



Monroe • Polkton • Wadesboro

IRB Closure Application

Principal Investigator:

Address:

Phone Number:

E-mail:

Department, school, or program you represent:

Title of Project:

Date of enrollment termination:

Reason for enrollment termination:

1. Please check the boxes below as appropriate to the research:

- The research is permanently closed to enrollment.
- All participants have completed all research-related interventions.
- Collection of identifiable private information is completed.
- Analysis of identifiable private information is completed.

If all four boxes are checked, the research no longer requires continuing review by the SPCC IRB. For multi-center studies, continuing review of the research by the SPCC IRB is no longer required after all human subject research activities have been completed at SPCC, even if (i) interactions or interventions with subjects may be occurring at other study sites; or (ii) data analysis of identifiable private information is ongoing at another central site that collects and analyzes data from all study sites.

If any of the four boxes above are not checked, the research must undergo continuing IRB review. Stop using this form and instead complete the IRB Renewal Application.

2. Subject Accrual

	Since Last Review	Cumulative
Number of subjects who completed the study:		
Number of subjects withdrawn from the study:		

Explain any withdrawals since the last continuing IRB review:

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

Note: For **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.

3. Were any unanticipated problems, serious adverse events, complaints, or other events requiring prompt reporting to the IRB encountered since the last continuing IRB review that were not previously reported to the IRB?

No

Yes. If yes, please explain.

4. Conflict of Interest

- a. 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.

No

Yes. If yes, please explain.

- b. 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?

No

Yes. If yes, please explain.

5. How did you inform research participants of the results of the study? If you did not inform subjects, please explain.

6. Please report the final findings of your study.

Signature of Study Principal Investigator

Date