**Human Subjects Research Protocol: Final Study Report**

# 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](mailto:irbsubmissions@south.edu)

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| --- | --- | --- |
| **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)**

**CO-PRINCIPAL INVESTIGATOR**

**(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:

**3. RESEARCH STATUS**

Check all that apply to the South College research: Research was never initiated.

No research participants were ever enrolled (or participant records, specimens, etc. obtained).

Research has been discontinued/completed, and there will be no further data collection (including long term follow-up or re-contact) or analysis of identifiable/coded data.

Sponsor is discontinuing the research.

Principal Investigator and/or Co-Investigator are leaving the college. Other, specify:

**4. RESEARCH PROGRESS**

1. Summarize the results of the study, including any plans for scholarly/scientific presentations or publications.
2. 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.
3. Discuss whether any significant new findings or other information should be provided to past participants.
4. Discuss what will happen to the identifiable/coded data, if any, at the end of the study.

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| **5. 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 did not prove eligible or complete the study.*** | |
| a. Is this a multi-center study? | Yes → Indicate total number of participants enrolled across all sites: No |
| 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 (5b.2) was significantly different (over or under) from the IRB approved number (5b.1), provide an explanation: | |

**6. 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 final or 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

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| **7. PARTICIPANT COMPLAINTS AND VOLUNTARY WITHDRAWALS** | | |
|  |  |  |
| a. Have any participants made complaints about the research since last IRB review? |  | Yes  No |
| **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). | | |

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| **8. PRINCIPAL INVESTIGATOR’S (and Co-PI’s, if PI is a student) ASSURANCE** | | | |
| I have followed all applicable federal regulations, guidance, state and local laws, and university 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 Final Study Report 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) | | | |