

GUIDANCE ON REVIEWING AND REPORTING UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS AND ADVERSE EVENTS

[OHRP's current thinking](#) on unanticipated problems should guide Jacksonville University IRB actions while reviewing and reporting adverse events and problems involving risks to human subjects.

a) Types of problems for which this policy applies:

1. Unanticipated problems involving risks to subjects or others;
2. Serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB; and

suspended or terminated, the chair of the IRB will contact the investigator, Senior Vice President of Academic Affairs, Dean of the Principle Investigator's academic unit and