Central Connecticut State University

-Institutional Review Board-

ADVERSE EVENT REPORTING FORM

IRB# ☐

Complete and submit this form together with any new or revised measures or forms attached as appendices in **a single Word or PDF** file to irb@ccsu.edu. Be sure to add your IRB number to the above box.

Investigator Information	**FACULTY MEMBERS:** ***Check one and complete section below*** ☐ Principal Investigator (PI) ☐ Faculty Advisor	**STUDENTS:** ***Complete section below*** ***NOTE:*** *Faculty advisors are to review and forward submissions t**o the IRB on their advisee's behalf.** Be sure to have the faculty advisor also complete their portion of this form.*
Full Name		
Email Address		
Department		
Institution Name **(if other than CCSU)**		

Study Title: _____

Today's Date: _____ **Date of Adverse Event:** _____

Incident involved the following: *Check and explain all that apply.*

☐ A single participant
☐ More than one participant
☐ other: _____

☐ De-identified data
☐ Data with identifying information

1. **Please describe the details and circumstances of this adverse event (**use extra space as necessary):

_____

2. **In your judgment, was this adverse event related to the procedures associated with your protocol? Explain:** ☐ **Yes** ☐ **No**

_____

3. **Is the risk of this adverse event contained in the current consenting process? Explain:** ☐ **Yes** ☐ **No**

_____

4. **In your judgment should the consent form or any portion of the study be revised as a result of this adverse event?** ☐ **Yes** ☐ **No**

== **If yes**, please describe proposed revisions and attach any revised documents.

_____

5. **Will current research participants be notified of this adverse event?** ☐ **Yes** ☐ **No**

== **If yes**, please describe the method of notification. If no, please explain why.

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