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

3. Suspension or termination of IRB approval.

b) Responsibilities for reporting risks to subjects and others

1. *Enabling subjects to report problems*. All informed consent forms must include information enabling subjects to contact both the investigator and the chair of the IRB. In the case when the chair of the IRB is the investigator, the contact information will include contact information for another member of the IRB.

2. *Enabling investigators to report problems*. On the application form for approval of research involving human subjects, researchers are reminded of their obligation to immediately inform the IRB of any risks to subjects.

3. *Reporting to the institution and to OHRP.* The IRB is responsible for sharing all reports of problems involving risks to human subjects with the Senior Vice President of Academic Affairs and Dean of the Principle Investigator's academic unit. When required by OHRP's current policies, reports of serious risks to human subjects must be reported to the OHRP within one week after receiving the initial report of problems.

c) Responsibilities for reporting serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB and reporting suspension or termination of IRB approval

1. The IRB is responsible for investigating any reports of noncompliance. The IRB must meet within 1 week of receiving such a report to decide the accuracy of such claims, with a quorum and a majority vote deciding the issue. Any members of the IRB with a conflict of interest in the case must recuse themselves from discussion and voting.

2. If the IRB decides that serious or continuing noncompliance has occurred, it will vote to suspend or terminate approval. In the event that approval is

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 if reporting is required by current OHRP's policy, the OHRP within one week with a detailed explanation of the decision and its rationale.

d) When an investigator receives a report of an external adverse event, the investigator should review the report and assess whether it identifies the adverse event as being:

1. unexpected;

2. related or possibly related to participation in the research; and

3. serious or otherwise one that suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

If the investigator determines that all three of the listed conditions are met, the investigator must immediately inform the IRB of the adverse event and related risks to research subjects or others.

e) When unapproved research is discovered, the IRB will act promptly to:

1. Halt the research;

2. Assure remedial action regarding any breach of regulatory or institutional human subject protection requirements; and

3. Address the question of the investigator's fitness to conduct human subject research.

Conducting research on human subjects without obtaining approval from the IRB, disregarding the outcome of the review process, or disregarding the rules established by federal regulations and the Jacksonville University IRB will be considered a violation of ethics (and an act of academic dishonesty), and possible violations will be adjudicated by the Senior Vice President of Academic Affairs. It is the responsibility of the Principle Investigator and Faculty Mentor supervising the research (if applicable) to ensure that all investigators involved in a project understand and follow procedures approved by the review process.