SOUTH PIEDMONT COMMUNITY COLLEGE

Monroe • Polkton • Wadesboro

IRB Application

Title of Project:

Date proposal submitted to the IRB:

Type of Proposal or Activity:

☐ New proposal

☐ Modification. If a modification, what was the date of last IRB approval?

1. Investigator information:
   - Name of Principal Investigator:
   - Address:
   - Phone Number:
   - E-mail:
   - Department, school, or program you represent:

2. List all Associate Investigators. Please include full name of each investigator. If more Associate Investigators are involved with this project, electronically insert their names.
   - Associate Investigator:
   - Associate Investigator:
   - Associate Investigator:

Please check the boxes below as appropriate to the research:

	Yes	No
Are any subjects under 18 years of age?		
Is your research on vulnerable subjects (see definition in application instructions)?		
Is your research on illegal activities such as drug use?		
Is your research on private activities such as sexual behavior?		
Does your research employ deception/withholding of complete information during initial consent?		
Are personal records (medical, academic, etc.) used without written consent?		
Are data from subjects (responses, information, specimens) directly or indirectly identifiable?		
Are data possibly damaging to subjects' financial standing, employability or reputation?		
Are there possible intentions to present/publish the data outside the College?		

I have reviewed the following research project and agree that the above answers represent an honest assessment of the research. I so attest and affix my signature and the date to this document.

Principal Investigator's Signature: _____ **Date** _____

Associate Investigator's Signature: _____ **Date** _____

Associate Investigator's Signature: _____ **Date** _____

Associate Investigator's Signature: _____ **Date** _____

PURPOSE OF THE STUDY

Briefly state the overall objectives and specific aims of the research. It is strongly suggested to do this in lay language appropriate for SPCC IRB's community members and faculty members outside of your field. Include the hypotheses or research question(s) you intend to answer. Applications submitted with overly technical language will be returned to the Principal Investigator for revision before review by the IRB.

SUBJECTS RECRUITMENT

Who are the subjects and how will they be recruited? Attach recruitment flyers, invitations, or similar documentation. Attach letters of approval if access to subjects is sought from clinics or other agencies.

Number of subjects you intend to solicit:

Approximate number of subjects you expect to participate:

Types of Subjects:

a. Age range of subjects:

b. Population from which subjects were derived:

c. Inclusion criteria for subjects:

d. Exclusion criteria for subjects (include any age, sex, physical, mental and health restrictions):

Does your study involve the collection of data from a population of diminished autonomy (see definition in application instructions)?

Yes ☐ No ☐

If yes, please specify type of population:

☐ Individuals with impaired decision-making capacity ☐ Minors

☐ Economically or educationally disadvanted persons ☐ Prisoners

☐ Individuals with language bariers ☐ Other:

Describe the specific steps to be used to identify and/or contact prospective participants. If applicable, describe how you have access to lists of potential participants. Recruitment telephone and/or e-mail scripts and advertisements should be submitted with this form as well.

Subject Screening Procedures: Describe the screening procedures you will use to determine if subjects are able to participate in your study. Please also attach any questionnaires or screening forms you will use.

PROCEDURES AND DATA COLLECTION

Describe the procedures to be used, especially any experimental and interventional procedures (interviews, surveys, focus groups, observation, review of existing records, etc.).

Will your project include deception? If deception is used, clearly explain what this entails and why it is needed.

RISK ASSESSMENT

Describe any foreseeable risks to subjects presented by the procedures described above in the Data Collection section, including any physical, psychological, social, economic, legal, or confidentiality risks. Include your assessment of the liklihood, magnitude, and repercussions of each risk presented.

RISK MANAGEMENT

For each possible risk presented, provide the measures and precautions you will take to minimize such risks or to respond to any adverse events, should they occur. What are the possible worst-case scenarios, and how do you plan to deal with them? How will any adverse effects on subjects be handled or remedied?

CONFLICT OF INTEREST

Do any of the participating study investigators or other key personnel (or their immediate family/significant other) have a financial or intellectual interest in, or are receiving compensation from, the sponsor or the drugs, devices or technologies used in this research? If yes, explain the conflict and any mitigating measures.

