Human Subjects Research Protocol: Exempt or Limited 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 → Complete **Appendix 2**

☐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.

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:

Email:

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

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. SCREENING QUESTIONS FOR EXEMPTION (CHECK THIS BOX IF YOU ARE **NOT** APPLYING FOR EXEMPTION ☐)

a. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life? ☐Yes ☐No

b. Could disclosure of participants' responses outside the research reasonably place participants at risk of criminal or civil liability or be damaging to participants' financial standing, employability, or reputation? ☐Yes ☐No

c. Does any part of the research require deception that is not disclosed to participants? ☐Yes ☐No

d. Will prisoners (or their data and/or specimens) be participants in the research? ☐Yes ☐No

e. For research proposed under category 1, will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices? ☐Yes ☐No or N/A

f. For research proposed under category 2, will the research involve children (< 18 years of age) AND will the investigator(s) participate in the activities being observed? ☐Yes ☐No or N/A

g. For research proposed under category 3, will the research involve children (< 18 years of age)? ☐Yes ☐No or N/A

h. For research proposed under category 4, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that participants could be identified directly or through identifiers linked to the participants? ☐Yes ☐No or N/A

i. For research proposed under categories 1-5, is the research subject to FDA regulations? ☐Yes ☐No or N/A

j. For research proposed under categories 6, does the food contain an ingredient, agricultural chemical, or environmental contaminant above the level found to be safe by the Food and Drug Administration or Environmental Protection Agency? ☐Yes ☐No or N/A

If you checked YES to ANY of the questions above, your research is NOT EXEMPT. See the screening questions for limited review below.

11. EXEMPT CATEGORY

Please check the categories of **exemption** for which you are applying. You may check more than one box. See the "*South College IRB Policies and Procedures Manual for Human Subjects Research*" for the list of categories and their descriptions.

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ ☐**N/A**

12. SCREENING QUESTIONS FOR LIMITED REVIEW (CHECK THIS BOX IF YOU ARE **NOT** APPLYING FOR LIMITED REVIEW ☐)

a. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life? ☐Yes ☐No

b. Does any part of the research require deception that is not disclosed to participants? ☐Yes ☐No

c. Will prisoners (or their data and/or specimens) be participants in the research? ☐Yes ☐No

d. For research proposed under category 1, will the research involve children (< 18 years of age)? ☐Yes ☐No or N/A

e. For research proposed under category 2, will the research involve children (< 18 years of age)? ☐Yes ☐No or N/A

If you checked YES to ANY of the questions above, your research does not qualify for LIMITED REVIEW. Do not complete this application. Submit the "Human Subjects Research Protocol: Expedited or Full Review" form.

13. LIMITED REVIEW CATEGORY

Please check the categories of **limited review** for which you are applying. You may check more than one box. See the "*South College IRB Policies and Procedures Manual for Human Subjects Research*" for the list of categories and their descriptions.

1 ☐ 2 ☐ ☐**N/A**

14. LOCATION OF THE RESEARCH

a. List the specific physical 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)

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).

b. Are all the sites named above domestic sites? ☐Yes, only domestic sites ☐No, some international sites → Complete **Appendix 3**

15. SUMMARY OF THE RESEARCH (ABSTRACT)

a. Provide an abstract of the proposed research using **non-technical language** that can be readily understood by someone outside the discipline. Explain clearly, yet briefly, the research design, procedures to be used, the risks and anticipated benefits of the research. Additional details about the proposed methods will be addressed in question 14. ***Use complete sentences (limit 500 words).***

b. Describe how the proposed research meets the criteria for exemption or limited review. Reference the exemption or limited review categories (see question #11 above) and the category's corresponding requirements.

c. Provide the estimated beginning and end dates of the project; ***start date must be after IRB approval***.

16. RESEARCH METHODS AND ACTIVITIES

Provide a description of the data being collected and the methods for collecting the data. ***Methods should be described in adequate detail so that IRB members may assess the potential study risks and benefits.***

Check all research activities that apply. ***Attach a copy of materials to be used (e.g., interview/focus group questions, instruments, data collection forms, etc.)***.

