**Human Subjects Research Protocol: Continuing Review**

# Institutional Review Board (IRB), Office of Sponsored Programs and Research (OSPR)

3904 Lonas Drive, Knoxville, TN 37909

Phone: (865) 288-8219 Fax: (865) 288-5900 irbsubmissions@south.edu

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| **OFFICE USE** | **DATE RECEIVED:** | **PROTOCOL NUMBER:** |

**1. PROJECT TITLE**

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| **2. PRINCIPAL INVESTIGATOR (If you are a CO-PRINCIPAL INVESTIGATOR****student, you must list a faculty advisor as the Co-PI) (Faculty advisor of student PI)** |
| Name (Last, First, MI): Name (Last, First, MI):**If any contact information has changed since last IRB review – provide below:**College Academic Title: College Academic Title:Department Name: Department Name:Campus Mailing Address: Campus Mailing Address:E-mail: E-mail:Phone: Phone: |
| Are you requesting a change in the Principal Investigator or the Co-Principal Investigator? | Yes → Complete **Appendix 20**No |

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| **3. CO-INVESTIGATOR(S) and KEY PERSONNEL (South College personnel only)** |
| Verify the names of all co-investigators and key personnel on the study as listed on the Continuing Review Notice. |
| Are you requesting any changes in South College study personnel? | Yes → Complete **Appendix 20**No |

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| **4. EXTERNAL CO-INVESTIGATOR(S) and KEY PERSONNEL (non-South College personnel only)** |
| Verify the names of all external co-investigators and key personnel on the study as listed on the Continuing Review Notice. |
| Are you requesting any changes in external study personnel? | Yes → Complete **Appendix 20**No |

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| **5. ADDITIONAL CONTACT(S)** |
| If additional contact information has changed since last IRB review, list all current contact(s) below. If no new information, go to Question #6. |
| Name (Last, First, MI): | Phone: |
| E-mail: | Fax: |
| Name (Last, First, MI): | Phone: |
| E-mail: | Fax: |
| Name (Last, First, MI): | Phone: |
| E-mail: | Fax: |

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| **6. HUMAN SUBJECTS RESEARCH TRAINING** |
| ***Educational requirements (initial and continuing) must be satisfied prior to submitting the application for continuing review. Directions for completing the CITI 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 |

**7. FINANCIAL CONFLICT OF INTEREST**

Does any South College investigator (including principal or co-investigator), key personnel, or their immediate family members have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research?

**If Yes** → Describe the conflict:

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| **8. FUNDING OR OTHER SUPPORT** |
| ***If the research is federally funded and involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. Contact OSPR for more information.*** |
| a. Is the research funded or has funding been requested? | Yes No |
| **If Yes** → Specify sponsor: |
| ***Provide a copy of the grant application or funding proposal. The college is required to verify that all funding proposals and grants (new or renewals) have been reviewed by the IRB before funds are awarded.*** |
| b. Is any support other than monetary (e.g., materials, equipment, drugs, etc.) being provided for the study? | Yes No |
| **If Yes** → Specify support and provider: |
|  |  |
| c. Is there a new, revised, or renewal grant application since the last IRB review? | YesNo |
| **If Yes** → ***Forward a copy of the current grant application with this submission. The college is required to verify that all funding proposals and grants (new or renewals) have been reviewed by the IRB before funds are awarded.******NOTE: Many funding agencies require IRB approval of the human subjects research protocol before they will accept a grant application. Some funding agencies will accept a grant application if the human subjects research protocol is pending IRB approval (i.e., the completed human subjects research protocol has been submitted to the IRB before the grant application is submitted, but review of the IRB protocol is pending). Other funding agencies have a Just-in-Time policy in which the grant application is first submitted for peer review. After the grant application has been peer reviewed and if it receives a score within a range of possible funding, the funding agency will contact the principal investigator (PI) and request certification of IRB approval of the human subjects research protocol. Researchers who learn that their proposal is within a range of possible funding should then submit the appropriate protocol to the IRB for review. It is the PI's responsibility to find out which method is used by the funding agency to which a grant application is being submitted.*** |

