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: _____

Research with Human Subjects
Expedited or Full Board 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** answer below.

☐ **Clinical studies of drugs and medical devices only when condition (a) or (b) is met: (1)**

a. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risk associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which: 1) an investigational device exemption application is not required; or 2) the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: (2)**

a. From healthy, non-pregnant adults, who weigh at least 100 lbs. For these subjects, the amounts drawn may not exceed 550 ml. in an eight week period and collection may not occur more than two times per week; OR

b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For those subjects, the amount may not exceed the lesser of 50 ml. or 3 ml. per kg. in an eight week period, and the collection may not occur more than two times per week.

☐ **Prospective collection of biological specimens for research purposes by non-invasive means. (3)**

This category can include the collection of things like: hair and nail clippings in a non-disfiguring manner; deciduous teeth at the time of exfoliation or if routine patient care indicates need for extraction; permanent teeth if routine patient care indicates need for extraction; excreta and external secretions (including sweat); uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or was or by applying a dilute citric solution to the tongue; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, supra- and subingival dental plaque and calculus, provided the collection procedures is not more invasive than routine scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, or mouth washings; or sputum collected after saline mist nebulization.

☐ **Collection of data through non-invasive procedures (not involving general anesthesia or sedation routinely employed in clinical practice, excluding procedures involving z-rays or microwaves. (4)**

Where medical devices are employed, they must be cleared/approved for marketing. (Note: Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

This category can include the collection of data though things like: physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow and echocardiography; or moderate exercise, muscular strength testing body composition assessment, and flexibility testing when appropriate given the age, weight, and health of the individual.

☐ **Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnoses). (5)**

☐ **Collection of data from voice, video, digital, or image recordings made for research purposes. (6)**

☐ **Research on individual or group characteristics, behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (7)**

☐ **Research presenting possible risk to human subjects.**

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. *Explain how informed consent will be obtained. *Include information about the setting, any time provided to consider participating in the research and opportunity to ask questions*.

2. If applicable, describe the safeguards in place to protect the rights and welfare of any vulnerable participants *(children, prisoners, pregnant women, or any population that may be relatively or absolutely incapable of protecting their interests through the informed consent process*).

3. *Select factor(s) that might interfere with informed consent:

- ☐ None known
- ☐ Participants or their authorized representative (parent/guardian) may not speak and/or read English
- ☐ Research will involve current students in a course/program taught by a member of the research team
- ☐ Participants are employees whose supervisor is recruiting or requiting participation
- ☐ Participants have a close relationship to someone on the research team

  Please explain:

- ☐ Other

For selected factor(s), **please describe** any and all efforts to mitigate this interference:

4. *Will participants sign an informed consent? Yes

If no, participants must still be provided with a statement regarding the research and one of the following criteria must be selected and met:

☐ The only record linking the participant and the research is the consent document, the principal risk is potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated. Each participants will be asked whether he/she wants documentation linking them with the research; OR

☐ The research presents no more than minimal risk of harm and involves no procedures for which written consent is normally required outside of the research context.

Attach *a copy of the consent form or documentation of the text to be used in obtaining verbal consent.*

5. Are you requesting a modification to the required elements for informed consent? No

If yes, attach an explanation.

Section VII: Risk

The risks (the probability and magnitude of harm) to participants must be reasonable in relation to any anticipated benefits for participants and the importance of the knowledge gain expected. When applicable, the research plan must include provisions for monitoring collected data to ensure the safety of human subjects.

*Assessment of level of risk:

This study contains **no more than minimal risk** to participants.

☐ The probability and/or magnitude of physical, emotional, social, legal or financial risks are the same as encountered in daily life or during the performance of routine physical or psychological examinations or tests.

This study contains **more than minimal risk** to participants.

☐ The probability and/or magnitude of harm or discomfort anticipated is greater than that encountered in daily life.

☐ Information collected could cause participants to be at risk of criminal or civil liability if response are disclosed outside of the research setting.

☐ Information collected could be damaging to participant's financial standing, employability or reputation if disclosed outside of the research setting.

*If **more than minimal risk** is selected, **please provide** descriptions of risks, mitigations and benefits below.

1. Describe the potential risks (*physical, psychological, legal, social harm, loss of confidentiality, etc.*)**.**

2. Describe procedures for protection against, or minimizing, the potential risks; *including (where applicable) how collected data will be monitored to protect the privacy and safety of human subjects.*

3. Describe the potential benefits of the study.

Potential benefit to participants (compensation is not considered a benefit):

Potential benefit to society:

If more space is needed for any response to questions 1-3, attach an additional document.

Section VIII: 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.