**The Citadel Institutional Research Board (IRB)**

**Protocol Amendment Application Form**

Research Study Title:

Primary Investigator Name:

Citadel Status (Student, Faculty, Staff):

Citadel Department:

Additional Investigator(s) with Status(es):

1. **Amendment Information**
   1. **IRB History**

*This information can be found on your IRB Approval Letter(s).*

* + 1. IRB Record Number (ex: IRB 2021-58):
    2. Initial Approval Date:
    3. Briefly describe your research study including the research questions and methods used to address the questions.
    4. Has this protocol previously been Renewed with IRB for an additional year of research?

Yes  No

* + 1. Has this protocol previously been Amended?

Yes  No

* + 1. Have subjects already been enrolled (i.e. completed consent process) and/or is data being collected from current subjects?

Yes  No

If yes, what is the total number of subjects: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. **Amendment Request**
     1. Which best describes the nature of the requested amendment?

Change to Research Investigators

Change to Research Questions and Objectives

Change to Subject Description or Sample Size

Change to Subject Recruitment Procedure or Subject Compensation

Change to Data Collection Method

Change to Data Storage or Analysis

Change to Informed Consent Methods

Other

* + 1. Briefly describe the requested amendment. If appropriate, please attach modified survey, test, or consent documents with red-line changes showing the amendment.
    2. Will this amendment affect the anticipated level of risk for subjects?

Yes  No

If yes, it is anticipated the amendment will:

Likely increase level of risk  Likely decrease level of risk

* 1. **Funding Information**
     1. Work to be completed as part of Funded Project or Grant:  Yes  No
     2. Project/Grant Name, if different than above:
     3. Agency Supporting Project/Grant:
     4. This Project/Grant is:

Accepted/Funded  Submitted  In preparation

* + 1. What is/was the expiration date of the funded project/grant?
  1. **Protocol Renewal**
     1. Are you requesting renewal of this protocol at this time?

Yes  No

If Yes, complete the Protocol Renewal Form and submit with this Amendment Form.

1. **Investigator Assurances**

By providing typing your name below, the Principal Investigator (PI) is certifying:

1. The information provided in this application and any attachments are complete and correct.
2. All PIs have current Human Protection training certifications on record with Citadel IRB. (As of 2023, Citadel subscribes to CITI Training. Certification from which is valid for 3 years.)
3. The PI understands that he/she has the ultimate responsibility for the protection of the rights and welfare of human research subjects during this research protocol.
4. The PI(s) agree to comply with all Citadel policies and procedures, the terms of the Citadel Federalwide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

**Principle Investigator:**

**Date:**