Human Subjects Research Protocol: Expedited or Full Review

South College Institutional Review Board (IRB)

Submit completed protocol to: Ms. Brittany Galyon, IRB Coordinator, 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):
University Academic Title:
Department Name:
Campus Mailing Address:
E-mail:
Phone:

CO-PRINCIPAL INVESTIGATOR (List a Co-PI only if you are the faculty advisor of a student PI)

Name (Last, First, MI):
University Academic Title:
Department Name:
Campus Mailing Address:
E-mail:
Phone:

3. SOUTH COLLEGE CO-INVESTIGATOR(S)

Are there any South College Co-Investigators on this protocol?

☐ Yes → Complete **Appendix 1**
☐ No

Signatures of Co-Investigator(s) are required on Appendix 1.

4. SOUTH COLLEGE KEY PERSONNEL

Are there any South College Key Personnel on this protocol?

☐ Yes → Complete **Appendix 1**
☐ No

Key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, or who collect study data.

5. EXTERNAL CO-INVESTIGATOR(S) AND KEY PERSONNEL

Are any external (non-South College) Co-Investigators or Key Personnel *engaged* in the South College research?

☐ Yes
☐ No → Go to Question #6

"Engaged" individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by South College. See OHRP Engagement Guidance or contact the IRB for more information.

If Yes → Who will provide approval for these external personnel?

☐ South College IRB → Complete **Appendix 2**
☐ Non-South College IRB → ***Provide a copy of the approval(s)***

External (non-South College) personnel may be subject to their own institutional review and/or local oversight requirements. Investigators are responsible for determining if other requirements apply and are encouraged to maintain documentation of any additional approvals/determinations for this study.

6. ADDITIONAL CONTACT

If further information about this application is needed, specify the contact person if other than the PI (e.g., study or regulatory coordinator, research assistant, etc.). ☐ **N/A**

Name (Last, First, MI): Phone:

E-mail: Fax:

7. HUMAN SUBJECTS RESEARCH TRAINING

Educational requirements (initial and continuing) must be satisfied prior to submitting the application for review. Directions for completing the CITI training are in the document "Human Subjects Research Training," which is available on the IRB 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

8. 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? ☐ Yes ☐ No

If Yes → Describe the conflict:

9. 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 the IRB for more information.

a. Is the research funded or has funding been requested? ☐ Yes ☐ No

If Yes → Specify sponsor: _____

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: _____

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.

10. OTHER SOUTH COLLEGE APPROVALS

Check all that apply and provide applicable documentation. ***Contact the IRB for information on obtaining approvals. IRB review cannot be conducted until required institutional approvals are obtained.***

☐ N/A

☐ Introduction of radioactive materials or radioactive devices into humans

☐ The use of recombinant DNA

☐ Gene therapy projects

☐ Vaccine trials

11. LOCATION OF THE RESEARCH

If the research will be conducted at any location other than South College, the investigator is responsible for obtaining a letter of support from each site. The letter will be from a person in authority to grant permission to perform research at the site. The letter will be addressed to the investigator and indicate that they are knowledgeable about the nature of the research project that will be performed and that they approve of this research to be conducted in their business or facility. Attach the letter(s).

a. List the specific site(s) at which the research will be conducted (include both domestic and international locations).

Location Name (or description)	Address (street, city and state, or country)

b. Are all the sites named above domestic sites?

☐ Yes

☐ No → Complete **Appendix 3**

c. Is the South College PI the lead investigator or is South College the lead site for collaborative research?

☐ Yes

☐ No → Go to **Question #12**

☐ Not collaborative research → Go to **Question #12**

i. Describe the communication between sites that might be relevant to the protection of participants, such as unanticipated problems, interim results, and protocol modifications.

ii. Describe IRB oversight arrangements for each collaborative site (i.e., who will provide IRB review and approval). ***Provide copies of the non-South College approvals, as applicable. Contact the IRB if requesting that South College serve as the IRB of record.***

12. EXPEDITED REVIEW

Are you requesting **Expedited Review**?

