**Request for Modification in Research**

Protocol for IRB of APPROVED RESEARCH –for Human Subjects Research

Institutional Review Board

Office of Research & Sponsored Program

Auburn University at Montgomery

[dtomblin@aum.edu](mailto:dtomblin@aum.edu) (334) 244-3250

***This form should be used when the researcher is requesting any change in the project such as additions to the research team, revised forms, change in methodology, location, target population, or adverse event reporting, etc). If the IRB has expired, the researcher must resubmit their protocol for complete review.***

Protocol # **\_ \_ \_ \_ - \_ \_ \_** (example: 2015-038)

Project Title

Principal/Student Investigator

Title

Investigator’s Phone

Investigator’s e-mail

Duration of Study (original dates) From:  To:

1. Has your project begun?  Yes No

2. If your project has NOT begun, do you want to CLOSE your project? Yes No

**If YES, complete FINAL REPORTS/STUDY CLOSURE FORM.** If no, continue.

**Study Accrual (to date)**

3. Number participants recruited (or charts/records reviewed) for study:

4. Number participants completed study:

5. Number of subjects who withdrew early due to adverse events:

Explain

6. Have there been any unanticipated benefits, etc. to participants resulting from this study?

Yes No

Explain

7. Do you plan to continue to enroll participants? Yes No

**Project Information**

10. Describe the modifications you are requesting (e.g. methodology, research team members, survey instruments, consent forms, research design, etc.)? List and Describe:

**If you have revised any of your research documents, attach them to this request. You may send this document and any attachments electronically (attached to an email) or you may send hard copies.**

Date:

Name of Person submitting report:

The IRB will review this request and any amendments. You will receive a memo from the IRB approving the modifications or requesting additional information.

Date Received in IRB office: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date reviewed by IRB: \_\_\_\_\_\_\_\_\_\_\_\_ Reviewed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approved or Authorized by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_