

IRB REPORTING – UNANTICIPATED PROBLEMS, NONCOMPLIANCE, SUSPENSIONS, AND TERMINATIONS

1. Overview

For federally sponsored research, regulations require that institutions and IRBs report the following determinations to investigators, the IRBs, institutional officials, and federal agencies:

- Unanticipated problems involving risks to subjects or others
- Serious noncompliance
- Continuing noncompliance
- Suspensions of IRB approval
- Terminations of IRB approval.

For all other research involving human subjects, reports of these determinations are made to investigators, the IRBs, and appropriate institutional officials. The content, timing, and communication of these reports are described in further detail below.

2. Report Content and Review

A. Reports of IRB actions/determinations are initially drafted by an ORRP staff member (e.g., IRB Protocol Analyst, IRB Administrative Manager, IRB Policy Analyst), with assistance from the Office of Research Compliance and/or Office of Legal Affairs, as required.

B. Each report includes (but is not limited to) the following information:

- Institution conducting the research (e.g., The Ohio State University)
- Title of the research protocol and grant proposal (as applicable) in which the problem, noncompliance, and/or suspension or termination occurred
- Principal investigator of the research
- Protocol number assigned to the study by the IRB and number of any applicable federal award (grant, contract, or cooperative agreement)
- Detailed description of the problem or noncompliance (if applicable)
- Reason(s) for IRB suspension or termination (if applicable)
- Plans for continued investigation (if applicable)
- Action(s) taken or plans for action to address the problem, noncompliance, and/or suspension or termination.

Reports may be accompanied by supplemental materials (e.g., redacted IRB minutes) to provide additional background and details as needed.

- C. Reports drafted by ORRP staff will be reviewed and approved by the applicable IRB Chair before being sent to the Institutional Official for signature.

3. Report Distribution and Timing

Reports of unanticipated problems, serious and/or continuing noncompliance, suspensions, and terminations will be distributed within 30 days of IRB review and determination, as described below.

3.1 Federally Sponsored Research

ORRP will distribute copies of the signed report (with applicable attachments) to the following as required by regulations:

- OHRP, for DHHS-regulated research
- FDA, for FDA-regulated research (except as described below)
- Other federal agencies when the research is overseen by the agency and separate reporting is required
- Sponsor of the research (if other than above)
- IRBs
- Institutional Official
- Principal Investigator
- Principal Investigator's Department Chair (or Signatory Official)
- Director of Sponsored Programs.

Copies of the report (without attachments) will also be sent to the following, as appropriate based on the nature of the report:

- Co-Investigator(s)
- Principal Investigator's College Research Officer and/or Dean
- Associate Vice President for Research Compliance
- Director of the Office of Responsible Research Practices
- Other institutional officials (e.g., Privacy Officer for issues involving PHI, etc.)
- Other site(s) involved in the research.

3.2 Research Not Federally Sponsored

ORRP will distribute copies of the signed report (with applicable attachments) to the following for unfunded or non-federally funded research:

- FDA, for FDA-regulated research (except as described below)
- IRBs
- Institutional Official

- Principal Investigator
- Principal Investigator's Department Chair (or Signatory Official).

Copies of the report (without attachments) will also be distributed to the following, as appropriate based on the sponsor (if any) and nature of the report:

- Co-Investigator(s)
- Principal Investigator's College Research Officer and/or Dean
- Associate Vice President for Research Compliance
- Director of the Office of Responsible Research Practices
- Other institutional officials (e.g., Privacy Officer for issues involving PHI, Director of Sponsored Programs for funded research, etc.)
- Sponsor and/or contract research organization.

4. Exceptions

- A. For serious incidents (e.g., requiring urgent suspension), a preliminary report may be sent prior to completion of investigation, IRB review, and/or corrective action(s). In such cases, one or more follow-up reports and/or a final report will be made when IRB findings and actions have been completed.
- B. Determinations made by Western IRB (WIRB) for OSU research will be reported as described above for non-federally sponsored research, within 30 days of OSU's notification of the action/determination, except that WIRB will report its finding(s) to FDA for FDA-regulated research.
- C. For incidents occurring at another site in multi-center or collaborative research not covered under OSU's FWA or for which an OSU IRB is not the IRB of record, OSU will rely on the external site to report to appropriate federal agencies and OSU, as described in IRB Authorization Agreements or other applicable agreements.

5. Applicable Regulations/Guidance

21 CFR 56.108, 45 CFR 46.103, OHRP "Guidance on Reporting Incidents to OHRP" (05/27/05)