

CONTINUING REVIEW OF PREVIOUSLY APPROVED RESEARCH
For Expedited and Full Review Research
HENDRIX COLLEGE HUMAN SUBJECTS REVIEW BOARD

The U. S. Department of Health and Human Services regulations for the protection of human subjects at 45 CFR 46.109(e) require that previously approved Full and Expedited research involving human participants be re-approved at intervals appropriate to the degree of risk, but not less than once per year.

Note: Research that qualified for Exemption does not require continuing review.

Continuing review and re-approval of research must occur before the one (1) year anniversary date of the original approval or the research must stop (no new participants enrolled and no research conducted with previously enrolled participants). Also, re-approval cannot occur more than 30 days prior to the expiration date. The expiration date is the anniversary date, which is listed on the original approval memo. It is the investigator's responsibility to apply for continuing review in a timely manner.

Federal regulations allow up to two (2) annual continuing reviews for a total project approval time of three years. If the research will continue beyond three years, a new application will need to be completed and submitted to the HSRB for review before the expiration date.

Continuing review and re-approval will be conducted through the same review process as the original application: Expedited review or Full committee review. *An exception is made if Full review research is in the "data analysis only" stage; it may be reviewed through an Expedited process.*

PROCEDURES FOR CONTINUING REVIEW

Submit the following documents 1) electronically as attachments to HSRB@hendrix.edu and 2) in person as paper copies with original signatures to the HSRB Chair, Dr. Stacey Schwartzkopf, Mills 306B:

- 1) A completed Continuing Review Form (see next page)
- 2) A copy of the most recently approved version of your original application (including all supporting documents), with any proposed modifications bolded or underlined.

Note: If your research has been completed since the last review, complete the Final Report For Research Form instead of applying for continuing review.

Before beginning this form, please make sure you are using the most recent version of Adobe Acrobat and can save your entries.

CONTINUING REVIEW FORM
For Expedited and Full Review Research
HENDRIX COLLEGE HUMAN SUBJECTS REVIEW BOARD

Project Title:

HSRB Approval Code #:

Investigator Name(s):

Faculty Sponsor (if student research):

Original Expiration Date: Original Type of Review: Expedited Full

1) Research Study Status (Check One):

Work Not Yet Started (no participants recruited) State Reason:

Active Project (participant enrollment and/or involvement continues)

Data Analysis Only (there will be NO additional participant contact)

2) Participant (and Control) Status Report:

- a. Are participants still being enrolled? Yes No
- b. Number of participants enrolled to date:
- c. Number of participants proposed for coming year:
- d. Is the total number of participants different than in the original approved application? Yes No
If YES, please explain.

4) Report briefly on the progress of the research to date and/or on the research findings.

4) Since the last review, were there any:

a. Adverse events or unanticipated problems involving risks to participants or others? Yes No
If Yes, please explain:

b. Participant withdrawals from the research? Yes No
If Yes, please explain:

c. Complaints about the research? Yes No
If Yes, please explain:

6) Do you wish to make any modifications to your currently approved application? Yes No
If Yes, please summarize your proposed modifications below in a list form.

SIGNATURES: I certify to the best of my knowledge that the information provided herein is an accurate reflection of the research study and that the research will continue to be conducted in full compliance with Federal Regulations and Hendrix College policies and procedures governing human participant research.

Signature of Investigator(s)

Date

Signature of Faculty Advisor (if student research)

Date

To submit your continuing review form for review, please submit one electronic copy to HSRB@hendrix.edu AND one signed paper copy (with original signatures) to the HSRB chair (Dr. Stacey Schwartzkopf, Mills 306B).