

INSTITUTIONAL REVIEW BOARD REPORT OF FINDINGS**I. PURPOSE / BACKGROUND**

This policy establishes guidelines to ensure prompt reporting that the Human Subjects Protection Program Office (HSPPO) must prepare in response to findings of a University of Louisville Institutional Review Board (IRB) of those events listed in Federal regulations. These regulatory requirements may be found in [45 CFR 46.103\(b\)\(5\)\(i\)](#) and [21 CFR 56.108\(b\)\(1\)](#).

II. POLICY

If the IRB determines that an event represents:

- a. An unanticipated problem involving risks to subjects or others,
- b. A serious or continuing noncompliance with research regulations or determinations of the IRB, or
- c. A suspension or termination of IRB approval,

the HSPPO staff will prepare a draft report within five (5) workdays after the IRB meeting at which the determination occurred.

III. PROCEDURE FOR POLICY

The report will contain:

- a. A summary of the event,
- b. The findings of the organization,
- c. Actions taken by the organization or IRB,
- d. Reasons for the organization's or IRB's actions, and
- e. Plans for continued investigation or action,
- f. Project title,
- g. Principal Investigator,
- h. Federal Support, if any.

The Director of HSPPO in consultation with the IRB chair and the Senior Vice President for Research will finalize the report within ten (10) working days after the IRB meeting at which the final determination occurred. The Senior Vice President for Research will send the report to the following:

- a. The IRB (as a information item with the agenda),
- b. OHRP*,
- c. FDA* (whenever the research is subject to FDA regulation),
- d. Department of Veterans' Affairs* (whenever the research involves the use of shared facilities or employees or agents with appointments at both the University of Louisville and the Louisville Department of Veterans Affairs Medical Center),
- e. Other Federal Agencies* that are a signatory to "The Common Rule" who conduct or oversee the research.
- f. Investigator.
- g. Dean/Research Dean

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The Director of the HSPPO will report to the following if the IRB or the Senior Vice President for Research deems appropriate:

- a. Departmental chair, program director and supervisor of the investigator,
- b. Other organizations involved with the research,
- c. The sponsor,
- d. The funding agency,
- e. The Grants Management and Industry Contracts offices.

*Reporting is not required if the agency has already been made aware of the event through other mechanisms, such as reporting by the investigator, sponsor, or another organization.

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