**9. LOCATION OF THE RESEARCH**

a. List the specific site(s) at which South College research was or is being conducted (include both domestic and international locations). ***Provide copies of all current IRB approvals for non-South College sites, as applicable.***

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| **Location Name (or description)** | **Address (street, city and state, or country)** |
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**10. EXPEDITED REVIEW**

Are you requesting **Expedited Review**? Yes → Complete **Appendix 23**

No

**11. RESEARCH STATUS**

1. Indicate the status of the research:

No research participants have been enrolled (or participant records, specimens, etc. obtained). Explain:

Research participants have been enrolled (or participant records, specimens, etc. obtained)

1. If participants have been enrolled, check all that apply: Recruitment is ongoing

Recruitment has been completed:

Participants have not completed research interventions. All participants have completed all research interventions.

Research remains active only for long-term follow-up (or re-contact) and data analysis. Research remains active only for data analysis.

**12. SUMMARY OF THE RESEARCH (Abstract)**

Provide an abstract of the research using [**non-technical language**](http://www.online-utility.org/english/readability_test_and_improve.jsp) that can be readily understood by someone outside the discipline. Explain briefly the research design, procedures to be used, risks and anticipated benefits, and the importance of the knowledge that may be expected to result. ***Use complete sentences (limit 500 words).***

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| **13. RESEARCH PROGRESS** |
| a. Summarize the progress of the South College research, including any interim findings. |
| b. For multi-site studies, summarize the overall progress of the research. ***Attach a copy of the most recent multi-site study report, if any.*** | N/A |
| c. Summarize any IRB-approved amendments or changes made to the research since last IRB review (initial or continuing). If IRB approval was not obtained for changes, provide an explanation. | N/A |
| d. Summarize recent literature or other new information relevant to the research, if any, since last IRB review (initial or continuing). | N/A |

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| e. Discuss significant new findings (e.g., affecting risks, benefits, or alternatives), if any, that could affect participants’ N/A willingness to continue in the research and how participants have been or will be informed. |
| f. Are you requesting any changes to the research, other than a change in study personnel or participant numbers (e.g., change in PI or changes to protocol, data collection forms, recruitment or consent processes, etc.)? | Yes → Complete **Appendix 22**No |
| g. Projected or actual completion (month and year)date: ***Indicate “ongoing” for repository research or program protocols*** |

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| **14. NUMBER OF PARTICIPANTS** |
| ***The number of participants is defined as the number of individuals who agreed to participate (i.e., those who provided consent or whose records were accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.*** |
| Yes → Ina. Is this a multi-site study?No | dicate total number of participants to be enrolled across all sites:  |
| b. For research approved by the South College IRB, provide: |
| 1) IRB approved number of participants (or records, specimens, etc.): |
| 2) Total number of participants enrolled in the research to date: |
| 3) Number of participants enrolled since last IRB review (initial or continuing): |
| c. If actual total enrollment to date (14b.2) is significantly different (over or under) from IRB approved number (14b.1), provide an explanation: |
| d. Are you requesting an increase in the total n participants? | umber of Yes → Complete **Appendix 21**No |

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| **15. PARTICIPANT POPULATION** |
| a. Specify the age(s) of the individuals who may participate in the research: |
| Age(s): |
| b. Specify the participant population(s) – check all for which you have approval: |
| Adults |  | Pregnant women/fetuses |
| Children (< 18 years) |  | Neonates (uncertain viability/nonviable) |
| Adults with decisional impairment |  | Student research pools (e.g., psychology, linguistics) |
| Non-English speaking |  | Specify: |
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| Prisoners |  | Unknown (e.g., research using secondary data/specimens,non-targeted surveys, program protocols) |

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| **16. RECRUITMENT AND INFORMED CONSENT PROCESS** |
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| a. Were recruitment materials used to enroll participants? |  | YesNo |
| **If Yes** → Are recruitment materials still being used? |  | Yes → ***Provide copies of the current recruitment materials (ads, radio/TV scripts, internet solicitations, etc.).***No |