Do you have or anticipate (within the year) any financial relationships (e.g., consulting, speaking, advisory boards, patents, equity, options) that could be perceived to overlap or present a conflict of interest with the current proposal? If yes, describe the overlap.

COSTS AND COMPENSATION

Will your subjects receive compensation in any form for participating in this study (i.e. monetary payments, course credit, services etc.)? If yes, please explain how and when subjects will be compensated.

Will there be any costs to be borne by subjects by virtue of their participation in this research?

BENEFITS

What are the likely benefits of this research to the subjects (other than any compensation described in the Costs and Compensation section above)? If the subjects will not directly benefit from the research, explain how the study will benefit others or contribute to your field of research.

PRIVACY, CONFIDENTIALITY AND DATA MANAGEMENT

1. Subject Privacy: When gathering data, what measures will you take to protect your subjects' privacy? Examples include interviewing subjects one at a time in a closed room, interviewing over the phone, or e-mailing a questionnaire in such a way that subjects cannot see identifying information of other subjects.

2. Subject Confidentiality: Will any identifying information (name, date of birth, company working for, etc.), protected health information, or protected educational records be collected?

Identifying information collected:	Yes ☐	No ☐
Protected health information collected:	Yes ☐	No ☐
Protected educational records collected:	Yes ☐	No ☐

If you intend to protect the confidentiality (identity) of your subjects, describe your methods of doing so prior to, during, and after data collection.

Remember: If you intend to keep a subject's identity confidential, when the results of your study are presented in publications (including theses and dissertations) and presentations, no information may be provided that would reveal the identity of that subject.

3. Data Confidentiality and Management:

Will you be audio or video recording subjects? Yes ☐ No ☐

a. If yes, please explain why this is necessary.

b. If you intend to protect the identities of subjects who have been recorded by audio or video, describe your method for doing so (the usual procedure is to transcribe recordings and then destroy the original audio or video recordings.)

4. Data Storage:

a. Please explain who will have access to the data and under what circumstances.

b. How and where will you store your data?

c. How long will you keep your data?

d. How will you dispose of your data?

e. How will you ensure your data remains secure and protected from unauthorized access?

Compliance with FERPA and HIPAA Privacy Regulations

All studies approved by the SPCC IRB must comply with other federal regulations including FERPA and HIPAA. In accordance with the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), investigators shall respect the confidential nature of all information that they may have access to, including but not limited to the subjects' personal health information provided to them orally or contained in medical records in written or electronic form. The Family Educational Rights and Privacy Act (FERPA) protects the confidentiality of all personally identifiable information contained in a student's educational record.

DISSEMINATION OF DATA/RESULTS

Identify the categories of all persons other than the research team to whom personally identifiable data will be disclosed and the purpose of each such disclosure (presentations at academic conferences, dissertation committee, etc.).

If planning to disseminate the results of your study outside the College, identify all methods in which you intend to publicly share results (meetings, journals, academic conference, thesis or dissertation, etc.).

INFORMED CONSENT

Indicate the consent process(es) and document(s) to be used in the study. Check all that apply. Please attach a copy of your Informed Consent form and/or Letter of Invitation.

- ☐ Informed Consent Form
- ☐ Informed Consent Parent-Minor Form
- ☐ Translated Consent Form
- ☐ Waiver of Consent Process

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

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

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.

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

Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension? Provide copies of these forms.

Final Checklist

- ☐ An Informed Consent Form will be used and is provided with this application.
- ☐ All investigators (PI and Co-PIs) have completed training on the protection of human subjects in the past two years. A certification of completion is provided from an approved training program in the protection of human research participants.
- ☐ This protocol uses questionnaires/surveys/instruments and the final documents are provided.
- ☐ Recruitment flyers/letters/emails will be used and copies are provided.
- ☐ Copy of thesis/ dissertation or approved proposal (if applicable) is provided.
- ☐ If this protocol has already been approved by another institution, their IRB approval letter is provided.
- ☐ The cover sheet (first two pages of this document) has been signed and sent to the IRB Chair at IRB@spcc.edu or via postal mail at:

  Institutional Effectiveness
  South Piedmont Community College
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