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

Proposal # _____

Date: _____

OFFICE OF SPONSORED PROGRAMS AND RESEARCH SERVICES
COASTAL CAROLINA UNIVERSITY

Research with Human Subjects
Amendment to an IRB Approved Protocol Request

Any field marked with a red asterisk (*) is REQUIRED. Incomplete forms will be returned without review.

Date:

Section I: Administrative Information

1. Protocol Information

Protocol #:

Study Title:

2. Contact Information

PI Name:

Email Address:

Faculty Advisor (if student PI):

Email Address:

College (if applicable):

Department:

Section II: Amendment Information

1. Please check at least one amendment you are requesting and as many as required.

- ☐ Change in study title
- ☐ Change in Principal Investigator
- ☐ Addition of/change in research personnel
- ☐ Addition of/change in funding source
- ☐ Change to research/study design, methods or procedures (ex: observations, interventions, collection of biological samples or biometric information, participant tasks, etc.)
- ☐ Addition of/change to study population
- ☐ Addition of/change to recruitment or compensation procedure(s)
- ☐ Addition of/change to survey(s), questionnaire(s), or other research instruments - attach the revised instrument(s)
- ☐ Addition of/change to the identifiers collected in the study, or any others that would impact the privacy and confidentiality of the study participants
- ☐ Addition of/change to informed consent/assent document(s) and/or procedures - attach all related documents
- ☐ Other changes

2. For each of the amendment categories checked, describe the proposed change.

3. Please state the reason(s) you are making an amendment(s) to the study.

4. Are any of these changes the result of something that occurred during human participant interaction or an unexpected event?

No

If yes, **explain** the event:

5. Will the proposed changes have an impact on the risks or benefits to research participants?

No

If yes, **explain** the impact:

6. Do these changes involve information that might relate to a subject's willingness to continue to take part in the research?

No

If yes, **explain** the impact:

Section III: 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 amendment for review by emailing the completed form and all attachments to: OSPRS@coastal.edu.