- ☐ Audio, video, digital, or image recordings
- ☐ Existing data, not publicly available
- ☐ Existing data, publicly available
- ☐ Focus groups
- ☐ Internet or e-mail data collection
- ☐ Observation of participants (including field notes)
- ☐ Record review (which may include PHI)
- ☐ Oral history (does not include medical history)
- ☐ Specimen research (must be existing at time of application)
- ☐ Surveys, questionnaires, or interviews (one-on-one)
- ☐ Surveys, questionnaires, or interviews (group)
- ☐ Taste-testing
- ☐ Other (specify):

17. PARTICIPANT POPULATION

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

Age(s):

b. Specify the participant population(s) to be included (check all that apply):

- ☐ Adults
- ☐ Children (< 18 years)
- ☐ Student research pools (e.g., psychology, linguistics)

Specify:

- ☐ Non-English speaking
- ☐ Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)
- ☐ Other

Specify:

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

d. Describe the characteristics of the population(s). ***If requesting exemption under category 4 (see question #11 above), include the date range of records/specimens to be accessed (e.g., patients admitted to the hospital between 01/01/2018 and 12/31/2021).***

18. PARTICIPANT IDENTIFICATION, RECRUITMENT, AND SELECTION

a. 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.

b. Describe the recruitment process, including the setting in which recruitment will take place. Explain how the process respects potential participants' privacy. ***Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters, and oral/written scripts).***

19. 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 participation withdrawals, as applicable.***

☐ Yes
☐ No

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

20. 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, as applicable. See the Consent, Assent, and Parental/Legal guardian Permission Templates on the IRB website or contact the 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/Online/Unsigned
☐ Assent – Form
☐ Assent – Verbal/Online/Unsigned
☐ Parental/Legal Guardian Permission – Form
☐ Parental/Legal Guardian Permission – Verbal Script/ Online /Unsigned
☐ Translated Consent/Assent – Form(s), Script(s), etc. (provide only English version)
☐ Other (Specify):

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.

b. **Waiver of Consent Documentation.** In some situations (e.g., telephone survey or mailed survey, internet research, certain international research), the IRB may waive the requirement for obtaining a **signed** informed consent form. *Complete Appendix 9 and submit with application*

Is the consent document the only record that will link the subject and the research? ☐ Yes ☐ No

Does the research present no more than minimal risk of harm to subjects and involve no procedures for which written consent is normally required outside of the research context? ☐ Yes ☐ No

c. **Alteration or Waiver of Informed Consent.** Some research studies (e.g., medical record review, deception research, collection of biological specimens) would not be possible if some/all elements of informed consent were required from participants. The IRB may consider waiving the requirements for some/all elements of informed consent when the research meets **all of the following conditions** (researcher needs to explain for each condition how it applies to the research).

1. The research involves no more than minimal risk to the subjects. ☐ Yes ☐ No **If Yes →** Explain:

2. The research could not practicably be carried out without the requested waiver or alteration. ☐ Yes ☐ No
If Yes → Explain:

3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. ☐ Yes ☐ No
If Yes → Explain:

4. The waiver or alteration will not adversely affect the rights and welfare of the subjects. ☐ Yes ☐ No
If Yes → Explain:

5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after the subject has participated in the study. ☐ Yes ☐ No ☐ N/A
If Yes or N/A → Explain:

21. 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. List the information source(s) (e.g., educational records, surveys, medical records, etc.).

22. 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.

b. Indicate what will happen to the identifiable data at the end of the study. ***Primary research data and research-related records should be retained for a period of at least three years after final project closeout.***

- ☐ Identifiers will be permanently removed from the data and destroyed (de-identified)
- ☐ Identifiable/coded (linked) data will be retained and stored confidentially
- ☐ Identifiable data will not be collected

23. 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**

24. APPLICATION CONTENTS

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

☒ **Application for Exemption or Limited Review**

☐ 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)

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

☐ Appendix 3: Research in International Settings (question 12)

☐ Other Committee Approvals/Letters of Support (questions 12)

☐ Instruments (e.g., questionnaires or surveys to be completed by participants) (question 14)

☐ Data Collection Form(s) involving protected health information (question 14)

☐ Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) (question 16)

☐ Informed Consent form(s), Assent Form(s), Permission Form(s), and Verbal Script(s) (question 18)

complete and attach Appendix 8 or Appendix 9 if necessary

☐ Written Authorization to Use Personal Health Information (question 21)

☐ Appendix 4: Waiver or Alteration of HIPAA Research Authorization (question 21)

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

25. 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 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 Exemption is accurate and complete. I will initiate this research only after having received notification of exemption determination.

Signature of Principal Investigator | Date

Type name of Principal Investigator

Signature of Co-Principal Investigator (Faculty Advisor of Student PI) | Date

Type name of Co-Principal Investigator (Faculty Advisor of Student PI)

26. 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)