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| b. How **was/is** informed consent or assent obtained? Check all that apply. ***Provide blank copies of all current documents***. |
| Assent – Form | Parental/Legal Guardian Permission – Form |
| Assent – Verbal Script | Parental/Legal Guardian Permission – Verbal Script |
| Informed Consent – Form | Translated Consent/Assent – Form(s) |
| Informed Consent – Verbal Script | Waiver or Alteration of Consent Process |
| Informed Consent – Addendum | Waiver of Consent Documentation |
| c. Is deception of participants part of the research? | Yes No |
| **If Yes** → ***Provide copy of current debriefing script or other information sheet(s) used to inform participants.*** |

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| **17. HIPAA RESEARCH AUTHORIZATION** |
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| Is individually identifiable protected health information (PHI) accessed, used, or disclosed in the research? |  | YesNo |
| See [**Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule**](http://privacyruleandresearch.nih.gov/pr_02.asp) for more information.**If Yes** → Check all that apply: |
| Written Authorization → ***Provide current Authorization Form*** |  |  |
| Partial Waiver (recruitment purposes only) |  |  |
| Full Waiver (entire research study) |  |  |
| Alteration (written documentation) |  |  |

**18. RISK ASSESSMENT**

* 1. Since the last IRB review (initial or continuing), did any unanticipated problems involving risks to subjects or others or adverse events occur in research at South College or at a site(s) approved by the South College IRB?

Yes → Complete **Appendix 24**

No

* 1. Was the research subject to Data and Safety Monitoring Board (DSMB) or other similar committee/group review? Yes → ***Provide a copy of the most current report.***

No → Indicate one of the following:

Events occurred in research approved by a non-South College IRB → Complete **Appendix 24**

No external events to report

* 1. Provide an assessment of the risks and potential benefits based on study results since last IRB review.

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| **19. PARTICIPANT COMPLAINTS AND VOLUNTARY WITHDRAWALS** |
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| a. Have any participants made complaints about the research since the last IRB review? |  | YesNo |
| **If Yes** → List and describe each **complaint** and any **actions taken** to resolve the complaint(s). |

b. Have any participants voluntarily withdrawn from the research since last IRB review? ***Do not include individuals whose participation was discontinued by the investigator or sponsor because of unanticipated problems, study completion, etc.***

Yes No

**If Yes** → List and describe each **withdrawal** and any **actions taken** (e.g., changes to the research or consent process) in response to the withdrawal(s).

**20. APPLICATION CONTENTS**

Indicate the documents submitted for this continuing review. Check all appropriate boxes.

**Human Subjects Research Protocol: Continuing Review** Appendix 20: Change in Study Personnel (questions 2, 3 and 4) CITI training completion reports (question 6)

Complete Grant Application or Funding Proposal, as applicable (new, revised, or renewals only) (question 8c) Current IRB approvals/Letters of Support from non-South College sites, as applicable (question 9)

Appendix 23: Expedited Review – Continuing Review (question 10) Multi-site study reports (question 13b)

Appendix 22: All Other Research Changes (question 13f) Appendix 21: Change in Number of Participants (question 14d)

Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) – only if still

being used (question 16a)

Currently Approved Consent Form(s), Assent Form(s), Permission Form(s), and Verbal Script(s) including translated documents (question 16b)

Script(s) or Information Sheet(s), including Debriefing Materials (question 16c) HIPAA Research Authorization Form(s) (question 17)

Appendix 24: Problem Summary Sheet (questions 18a and 18b) Data and Safety Monitoring Reports (question 18b)

Data Collection Form(s) for Investigator-Initiated Studies – ***only if new or revised since last IRB review***

Instruments (e.g., questionnaires or surveys completed by participants) – if still being used Other supporting documentation and/or materials, such as a research protocol

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| **21. 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 Continuing Review of Human Subjects Research Protocol is accurate and complete. |
| 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)