Algorithm for Determining Whether an Adverse Event is an Unanticipated Problem

An adverse event occurs in one or more subjects.

1. Is the adverse event unexpected in nature, severity, or frequency?
   - No
   - Yes

2. Is the adverse event related or possibly related to participation in the research?
   - No
   - Yes

3. Does the adverse event suggest that the research places subjects or others at greater risk of physical or psychological harm than was previously known or recognized?
   - Yes
   - No

   **NOTE:** If the adverse event is serious, the answer is always "Yes."

Report AE promptly to the Upstate IRB.
Use the Report of Unanticipated Problems & Adverse Events Form.

The AE need not be reported to the Upstate IRB.
**NOTE:** Reporting to the sponsor, CRO, or data monitoring entity should be followed per study protocol.