## **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? 2. Is the adverse event definitely, probably or more likely than not related to participation in the NO research? 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? NOTE: If the adverse event is serious, the answer is always "YES" **STOP** Report the adverse

The adverse event is not

an unanticipated problem

and need not be reported under 45 CFR part 46

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

event as an unanticipated

CFR part 46

problem under 45