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**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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