You MUST download and save this form to your computer to complete.

OFFICE OF SPONSORED PROGRAMS AND RESEARCH SERVICES
COASTAL CAROLINA UNIVERSITY

Research with Human Subjects
Continuing Renewal Request

Fields marked with a red asterisk (*) are REQUIRED. Incomplete forms will be returned without review.

*PI Name:

*PI Email:

*Protocol Number:

*Protocol Expiration Date:

*Study Title:

*Proposed Start Date:

*Proposed End Date:

Section I: Research Team

***Current protocol status** (check all that apply)**:**

- ☐ Active (i.e., study is ongoing)
- ☐ All interactions with participants have ended. Remaining research activities are limited to data analysis.
- ☐ No additional risks have been identified.
- ☐ Inactive (study was not started). Anticipated start date is:

Section II: Recruitment and Withdrawals/Complaints

1. Number of subjects used:

Number of subjects sought:

Describe any difficulties in participant enrollment if enrollment goals have not been met, and whether/how it will impact the study:

2. If you have exceeded the sample size initially approved for the study, explain why:

3. Have any subjects withdrawn (voluntarily or initiated by PI) since the last review?

No

If yes, explain.

4. Were there any complaints regarding the research?

No

If yes, explain.

Section III: Changes, Modifications & Addendums

1. Since the last review, are there any new relationships between the researcher(s) and agencies (e.g., schools, hospitals, homes) involved in the research, and/or have any new or potential conflicts of interest related to this research been identified?

Conflict of interest relates to situations in which financial or other personal considerations may compromise or involve the potential/have the appearance for compromising an employee's objectivity in meeting University responsibilities including research activities.

No

If yes, explain.

2. Since the last review, (check all that apply)

- ☐ there have been no changes in research personnel or their roles and responsibilities
- ☐ research personnel no longer associated with the study:
- ☐ research personnel are new to the study
- ☐ research personnel have changed roles with the study

***Enter each new team member or team members with changed roles (including PI) in the table below. A member of the research team is defined as one who will:** *1) access participants' private identifiable information; 2) obtain informed consent; or 3) interact with participants.*

All members of the team must complete the **REQUIRED** CITI training.

Name	**Role**	**Responsibilities** Select all that apply from the list of Responsibilities below (e.g., "a, b, c")	**Receive IRB Correspondence** Yes or No	**CITI Completion Report #**
	Other		Yes	
	Other		Yes	

Responsibilities:

a. Screens potential participants	h. Conducts physical exams
b. Obtains Informed Consent	i. Collects biological specimens (e.g., blood samples)
c. Has access to identifiable data	j. Conducts study procedures
d. Administers survey	k. Dispenses medications
e. Conducts interviews	l. Supervises exercise
f. Enters subject data into research records	m. Educates participants, families or staff
g. Analyzes data with identifiable information	n. Other: describe

3. Since the last review,

☐ there have been **no** modifications or addendums to the research study or consent

☐ there **have been** modifications or addendums to the research study and/or consent form

Section IV: Events and/or Findings

1. Since the last review, have there been any events, findings from the study or relevant literature that may impact a participants' willingness to participate in this type of research?

No

If yes, explain.

2. Is there any other information discovered during the course of the research that the IRB should know to inform further reviews, including a) any adverse events involving risks; or b) any serious adverse events that were unrelated to the research but which affected a human subject in the study?

No

If yes, explain.

Check the materials that will be submitted with this continuing review request:

☐ Request to amend or study modification

☐ Copy of grant/contract/agreement wording, if changed or new

☐ Updated consent form(s)

☐ Instrument (survey questions, interview questions, etc.) if changed

☐ Other (describe):

☐ N/A

Attach the documentation to support any checked items.

Section V: PI Statement of Assurance

By signing this Assurance, I understand that I am responsible for the activities related to the completion of this study, the protection of the rights and welfare of the human subjects and strict adherence by anyone on the research team to all Coastal Carolina University Institutional Review Board (IRB) requirements, federal regulations and state statutes for research involving the use of human subjects.

I understand that, should I use the project described in this protocol as a basis for a proposal for funding (either internal or external), it is my responsibility to ensure that the description of human subject activities in the funding proposal is identical in principle to that contained in this application.

I assert that the information provided in this application is accurate to the best of my knowledge and hereby agree to:

- Conduct this research in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the IRB, except when necessary to protect the safety, rights or welfare of subjects.
- Ensure that all research procedures involving human subjects will be performed under my supervision or that of another qualified research team member listed on this protocol.
- Inform all research subjects or legally authorized representative of the nature of this research project as required in 21 CFR Part 50 and 45 CFR Part 46. This includes allowing subjects, or legally authorized representatives, sufficient opportunity to review the consent document, to discuss the research with other people and to ask questions before signing the informed consent document.
- Ensure that the requirements for obtaining informed consent are met per the regulations found at 21 CFR Parts 50 and 56, and 45 CFR Part 46.
- Promptly report to the IRB all changes in the research activity, all unanticipated problems or any adverse experiences that occur in the course of the study.
- Ensure that all associates, colleagues and employees assisting in the conduct of the research are fully informed about the protocol and their respective research related duties and functions.
- Ensure that all research team members have completed the required CITI human subjects training program modules.
- Immediately notify the IRB upon termination of the study or departure of the PI from CCU.
- Maintain adequate and accurate records in accordance with the regulations and to make those records available for inspection in accordance with the regulations.
- NOT begin this study until final IRB approval has been obtained.

Entering my name and email address together constitute my intent to sign this application.

PI Name: _____ **PI Email:** _____

Date:

Submit this request for review by emailing the completed form and all attachments to: OSPRS@coastal.edu.