☐ Yes → Complete **Appendix 5**

☐ No

13. SUMMARY OF THE RESEARCH (Abstract)

Provide an abstract of the proposed research using non-technical language that can be readily understood by someone outside the discipline. Explain briefly the research design with sufficient details, procedures to be used, risks and anticipated benefits, and the importance of the knowledge that may reasonably be expected to result. Additional details about the proposed methods will be addressed in question 16. ***Use complete sentences (limit 500 words).***

14. SCIENTIFIC BACKGROUND AND LITERATURE REVIEW

Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. ***Use complete sentences (limit 300 words).***

a. When was the literature review conducted (DD/MM/YYYY):

b. What date range did the literature search cover:

c. List the key words used in the literature search:

15. RESEARCH OBJECTIVES

List the specific scientific or scholarly aims of the research study.

16. RESEARCH METHODS AND ACTIVITIES

a. Identify and describe all interventions and interactions that are to be performed solely for the research study. Distinguish research (i.e., experimental) activities from non-research activities. ***Methods should be described in adequate detail so that IRB members may assess the potential study risks and benefits. Provide a clear description of the data being collected and the methods for collecting the data and conducting data analysis and reporting.***

Attach data collection forms and instruments (e.g., forms that investigators will use to collect or record data; questionnaires or surveys to be completed by participants).

b. Check all research activities that apply:

- ☐ Anesthesia (general or local) or sedation
- ☐ Audio, video, digital, or image recordings
- ☐ Biohazards (e.g., rDNA, infectious agents, select agents, toxins)
- ☐ Biological sampling (other than blood)
- ☐ Blood drawing
- ☐ Data, not publicly available
- ☐ Data, publicly available
- ☐ Data repositories → Complete **Appendix 6** (future unspecified use, including research databases)
- ☐ Deception → Complete **Appendix 7** and **Appendix 8**
- ☐ Devices → Complete **Appendix 10**
- ☐ Diet, exercise, or sleep modifications
- ☐ Drugs or biologics → Complete **Appendix 11**
- ☐ Emergency research
- ☐ Focus groups
- ☐ Food supplements
- ☐ Gene transfer
- ☐ Genetic testing → Complete **Appendix 12**
- ☐ Internet or e-mail data collection
- ☐ Magnetic Resonance Imaging (MRI)
- ☐ Materials that may be considered sensitive, offensive, threatening, or degrading
- ☐ Non-invasive medical procedures (e.g., EKG, Doppler)
- ☐ Observation of participants (including field notes)
- ☐ Oral history (does not include medical history)
- ☐ Placebo
- ☐ Pregnancy testing
- ☐ Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures) → Complete **Appendix 13**
- ☐ Randomization
- ☐ Record review (which may include PHI; e.g., medical history items)
- ☐ Specimen research
- ☐ Stem cell research
- ☐ Storage of biological materials → Complete **Appendix 14** (future unspecified use, including repositories)
- ☐ Surgical procedures (including biopsies)
- ☐ Surveys, questionnaires, or interviews (one-on-one)
- ☐ Surveys, questionnaires, or interviews (group)
- ☐ Other – specify:

17. DURATION

Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.

18. NUMBER OF PARTICIPANTS

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are 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.

a. Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking South College IRB approval.

b. Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).

c. Is this a multi-site study?

☐ Yes → Indicate the total number of participants to be enrolled across all sites:

☐ No

19. PARTICIPANT POPULATION

a. Specify the age(s) of the individuals who may participate in the research:

b. Specify the participant population(s). Check all that apply:

☐ Adults

☐ Children (< 18 years) → Complete **Appendix 15**

☐ Adults with decisional impairment → Complete **Appendix 16**

☐ Non-English speaking → Complete **Appendix 17**

☐ Student research pools (e.g., psychology, linguistics)
Specify: _____

☐ Pregnant women/fetuses → Complete **Appendix 18**
Do not complete Appendix 18 unless pregnant women will be intentionally recruited and/or studied.

☐ Neonates (uncertain viability/nonviable) → Complete **Appendix 18**

☐ Prisoners → Complete **Appendix 19**

☐ Unknown (e.g., secondary use of data/specimens, non-targeted surveys, program protocols)

c. Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.

d. Will any participants be excluded based on age, gender, race/ethnicity, pregnancy status, language, education, or financial status? ☐ Yes ☐ No

If Yes → Explain the criteria and reason(s) for each exclusion. ***Consider the study's scientific or scholarly aims and risks.***

e. Are any of the participants likely to be vulnerable to coercion or undue influence? ***Consider students, employees, terminally ill persons, or others who may have limited autonomy.*** ☐ Yes ☐ No

If Yes → Describe additional safeguards to protect participants' rights and welfare. ***Consider strategies to ensure voluntary participation.***

20. PARTICIPANT IDENTIFICATION, RECRUITMENT, AND SELECTION

a. Provide evidence that you will be able to recruit the necessary number of participants to complete the study.

b. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

c. List the names of investigator(s) and/or key personnel who will recruit participants.

d. Describe the process that will be used to determine participant eligibility.

e. Describe the recruitment process; including the setting in which recruitment will take place. ***Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, and oral/written scripts).***

f. Explain how the process respects potential participants' privacy.

