UNIVERSITY OF CENTRAL ARKANSAS

RESEARCH COMPLIANCE
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CONTINUING REVIEW OF PREVIOUSLY APPROVED RESEARCH
For Expedited and Full Review Research

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 IRB 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 at a convened meeting. *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 a *.pdf file of the following documents:

1) A completed Continuing Review Form
2) A copy of the final approved version of the original application including any modifications previously approved by the IRB
3) A copy of the current informed consent document and any newly proposed consent document

Allow at least two (2) weeks for Expedited Review. Full Reviews may take longer as meetings are conducted at scheduled meeting times during the academic year. Check the Research Compliance website for the IRB meeting calendar or call the Research Compliance Office to confirm the meeting date so that the review can be completed before the expiration date.

Submit one (1) *.pdf file of the documents listed above (including signature pages and attachments) to researchcompliance@uca.edu. DO NOT submit hard copies of documents.

Note: If your research has been completed (including all data analysis) since the last review, complete the Final Report Form instead of applying for continuing review.

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Date Received in Office _____

CONTINUING REVIEW FORM

For Expedited and Full Review Research

This form may be downloaded at http://www.uca.edu/sponsoredprograms/institutionalreviewboard/

Project Title:

IRB #: Investigator Name(s):

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 subjects (and controls) different than in the original approved application? ☐ Yes ☐ No

If YES, please explain.

3) Supported Financially? ☐ Yes ☐ No

If **Yes**, Funding Source:
(If externally funded, attach a copy of the annual report to the agency.)

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

5) Since the last review were there any:

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

b. Participants withdrawals from the research? ☐ Yes ☐ No
If **Yes**, explain:

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

6) Were there any amendments or modifications since the last review? ☐ Yes ☐ No
If **Yes**, attach updated materials. Please highlight the changes.

7) Were there any changes to the consent documents? ☐ Yes ☐ No
If **Yes**, attach updated materials. Please highlight the changes on the modified document.

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 University of Central Arkansas policies and procedures governing human participant research.

_____ _____
Signature of Principal Investigator Date

_____ _____
Signature of Co-PI Date

_____ _____
Signature of Co-PI Date

_____ _____
Signature of Co-PI Date

_____ _____
Signature of Research Advisor (if student research) Date