SOUTH PIEDMONT COMMUNITY COLLEGE

Monroe • Polkton • Wadesboro

IRB Renewal Application

Principal Investigator:

Address:

Phone Number:

E-mail:

Department, school, or program you represent:

Title of Project:

IRB expiration date:

SUBJECT RECRUITMENT

What number of subjects did the IRB approve for you to enroll?

Do you wish to request a change in this number at this time? Yes* ☐ No ☐
*If yes, you must create and submit a modification. Otherwise, your enrollment target will not be increased.

	During the Past Year	Cumulative Accrual
Number Enrolled: This is the number of subjects who signed a consent form; OR who gave verbal consent on a study conducted under a waiver of documentation of consent; OR the number of records reviewed if a retrospective study conducted under a waiver of consent and authorization		
Number of potentially vulnerable subjects enrolled (Minors, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons):		
Number of subjects who read the consent form and/or discussed the study with study staff as part of the consent process but refused to participate		
Number of consented subjects who voluntarily withdrew		
Number of consented subjects who are lost to contact		
Number of consented subjects who were withdrawn by the PI		
Number of consented subjects who completed the study: (all interventions and follow-up are complete)		

If no subjects were enrolled this year, please provide an explanation.

Explain the reason for all subject withdrawals (either subject or PI initiated) since initial IRB review or the last renewal.

Total Enrollment Report: Number of Subjects Enrolled to Date (Cumulative) By Ethnicity and Race

Note: F**or retrospective medical record review studies**, the race and ethnicity tables below are not necessary if the answer is "Yes" to the following statement: The medical record reviews in this study included all eligible subjects regardless of their race or ethnicity.

Yes ☐ No ☐

Ethnic Category	**Females**	**Males**	**Unknown or not reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total All Subjects*				
Racial Categories	**Females**	**Males**	**Unknown or not reported**	**Total**
American Indian/ Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

*****The Ethnic Category total must equal the Racial Categories total.

STUDY PROGRESS

Please provide a narrative summary of the study progress to date. If your study is closed to enrollment and subjects are in follow-up, please detail your follow-up.

CONFLICT OF INTEREST

Have any conflicts of interest been identified that have not already been disclosed to the SPCC IRB? 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 additional conflicts have been identified, 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.

RISK ASSESSMENT & MANAGEMENT

Since the initial IRB review or last renewal:

Have there been any events requiring prompt reporting to the IRB, such as a study-related adverse event of any severity, injury, or protocol deviation/violation, that was both unanticipated and indicated that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized? If yes, please summarize the events. State whether the incident was promptly reported to the IRB by submitting the IRB Unexpected Event Report Form (if not already completed, submit the form along with this application).

Has the occurrence of the event(s) changed your current risk-benefit assessment (increased potential for risk or decreased potential for benefit to study participants)? Explain your answer and how you responded.

DISSEMINATION OF DATA/RESULTS

Since initial IRB review or the last renewal:

Has there been any literature or new information that relates to your research, such as information about possible risks to human subjects associated with this research or any significant new findings which may relate to the subjects' willingness to continue participation? If yes, please explain. (Note: Any significant new findings which may relate to the subjects' willingness to continue participation must be conveyed to the subjects in the consent form.)

Have any preliminary results or publications of the research come available since initial IRB review or the last renewal? If yes, please explain. (Note: Any significant new findings which may relate to the subjects' willingness to continue participation must be conveyed to the subjects in the consent form.)