21. INCENTIVES TO PARTICIPATE

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? ***Compensation plans should be pro-rated (not contingent upon study completion) and should consider participant withdrawals, as applicable.***

☐ Yes
☐ No

If Yes → Describe the incentive, including the amount and timing of all payments.

22. ALTERNATIVES TO STUDY PARTICIPATION

Other than choosing not to participate, list any specific alternatives, including available procedures or treatments that may be advantageous to the subject.

23. INFORMED CONSENT PROCESS

a. Indicate the consent process(es) and document(s) to be used in the study. Check all that apply. **Provide copies** of documents and/or complete relevant appendices, as needed. **See the Consent, Assent, and Parental Permission Templates on the IRB website** or contact IRB for more information. **For informed consent, download and complete the document titled, "Informed Consent Template" and submit it with your research protocol.**

☐ Informed Consent – Form

☐ Informed Consent – Verbal Script → Complete **Appendix 9**

☐ Parental/Legal Guardian Permission – Form

☐ Parental/Legal Guardian Permission – Verbal Script → Complete **Appendix 9**

☐ Assent – Form
☐ Assent – Verbal Script
☐ Informed Consent – Addendum
☐ Translated Consent/Assent – Form(s) → Complete **Appendix 17**
☐ Waiver or Alteration of Consent Process → Complete **Appendix 8**
☐ Waiver of Consent Documentation → Complete **Appendix 9**

b. List the names of investigator(s) and/or key personnel who will obtain consent from participants or their legally authorized representatives.

c. Who will provide consent or permission (i.e. participant, legally authorized representative, parent and/or guardian)?

d. Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation.

e. Explain how the possibility of coercion or undue influence will be minimized in the consent process.

f. Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension?
☐ Yes → ***Provide copies of these tools***
☐ No

g. Will any other consent forms be used (e.g., for clinical procedures such as MRI, surgery, etc. and/or consent forms from other institutions)?
☐ Yes → ***Provide copies of these forms***
☐ No

24. PRIVACY OF PARTICIPANTS

a. Describe the provisions to protect the privacy interests of the participants. ***Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants' expectations of privacy.***

b. Does the research require access to personally identifiable private information?
☐ Yes
☐ No

If Yes → Describe the personally identifiable private information involved in the research (e.g., Medical record, SS#, etc). List the information source(s) (e.g., educational records, surveys, medical records, etc.).

25. CONFIDENTIALITY OF DATA

a. Explain how information is handled, including storage, security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records. ***Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with South College policies.***

b. Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected. ☐ N/A

c. Will you be obtaining an NIH Certificate of Confidentiality? ☐ Yes → ***Provide a copy before you begin the research*** ☐ No

d. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality. ☐ N/A

e. Indicate what will happen to identifiable data at the end of the study. ***Primary research data and all other research-related records should be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data).***

- ☐ Identifiable data will not be collected
- ☐ Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)
- ☐ Identifiable or coded/linked data will be retained and stored securely (as appropriate)
- ☐ Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

26. HIPAA RESEARCH AUTHORIZATION

Will individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements be accessed, used, or disclosed in the research study? See **Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule** for more information.

- ☐ No
- ☐ Yes → Check all that apply:
  - ☐ Written Authorization to Use Personal Health Information → ***Provide a copy of the Authorization Form***
  - ☐ Partial Waiver (recruitment purposes only) →Complete **Appendix 4**
  - ☐ Full Waiver (entire research study) → Complete **Appendix 4**
  - ☐ Alteration (written documentation) → Complete **Appendix 4**

27. REASONABLY ANTICIPATED BENEFITS

a. List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants. ***Compensation is not to be considered a benefit.***

b. List the potential benefits that society and/or others may expect as a result of this research study.

