

**IRB @ FORM**

*This form should be used for the submission of interim reports to the COCC IRB. Reporting requirements are detailed in the COCC IRB SOP Manual and include, but are not limited to, reports of adverse events, protocol deviations, unanticipated problems, subject complaints, potential noncompliance, and suspensions of study activities.*

*All incidents of injury or other adverse effects experienced by participants must be reported by the principal investigator to the Institutional Review Board (irb@cocc.edu) within 48 hours after the event.*

**SECTION A: General Information**

IRB Approval Number:

Project Title:

Principal Investigator(s):

Co-Principal Investigator(s):

**SECTION B: Type of Report**

Adverse event

*Change made to the research without IRB approval to eliminate an apparent immediate hazard to the subject(s). Section D is not required, instead detail for these issues, including the reason the change was made, why prior IRB approval was not possible, any potential impact of the change on the subject or the study (e.g., inclusion, analysis, or reporting of data), and any other relative information should be described in Section C or in an attached memo.*

Hold or suspension of a study or certain study activities initiated by an investigator, collaborator, sponsor, or others

Incarceration of a subject in a protocol not approved for enrollment of prisoners

Known or potential issue impacting subject privacy or confidentiality (e.g., lost laptop)

Known or potential noncompliance

Known or suspected Unanticipated Problem (UAP) involving risks to subjects or others

New information that may impact participants' health, rights, welfare, or willingness to continue in the research

Protocol deviation report

Subject complaint

Other:

**SECTION C: Event/Report Description**

Name of individual(s) involved:

Location (if applicable):

Date(s) of occurrence:

Description of issue/event/report:

**SECTION D: Evaluation**

Incident involved:

Drug/Device	Procedure
Treatment	Intervention
Other:	

Severity of incident:

<b>Mild</b>	<b>Moderate</b>	<b>Severe</b>
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Was this incident unexpected (i.e., not an anticipated risk described in the initial protocol application and informed consent documents, or was described but was of a nature, severity, or frequency that was unexpected)?

<b>NO</b>	<b>YES</b>	If YES, explain:
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In your judgment, was the event caused by procedures associated with this protocol?

Related	Possibly related
Not related	Possibly not related
Not enough information	

If RELATED or POSSIBLY RELATED, explain what procedures were already in place to minimize or reduce the risk of the event.

In your judgment, does the event or issue suggest that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized?

<b>NO</b>	<b>YES</b>	If YES, explain:
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Did the event or issue otherwise affect the health, rights, safety, or welfare of the subjects?

<b>NO</b>	<b>YES</b>	If YES, explain:
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In your judgment, should the informed consent process or any part of the protocol be modified as a result of this event?

<b>NO</b>	<b>YES</b>
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***If YES, submit a modification form, found on the IRB intranet page.***

**SECTION E: Treatment Information (If Applicable)**

Not Applicable:

Date of treatment:

Name of individual(s) who received treatment:

Name of individual(s) who provided treatment:

Location of treatment:

Describe the treatment provided to the participant(s) in detail:

Individual's recovery was:

Complete                      Moderate  
 Minimal                        Not resolved at this time  
 Other:

### SECTION F: Additional Information

Other than this report, have any other reports been submitted to other offices/departments regarding this event? Indicate where and when these reports have been submitted.

Please provide any additional information relevant to this report:

### SECTION G: Signatures

Principal Investigator  
(PRINT)

Signature

Date

Co-Principal  
Investigator (PRINT)

Signature

Date

**Submit as a scanned PDF to the IRB Chair at [irb@cocc.edu](mailto:irb@cocc.edu).**