Human Subjects Research Protocol: Project Revision or Amendment

South College Institutional Review Board (IRB)
400 Goody's Lane, Knoxville, TN 37922
Submit completed form to: Ms. Brittany Galyon, IRB Coordinator at bgalyon@south.edu

OFFICE USE	DATE RECEIVED:	PROTOCOL NUMBER:

1. PROJECT TITLE

2. PRINCIPAL INVESTIGATOR (If you are a student, you must list a faculty advisor as the Co-PI)

Name (Last, First, MI):

If any contact information has changed since last IRB review – provide below:

College Academic Title:
Department Name:
Campus Mailing Address:

E-mail:
Phone:

CO-PRINCIPAL INVESTIGATOR (Faculty advisor of student PI)

Name (Last, First, MI):

College Academic Title:
Department Name:
Campus Mailing Address:

E-mail:
Phone:

3. ADDITIONAL CONTACT(S)

If additional contact information has changed since the last IRB review, list all current contact(s) below.
If there is no new information, go to Question #4.

Name (Last, First, MI):
E-mail:
Phone:
Fax:

Name (Last, First, MI):
E-mail:
Phone:
Fax:

4. PROPOSED CHANGE(S)

Indicate each change for which you are seeking IRB review and approval (check all that apply).

- ☐ Change in study personnel (including change in PI) → Complete **Appendix 20**
- ☐ Change in the number of participants → Complete **Appendix 21**
- ☐ All other research changes → Complete **Appendix 22**

If personnel are being added to the protocol, educational requirements (initial and continuing) must be satisfied prior to submitting the application for review. Directions for completing the training are in the document "Human Subjects Research Training," which is available on the OSPR website.

Have all South College investigators and key personnel completed the required web-based course (CITI) in the protection of human research subjects? ***Attach a copy of the CITI training completion report for each person.***

- ☐ Yes
- ☐ No

5. REVISED DOCUMENT(S)

This request requires the revision(s), addition(s), and/or deletion(s) to the following (check all that apply):

- ☐ CITI training completion report(s) (***for new personnel being added to the protocol***)

- ☐ Consent Form(s), Assent Form(s), Permission Form(s), and Verbal Script(s) including translated documents
- ☐ HIPAA Research Authorization Form(s)
- ☐ Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations)
- ☐ Script(s) or Information Sheet(s), including debriefing materials
- ☐ Instruments (e.g., questionnaires or surveys completed by participants)
- ☐ Other, Specify:

For all items checked, provide the currently approved materials (marked as "current"), and the revised materials, one copy with change(s) underlined (or "tracked") and one copy with change(s) incorporated (clean). All materials should be submitted single sided. Re-submission of the IRB Application for Initial Review of Human Subjects Research is not required.

6. PRINCIPAL INVESTIGATOR'S (and Co-PI's, if PI is a student) ASSURANCE

I agree to follow all applicable federal regulations, guidance, state and local laws, and college policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators, including, but not limited to, the responsibilities of all individuals conducting human subjects research, as described in the *South College IRB Policies and Procedures Manual for Human Subjects Research*.

I verify that the information provided in this IRB Project Revision/Amendment form is accurate and complete. I will initiate change(s) to this research only after having received notification of final IRB approval (unless necessary to eliminate apparent immediate hazards to participants).

Signature of Principal Investigator _____ Date _____

Printed name of Principal Investigator _____

Signature of Co-Principal Investigator (if PI is a student) _____ Date _____

Printed name of Co-Principal Investigator (if PI is a student) _____