Event Report Form

Appalachian IRB / Human Research Protection Program

Instructions: Complete and sent the request form electronically to irb@appstate.edu.

IRB #: _____ Study Title: _____

Date of report: _____

Sponsor of study and OSP # (if any): _____

The parties (i.e., IRB and PI and faculty advisor if PI is a student) have agreed to conduct this event report by electronic means, and this report is signed electronically by the Principal Investigator (PI) and by the faculty advisor if a student is the PI.

My name and email address together constitute the symbol and/or process I have adopted with the intent to sign this report, and my name and email address, set out below, thus constitute my electronic signature to this application.

Principal Investigator(s): _____ Email: _____

Faculty advisor if student is the PI: _____ Email: _____

Department(s): _____

1. Event date: _____ Date of Event Discovery by PI: _____
2. Research Site (where research activity was conducted and where the event occurred):

3. Detailed description of even including a) number of subjects affected by event, and b) whether the event was anticipated and described in the consent form or other information provided to subjects:

4. Event Summary

   a. Probability:

      ☐ **Expected** (reasonably anticipated, and are described in the informed consent process)
      ☐ **Unexpected** (in terms of nature, severity, or frequency in the consent form)

   b. Causality

      ☐ **Related** (in the opinion of the PI, the adverse event more likely than not was caused by the study drug or procedures)

      ☐ **Possibly related*** (in the opinion of the PI, there is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research

      ***Provide a justification for this determination**:

   c. Event Severity (if applicable):

      ☐ **Unanticipated Problem** (*must meet all three criteria)*
      - Unexpected
      - Related or possibly related to the study
      - Places subjects at greater risk of harm than previously recognized

      ☐ **Serious Adverse Event** (Select one of the following and note that a modification should be considered):
      ☐ Death
      ☐ Life threatening (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 persistent or significant disability/incapacity
      ☐ Results in a congenital anomaly/birth defect
      ☐ Based upon appropriate medical judgement, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

5. What corrective actions have been taken or are proposed in response to the event?

6. Are you aware if this event (or related event) occurred previously in this study or other research studies involving in the same research intervention/interaction?
   - ☐ No
   - ☐ Yes, provide a summary of previous reports:

7. Status of subject(s) involved in the event:
   - ☐ Subject withdrew from research participation
   - ☐ Subject continued research participation
   - ☐ Subject has already completed the research
   - ☐ Investigator withdrew subject from further participation
   - ☐ Other:

8. How many subjects have been accrued to date?: _____
   a. Study status:
      - ☐ Ongoing intervention/interaction without change in research protocol
      - ☐ Ongoing but all interventions/interactions have been completed for study
      - ☐ Research activitites have been temporarily stopped for all subjects
      - ☐ Stopping all new subject enrollment
      - ☐ Stopping certain research activities for all subjects
      - ☐ Other:

9. Do you propose a modification to the study protocol/consent form to address the event?
   - ☐ Yes, a modification request will be submitted
   - ☐ No, explain why: