Problems Involving Risk - Adverse Event Algorithm

An adverse event occurs in one or more subjects.

1. Is the adverse event unexpected in nature, severity, or frequency?
   - YES
   - NO

2. Is the adverse event definitely, probably, or more likely than not related to participation in the research?
   - YES
   - NO

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

STOP

The adverse event is not an unanticipated problem and need not be reported under 45 CFR part 46

Note: If the adverse event is serious, the answer is always “YES”

Report the adverse event as an unanticipated problem under 45 CFR part 46

(Taken from www.hhs.gov/ohrp/policy)