Purpose

This guide has been drafted by the Saint Francis Hospital and Medical Center Research Development Office to use as a reference while completing the Trinity Health Of New England IRB's Unanticipated Problem and Adverse Event Form located in the electronic IRB system (iRIS).

Policy

Trinity Health Of New England IRB requires all Investigators to report to the IRB the following using the Full Unanticipated Problem and Adverse Event Report Form when discovered during the course of research and no later than five (5) working days after their occurrence:

1. Unexpected AND related adverse events (on-site or off-site)
2. The death of a research subject on site
3. Unanticipated problem that is a serious adverse event (on-site or off-site)
4. Any complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff
5. Any other event or other problems which in the opinion of the principal investigator was (a) previously unforeseen and (b) presents risks to research subjects or others
6. Any event that requires prompt reporting according to the protocol or the sponsor

Events that do not meet the above reporting requirements, but which sponsors request Investigators to report to the IRB, should be logged on a Tracking Form for Unanticipated Problems and Adverse Events Form and submitted to the IRB as soon as possible. Multiple events can be reported on a single form, with the Investigational New Drug (IND) or manufacturer’s safety report attached. If the investigator answers “yes” to the following three questions on the form, a Full Unanticipated Problem and Adverse Event Report Form must be filled out and submitted for that event:

1. Was the event unexpected?
2. Was the event related to study drug/device or procedure?
3. An event that placed the subject or others at greater risk of harm than was previously known or recognized?

Definitions

Protocol deviation is an incident involving non-compliance with the approved protocol, but typically does not have a significant effect on subjects’ rights, safety or welfare, or the integrity of the study.

Related event is an event that in the opinion of the investigator is more likely than not to be caused by or affects the research procedures.

Unanticipated problem involving risks to subjects or others is an event that includes any incident, experience, or outcome that meets all of the following criteria:

1. unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. related or possibly related to participation in the research; and
3. 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.

**Adverse event** is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.

**Unexpected adverse event** is an adverse event occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is not consistent with either:

1. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
2. the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject’s predisposing risk factor profile for the adverse event.

**Serious adverse event** is any event that results in death; is life-threatening and places the subject at immediate risk of death from the event as it occurred; results in inpatient hospitalization or prolongation of existing hospitalization; results in a persistent or significant disability or incapacity; results in a congenital anomaly or birth defect; or based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

**Expected adverse event** is an adverse event that does not meet the criteria for an “unexpected event.”

**Link to the Policy**

**Note:** It is the responsibility of the Investigator to report all Serious Adverse Events to the study sponsor as soon as they are identified. The Investigator should also report all non-serious events to the sponsor following the sponsor’s reporting requirements. The study sponsor is responsible for reporting all applicable events to the Food and Drug Administration (FDA).

Investigators, who have obtained their own Investigational New Drug (IND) or Investigational Device Exemption (IDE), are required to report to the FDA any adverse event that is serious, unexpected, and related to the investigational product as soon as possible but in no case later than seven (7) calendar days after they are identified (FDA Form 35000A with FDA Form 1571).

Always provide as much accurate and complete information as available at the time of reporting.

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**Steps and Procedures**

1. **Log on to iRIS (electronic IRB system)**

**iRIS is not compatible with Safari or Excel**

- iRIS website: [https://stfrancis.imedris.net](https://stfrancis.imedris.net)
- If you don’t know your user ID, please contact the Trinity Health Of New England IRB: Telephone: (860) 714-4068 or Kathy Alexander ([Kathyne.Alexander@TrinityHealthOfNE.Org](mailto:Kathyne.Alexander@TrinityHealthOfNE.Org))
2. Access the Unanticipated Problem and Adverse Event Form by the following method:

a. Click the notepad to open study

b. Add a new form

c. Check Other and Save

3. Add a new form

4. Check Other and Save

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5. **Complete Event Information:**

   Provide a detailed description of event (do not use acronyms). If applicable, include what steps have been taken to prevent the event from happening again.

6. **Click Save Form**

7. **Notify PI to Signoff:**