IRB Review Application

CHECKLIST

FACULTY/STAFF

Be sure you have:

☐ Responded to all of the questions on this Review Form

☐ Completed required CITI training modules (student(s) and faculty advisor)

☐ Attached an Informed Consent document or the proposed language for a verbal consent

Required statement on ALL Informed Consent documents:

The Office of Sponsored Programs and Research Services is responsible for the oversight of all human subject research conducted at Coastal Carolina University. If you have any questions about your rights as a research participant, you may contact this office by calling (843) 349-2978 or emailing OSPRS@coastal.edu.

☐ Attached ALL supporting documents (ex: surveys, recruitment letters, flyers, brochures, etc.

☐ Attached a Debriefing Statement (if applicable)*

☐ Attached Permission/Acknowledgment Letter from External Site (if applicable)

*If your research is related to a sensitive subject, it is suggested that the contact information for Counseling Services be added to the informed consent document and debriefing information, if applicable.

Office of Counseling Services
251 University Blvd.
(843) 349-2305

Failure to provide all documents can result in a delay in the review process.

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
Exempt Review Request

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

*PI Name:

*PI Email: Ext.

*Department:

*Study Title:

*Proposed Start Date: *Proposed End Date:

Section I: Research Team

***Enter each team member (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	
	Other		Yes	
	Other		Yes	
	Other		Yes	
	Other		Yes	
	Other		Yes	

Note: Any changes in personnel must be submitted to the IRB at: OSPRS@coastal.edu.

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(s)	**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

Note: In some cases, expertise to perform study procedures (e.g., blood draws, interviewing participants about sensitive topics) must be documented to show that risks to participants are minimized. The Research Personnel Form and/or a CV may be attached to document expertise.

Section II: Study Details

1. *Study Description:

Briefly describe any relevant background, the purpose of the research, any literature searches performed, the research question and anticipated plans for disseminating results. If more space is needed, attach an additional document when submitting this form.

2. *Procedures of the research as they relate to the participant:

Procedures must include: 1) summary of participant recruitment plans; 2) description of the data that will be collected; and 3) explanation of how the data will be stored and destroyed upon completion of the research. If more space is needed, attach an additional document when submitting this form.

3. *Type of Research (check all that apply)**:**

- ☐ Faculty Research
- ☐ Dissertation/Thesis/Honor's Thesis
- ☐ Product of Learning
- ☐ Class Project – Course Number:
- ☐ Other
- Describe "Other":

4. *Results Dissemination (check all that apply)**:**

- ☐ Plan to publish (thesis, dissertation, journal, book, etc.)
- ☐ Plan to publicly present off-campus
- ☐ Plan to publicly present on-campus
- ☐ Will not publish or present outside of classroom assignment setting

5. *Source of Funding

- ☐ N/A
- ☐ University
- ☐ Federal
- ☐ Other:

If federal or other funds are selected, attach a copy of the grant award/contract/cooperative agreement.

6. *Is another organization engaged in the research (i.e., will an agent of another organization/institution obtain informed consent or interact with research participants)**?**

No

If yes, **please list** the organization/institution(s) and indicate whether that IRB will review or rely on the CCU IRB.

If yes, **please explain** what, if any, relationship exists between the PI(s) and the organization/institution?

If applicable, attach statement of approval (e.g., letter of agreement) from any organization/institution that will need to approve the research.

Section III: Review Categories

This section is REQUIRED – please select **at least one** category below.

☐ (1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

☐ (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if *at least one* of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts at least a *limited review*.

☐ (3) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts at least a *limited review* to make the determination.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

☐ (4) Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable bio-specimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable bio-specimens are publicly available;

ii. Information, which may include information about bio-specimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA (i.e., 45 CFR parts 160 and 164, subparts A and E), for the purposes of "*health care operations*" or "*research*" as those terms are defined at 45 CFR 164.501 or for "*public health activities and purposes*" as described under 45 CFR 164.512(b); or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, and conducted in compliance with 45 CFR 46.104(d)(4)(iv).

☐ (5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine:

- public benefit or service programs;
- procedures for obtaining benefits or services under those programs;
- possible changes in or alternatives to those programs or procedures; or
- possible changes in methods or levels of payment for benefits or services under those programs.

☐ (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ (7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts at least a *limited review* and makes the determinations.

☐ (8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with
   a. § .116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained;

(iii) An IRB conducts at least a *limited review* and makes the determination that the research to be conducted is within the scope of the broad consent; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

Section IV: Conflict of Interest

1. ***Do any of the researchers responsible for the design, conduct or reporting of this research have a known or potential conflict of interest related to this research?**

   No

Conflict of interest relates to situations in which financial or other personal considerations, circumstances or relationships may compromise, involve the potential for compromising or have the appearance of compromising a researcher's objectivity in fulfilling research responsibilities.

If yes, **please explain** who has the conflict, whether the conflict has been disclosed and/or managed and **explain how** participants will be protected from the influence of competing interests:

Section V: Participant Population and Recruitment

1. ***Number of participants sought:** ☐

2. ***Targeted participant population** (check all that apply, select at least one)**:**

- ☐ College students (= or >18 years)
- ☐ College students (<18 years may participate)
- ☐ Prisoners
- ☐ Cognitively or emotionally impaired
- ☐ Non-English speaking
- ☐ Pregnant
- ☐ Employees of a profit or non-profit organization
- ☐ Adults (non-college students >18 years)
- ☐ Minors (<18 years/Age range): ☐
- ☐ Minorities
- ☐ Institutionalized
- ☐ In-patient (medical)
- ☐ Outpatient (medical)
- ☐ International research

3. ***Federal regulations require the equitable selection of participants. Is the targeted population an appropriate group to bear the burdens of this research?**

Yes

If no, **please explain**:

***Are participants a subset of the population most likely to receive the benefits of this research?**

Yes

If no, **please explain**:

4. **Explain any inclusion and exclusion criteria for the study.**

5. ***Describe how subjects will be recruited.**

If applicable, attach a copy of any recruitment materials being used.

6. ***Does the research include any compensation or incentive for participation?**

No

If yes, **please explain**:

Section VI: Informed Consent

1. *Consent to participate in the research will be sought by providing (check all that apply)**:**

- ☐ A statement of the purpose of the research
- ☐ An explanation of the procedures of the study
- ☐ An explanation of the foreseeable risks or benefits to the participant
- ☐ An explanation that participation is voluntary and that there are no consequences if the subject refuses to participate or decides to discontinue participation at any time
- ☐ Contact information for the investigator
- ☐ Statement of oversight and contact information for the OSPRS

If any of the consent items above are not checked, **please explain**:

2. *Will participants sign an informed consent?

No

Attach *a copy of the consent document, proposed online consent text or proposed wording to obtain verbal consent.*

Section VII: 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:

Date:

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