UNIVERSITY OF ARKANSAS – FORT SMITH
IRB Request for Continuing Review

Reviewing IRB IRB STUDY NUMBER: _____

Type only in the gray boxes. To mark a box as checked, double-click the box, select "checked", and click "OK".

SECTION I: INVESTIGATOR INFORMATION

Principal Investigator:
Name *(Last, First, Middle Initial)***:** _____
Department: _____ Phone: _____ E-Mail: _____

Additional Study Contact:
Name: _____ Phone: _____ E-Mail: _____

Project Title:
Funding Status: ☐ NA ☐ Funded
Funding Source: _____ Sponsor Number: _____

SECTION II: CURRENT STUDY STATUS

Place an X on the line for ONGOING Open Enrollment or ONGOING Closed Enrollment

____ ONGOING – OPEN TO ENROLLMENT
Date study was initiated: _____
Projected date of completion: _____

(Select one below)
☐ Enrollment of new participants or review of records/specimens continues
☐ No participants have been enrolled to date. Please explain: _____

☐ **Please check here if the study is currently suspended (temporarily) and indicate the reason(s) for the suspension:**

_____

_____ **ONGOING – CLOSED TO ENROLLMENT**
Date study was initiated: _____
Projected date of completion: _____

☐ **Re-consenting/re-authorizing**

☐ **NOT re-consenting/re-authorizing**

(Select one)
☐ Participants are still receiving research-related intervention or interaction.
☐ Participants have completed research-related interventions; however, long-term follow-up continues. Long term follow-up includes research interactions that involve no more than minimal risk to subjects, or collection of follow-up data from procedures or interventions that would be done as part of routine clinical care. Research interventions which would not be performed for clinical purposes are considered research-related intervention are not considered follow-up.
☐ Participants have completed all research-related intervention or interaction and long-term follow-up has been completed. The remaining research activities are limited only to data analysis that may require access to records and/or specimens.
☐ **Check here if the study is currently suspended (temporarily) and indicate the reason(s) for the suspension:**

_____

SECTION III: INVESTIGATOR STATEMENT OF COMPLIANCE

By submitting this form, the Principal Investigator assures that all information provided is accurate. He or She assures that procedures performed under this project will be conducted in strict accordance with federal regulations and University policies and procedures that govern research involving human subjects. He or She acknowledges that he or she has the resources required to conduct research in a way that will protect the rights and welfare of participants, and that he or she will employ sound study design which minimizes risks to subjects. He or She agrees to submit *any* change to the project (e.g. change in principal investigator, research methodology, subject recruitment procedures, etc.) to the Board in the Change in Protocol form for UAFS IRB approval prior to implementation.

SECTION IV: IRB APPROVAL

For Human Subjects Office Use Only

Type of review: ☐ Full Board
☐ Expedited, Category: ______ Approved for a period of: ☐ one (1) year

STATUS OF STUDY: <u>ONGOING</u>

This continuing review has been reviewed and approved as meeting the criteria for IRB approval as outlined in 45 CFR 46.111(a) by the University of Arkansas – Fort Smith IRB. Based on the criteria for determining the frequency of continuing review and the level of risk, this study will expire on: ____________________. If the study is not re-approved prior to that date, all research activities must cease on that date, including enrollment of new subjects, intervention/interaction with current participants, and analysis of identified data.

Authorized IRB Signature: ____IRB Approval Date: ______________

Printed Name of IRB Member: ____________________________________