INSTITUTIONAL REVIEW BOARD
Adverse Event / Unanticipated Problem

Principal Investigator:

Study Title:

PI Address:

PI Telephone / Email:

Date:

Definitions

Adverse Event – Any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm from the research, or had an unfavorable impact on the risk/benefit ratio, that was temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious Adverse Event – Any experience occurring that results in any of the following outcomes: death, life-threatening experience, requires in-patient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the subject and may require medical or surgical intervention to prevent one of these outcomes.

Unanticipated Problems - Any incident, experience, or outcome that is 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; AND is related **or** possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); 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. Examples include, but are not limited to, breach of confidentiality, protocol violations and deviations, and complaints about the research procedures or treatments by key personnel on the research team.

Unanticipated Adverse Event – Any 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.

Related – An event is related to research procedures if in the opinion of the principle investigator, it was more likely than not to be caused by the research procedures or if it is more likely that not that the event affects the rights and welfare of current participants.

Type of Event

Any of the following must be reported to the IRB within 48 hours of the event or notification of its occurrence:

☐ Internal Adverse Event that is determined to be serious and unanticipated

Any of the following must be reported to the IRB as soon as possible, but in all cases within 5 working days:

☐ External Adverse Event that is determined to be serious, unanticipated, and possibly related to the study.

☐ An Unanticipated Problem (internal or external) related to the research that exposes subjects or others to potential risk.

☐ Information that indicates a change to the risks or potential benefits of the research. For example:

- An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB, or
- A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.

☐ Breach of confidentiality

☐ Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant

☐ Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team

☐ Event that requires prompt reporting to the sponsor

☐ Sponsor imposed suspension for risk

Event Information

Location of event:

☐ Phoebe Affiliate:

☐ Off-site

☐ Single Event

☐ Multiple Events (# of events:) For each event, submit *Supplemental Form I Multiple Adverse Events*

Is this a follow-up report?

☐ Yes; original report date was:

☐ No; date Event occurred:

Is study open to enrollment?

☐ Yes

☐ No

a) Briefly describe the circumstances of this event:

b) Describe this Event using the drop down menu below or add other and describe (use drop-down menu):

Other:

Date of the Event:

c) Intensity (use drop-down menu):

d) Was event study-related (use drop-down menu)?

e) How long did the event last?

f) Currently enrolled participants will be notified of this event?

- ☐ Yes
- ☐ No

g) Previously enrolled participants will be notified of this event?

- ☐ Yes
- ☐ No

h) P.I.'s statement of this Event in relation to the study:

Attachments

a) This event has prompted a change to the Informed Consent(s):

- ☐ Yes (if yes, please complete and submit a Report of Amendment form)
- ☐ No

b) This event has prompted a change to the Protocol:

- ☐ Yes (if yes, please complete and submit a Report of Amendment form)
- ☐ No

Principal Investigator Acknowledgement
I attest that the information contained herein is a true and accurate representation of my ongoing study.
P.I.'s Name: _____ Date: _____
Electronic Signature:

Submit Form

Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" to the left or at top of page.

IRB Review of Adverse Event / Unanticipted Problem Report Form (Completed by IRB Office Only)
Date of Receipt: _____
Is the Report Form Complete? ☐ Yes ☐ No
Has supporting documentation been submitted, if applicable? ☐ N/A ☐ Yes ☐ No
Report returned to Investigator (indicate reason):
Date of Full Board Review: _____