28. RISKS, HARMS, AND DISCOMFORTS

a. Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant. ***Consider the range of risks, including physical, psychological, social, legal, and economic***.

b. Describe how risks, harms, and/or discomforts will be minimized. ***If testing will be performed to identify individuals who may be at increased risk (e.g., pregnant women, individuals with HIV/AIDS, depressive disorders, etc.), address timing and method of testing; include how positive test results will be handled.***

29. MONITORING

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described in Question #28 beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)? ☐ Yes ☐ No

If Yes → Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected);
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled);
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

30. ASSESSMENT OF RISKS AND BENEFITS

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

31. PARTICIPANT COSTS/REIMBURSEMENTS

a. List any potential costs participants (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic tests, etc.).

b. List any costs to participants that will be covered by the research study.

32. APPLICATION CONTENTS

Indicate the documents being submitted for this research project. Check all appropriate boxes.

☒ **Human Subjects Research Protocol: Expedited or Full Review form**

☐ Appendix 1: South College Co-Investigators and Key Personnel (questions 3 and 4)

☐ Appendix 2: External (non-South College) Co-Investigators and Key Personnel (question 5)

☐ Approvals for external co-investigators and key personnel if they are being covered by an external IRB (question 5)

☐ CITI training completion report(s) (question 7)

☐ Approvals for: radioactive materials/devices into humans; recombinant DNA; gene therapy; and/or vaccine trials (question 10)

☐ Letter(s) of support from sites where research activities will be conducted, as applicable (question 11)

☐ Appendix 3: International Research (question 11)

☐ Non-South College IRB approval(s) for collaborative research, as applicable (question 11)

☐ Appendix 5: Expedited Review – Initial Review (question 12)

☐ Data Collection Form(s) and Instrument(s) (question 16a)

☐ Appendix 6: Data Repositories (question 16b)

☐ Appendix 7: Deception (question 16b)

☐ Appendix 8: Waiver or Alteration of Consent Process (questions 16b and 23)

☐ Appendix 9: Waiver of Consent Documentation (questions 16b and 23)

☐ Appendix 10: Devices (question 16b)

☐ Appendix 11: Drugs or Biologics (question 16b)

☐ Appendix 12: Genetic Testing (question 16b)

☐ Appendix 13: Radiation (question 16b)

☐ Appendix 14: Storage of Biological Materials (Repository) (question 16b)

☐ Appendix 15: Children (question 19)

☐ Appendix 16: Adults with Decisional Impairment (question 19)

☐ Appendix 17: Non-English Speaking Research Subjects (questions 19 and 23)

☐ Appendix 18: Pregnant Women/Fetuses/Neonates (question 19)

☐ Appendix 19: Prisoners (question 19)

☐ Recruitment materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) (question 20)

☐ Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s), including translated documents (question 23)

☐ NIH Certificate of Confidentiality (question 25)

☐ HIPAA Authorization Form (question 26)

☐ Appendix 4: Waiver or Alteration of HIPAA Research Authorization (question 26)

☐ Other supporting documentation and/or materials, such as a research protocol

For Multi-Site Clinical Trials supported by DHHS, the submission will also include:

☐ DHHS-approved Sample Informed Consent Document (if one exists)

☐ DHHS-approved Protocol (if one exists)

33. ASSURANCE: PRINCIPAL INVESTIGATOR (If PI is a student, faculty advisor must be listed as Co-PI)

I agree to follow all applicable federal regulations, guidance, state and local laws, and South 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 described in the *South College IRB Policies and Procedures Manual for Human Subjects Research: Responsibilities of All Individuals Conducting Human Subjects Research*.

I verify that the information provided in this Application for Expedited or Full Review is accurate and complete. I will initiate this research only after having received notification of final IRB approval.

Signature of Principal Investigator Date

Type name of Principal Investigator

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

Type name of Co-Principal Investigator (Only if PI is a student)

34. DEPARTMENT CHAIR (or Signatory Official)

As Department Chair (or Signatory Official) for the Principal Investigator, I acknowledge that this research is in keeping with the standards set by our department and that it has met all Departmental/School requirements for review.

If the PI or any co-investigator is also the Department Chair, the signature of the Dean or other appropriate Signatory Official must be obtained.

Signature of Department Chair (or Signatory Official) Date

Type name of Department Chair (or Signatory Official)