



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 provided 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 with assistance from the Office of Research Compliance and/or Office of Legal Affairs, as needed.
- 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 and award, as applicable
 - Protocol number assigned to the study by the IRB and number (internal and sponsor-defined) of any applicable federal award(s) (grant, contract, or cooperative agreement)
 - Number of participants enrolled in the study
 - 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.** For research not federally sponsored or FDA-regulated, internal reports are based upon meeting minutes and are composed by ORRP staff. Internal notifications of Board determinations may be sent via Buck-IRB.



- D. Federally sponsored and/or FDA-regulated research reports are sent to the Institutional Official for approval and signature prior to internal and external distribution.

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 staff 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
- Principal investigator
- Co-investigator(s)
- Principal investigator's Department and/or Division Chair (or Signatory Official)
- Director of Sponsored Programs and/or designee
- Principal investigator's College Research Officer and/or Dean
- Director of the Office of Responsible Research Practices.

Copies of the report will also be sent to the following based on the nature of the report and at the discretion of the Institutional Official:

- Office of Research Compliance
- Other institutional officials (e.g., Privacy Officer for issues involving PHI)
- Other site(s) involved in the research.

3.2 Research Not Federally Sponsored

ORRP staff 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
- Co-investigator(s)
- Principal investigator's Department and/or Division Chair (or Signatory Official)
- Principal investigator's College Research Officer and/or Dean



- Director of the Office of Responsible Research Practices

Copies of the report will also be distributed to the following, as appropriate, based on the sponsor (if any), nature of the report, and at the discretion of the IRB Chair or Vice-Chair:

- Office of Research Compliance
- 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 immediate suspension), a preliminary report may be sent prior to completion of an investigation, IRB review, and/or corrective action(s). In such cases, one or more follow-up reports and/or a final report will be provided when IRB findings and actions have been completed.
- B.** Determinations made by Western IRB (WIRB) for Ohio State research will be reported as described above for non-federally sponsored research, within 30 days of Ohio State'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 the university's FWA or for which an Ohio State IRB is not the IRB of record, Ohio State will rely on the external site to report to appropriate federal agencies and to Ohio State, as described in an IRB Authorization Agreement or other applicable agreement.

5. Applicable Regulations/Guidance

21 CFR 56.108, 45 CFR 46.103, OHRP "Guidance on Reporting Incidents to OHRP" (06/20/2011)

6. History

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