the application has passed the test. This applies to all submissions (new, continuation and/or amendment) regardless of funding or rank of the PI, sponsor and co-investigators.

Those individuals specifically listed in the application as PI, sponsor, and/or co-investigators must provide proof of having passed the test.

2. Approval Stamps: For all approved new studies, amendments and continuing reviews researchers will be required to give subjects the version of the consent form and/or study information sheet that has been stamped showing the approval and expiration dates of the form. (E-mail information sheets must carry these dates at the end of the "sheet.")

Be certain that your consent form/information sheet has a blank space at least 1" high by 2 1/2" wide at the bottom of the last page where the stamps can be affixed.

3. Federal grant requirements: All studies that are being submitted to any HHS agency for funding must submit the identical information to the Human Subjects Committee (HSC) as was submitted in the grant application. And, a copy of the grant application must be provided with the HSC application.

The information provided in the Committee packet must coincide with the information provided in the human subjects section of the grant application. ONE COPY of the grant application must be provided with the completed application to the Committee

The agencies involved include CFDCP, HRSA, FDA, NIH and its sub-agencies among several others. If you are unsure as to whether an agency is part of HHS, call the Committee office.

Any questions about these requirements may be addressed to the Committee's office at iub_hsc@indiana.edu or (812) 855-3067.

INDIANA UNIVERSITY
BLOOMINGTON CAMPUS COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

STUDY AMENDMENT

Study # _____ of
Research Project Utilizing Human Subjects

NOTE TO INVESTIGATORS: Study amendments may not be instituted until written approval from the IUB Campus Committee for the Protection of Human Subjects has been given. Return this form to: HSC, Carmichael Center L03, 530 E. Kirkwood Ave., IUB. Please complete by filling in the blanks marked by red boxes. This entire page **MUST be on a single sheet of paper. Use this as a cover page and attach additional pages with the information requested in items 1 and 2. PLEASE DO NOT PRINT THE FORM THEN FILL IN BY HAND.**

TITLE OF PROJECT _____

PRIN. INVESTIGATOR _____

SCHOOL/DEPARTMENT _____

ADDRESS _____

E-MAIL _____

PHONE _____

FUNDING AGENCY: _____

ATTACH PAGE(S) 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. If adding co-investigators, have them sign by their name.
2. Describe how the amendment will affect the risk:benefit ratio for subjects.
3. Does the proposed amendment require changes in the Consent Statement/Information Sheet?
If the answer is **yes**, check the appropriate line and attach a copy of the revised Consent Statement/Information Sheet, **with** changes highlighted.

The new Consent Statement/Information Sheet is in addition to the current one
The new Consent Statement/Information Sheet is to replace the current one.

Principal Investigator (typed/printed name) _____

(signature—must be PI's own signature)

(date)

Faculty Advisor/Sponsor (typed/printed name) _____

(signature—must be sponsor's own signature)

(date)

CAMPUS LEVEL REVIEW

The Amendment of this protocol for use of human subjects has been reviewed and approved by the IUB Campus Committee for the Protection of Human Subjects.

_____ Exempt review ¶# _____ _____ Exempt review with documentation of consent ¶# _____

_____ Expedited review ¶# _____ _____ Full Committee review

Chairperson/Agent IUB Committee

Date

logged in ts _____ approval logged _____ copy to PI _____ rank code _____ Col _____

test: PI _____ sponsor _____ co-PI _____