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

**Adverse Event Reporting Form**

Research Study Title:

Primary Investigator Name:

Citadel Status (Student, Faculty, Staff):

Citadel Department:

Additional Investigator(s) with Status(es):

1. **Adverse Event 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.
  1. **General Study Subject Status**
     1. Total number of subjects enrolled (i.e. completed consent process) since study initial approval, including any who have withdrawn: \_\_\_\_\_\_\_\_\_\_\_\_
     2. Have subjects withdrawn:  Yes  No

If Yes, describe reasons for withdrawal:

* + 1. Are subjects still being enrolled:  Yes  No
    2. Is data still being collected from current/future subjects:

Yes  No

* 1. **Adverse Event Report**
     1. Type of Report:

Initial: Event is or has occurred

Follow-up: Response in progress to treat/manage event

Final: Response has concluded

* + 1. Onset (or discovery) date of adverse event:
    2. Location of adverse event (e.g. at study site or elsewhere):
    3. Brief description of subject(s) involved in adverse event. Include count of subjects involved, age, sex, etc. Do not include personal identifiers.
    4. Brief description of adverse event:
    5. Brief description of planned, on-going, or concluded response to adverse event:
    6. Relationship of event to research protocol:

Unrelated (clearly not related to the research protocol)

Possible (may be related to the research protocol)

Definite (clearly related to the research protocol)

* + 1. Was this an unexpected adverse event? Was this adverse event discussed as a possible outcome in IRB application and/or Consent Documentation?

Yes  No

* + 1. Adverse event primarily affected:

Subject Physical Welfare

Subject Psychological Welfare

Subject Socio-Economic Welfare

Other

* + 1. Was research protocol discontinued for the subject(s) due to event?

No

Yes, for subject(s) directly involved in event

Yes, for all subjects

Other:

* + 1. Will the research protocol be amended in response to this adverse event?

Yes  No

If yes, please submit a Protocol Amendment Form to the Citadel IRB in addition to this Adverse Event Reporting 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:**