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Description automatically generated**

**Event Reporting Form (IRB)**

*Per Policy 700-31 and 700-32 the IRB requires investigators to submit reports of:*

1. *Events that may represent unanticipated problems involving risks to research participants and others, including unexpected and related adverse events*
2. *Protocol deviations that meet one or more of the following criteria:* 
   * *intended to eliminate apparent immediate hazard to a research participant; or*
   * *caused possible harm to participants or others, or placed them at increased risk of harm (including physical, psychological, economic, or social harm); or*
   * *possible serious or continued non-compliance*

**Complete this form and then submit it using the link below.** *Doctoral students should complete the form and send to their chair who will submit on their behalf.*

<https://forms.gle/sb8o9WEK43XRdLXD8>

*(If this link does not take you to the Google Form, then copy and paste it into your browser).*

**IRB Number** (this number will be found on the documents sent to you when your project/study was reviewed by the IRB)

**Project/Study Expiration Date**

**Investigator’s Name** *(Last, First)*

**Investigator’s USU email address**

**If the investigator is a doctoral student:**

**Chair’s name** *(Last, First)*

**Chair’s USU email address**

**Part 1. Type of Event – Check all that apply**

1. **Unanticipated Problem(s)** – An unanticipated problem involve risks to research participants or others and are defined as any incident, experience, or outcome that meets all the following criteria:

unexpected (not foreseeable by the investigator or the research participant) given the research procedures and the subject population being studied;

related or probably related to participation in the research or if the event or problem probably or definitely affects the safety, rights, and welfare of current participants; and

suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

1. **Unexpected Adverse Event** - An unexpected adverse event is any adverse event occurring in one or more subjects participating in a research protocol in which the nature, severity, or frequency is not consistent with either:

the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, the current IRB-approved informed consent document, and other relevant sources of information, such as product labeling and package inserts; or

the expected natural progression of any underlying disease or condition of the participant(s) experiencing the adverse event.

1. **Related Adverse Event** – A related adverse event is “related to the research” if in the opinion of the investigator, it was more likely than not related to participating in the research.

Breach of Confidentiality

Suspension or termination of the research study by the Sponsor or other agency

Incarceration of a research subject enrolled into the study

Study Staff misconduct

New information that suggests that there are new or increased risks to subject or others

Complaint by a research subject or others that suggests that rights, welfare, or safety of a subject has been adversely affected.

Deviation: Any change/alteration to the CRC IRB-approved protocol without prospective IRB approval

Death of a research subject: If the death is related or possibly related to the research study

Premature completion of a study

Other: (e.g. loss of study data, lapsed study approval, missing consent forms, etc.)

**Part 2. Event Description**

Provide a summary of the event in the box below. Do not include subject identifiers in the summary.

**Part 3. Assessment of Event (check the appropriate box)**

In your judgment, should the research continue as planned with no changes to the research protocol or consent process. Explain why

Continue with changes to the research protocol or consent process (if you select this, you must also submit an Amendment Form)

Suspend new subject enrollment until the event is further examined

Be terminated (stopped completely), with all subjects removed from research

**Part 4. Other Agencies, Sponsors, and/or Collaborating Organizations (check the appropriate box)**

Other agencies, sponsors, or collaborating organizations have been notified of this event.

* If you checked this box, list agencies/sponsors notified including dates and methods used)

Other agencies, sponsors, or collaborating organizations have not been notified of this event.

* If you checked this box, describe steps to be taken to notify appropriate parties or type N/A if not appliable)

**Part 5. Corrective Action Plan**

Provide a summary of the Corrective Action Plan. If there is no corrective action plan, provide justification**.**

By submitting this form, the investigator certifies that the information in this form is true, complete, and accurate.

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