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SCOPE

This policy applies to Office of Research Integrity and Compliance (ORIC) Director, Institutional Review Board (IRB) Chair, IRB staff, institutional official(s), who are involved in reporting unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval within the institution, federal departments and agency head(s).

For investigator’s reporting requirements, please refer to IRB-P100 document entitled, “Post-approval Reporting Requirements for Investigators” (reporting of unanticipated problems, adverse events, protocol deviations and incidents, and updated safety information).

REASON FOR POLICY

The Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) requires that institutions have “written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risk to subjects or others or any serious or continuing noncompliance with this guidance or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval” [45CFR46.103(b)(5) and 21CFR56.108(b)].
POLICY STATEMENT

1. CDU IRB will report any unanticipated problems involving risk to research participants or others, any serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB, and any suspension or termination of IRB approval to the institutional official(s), federal department or agency head(s), and other appropriate entities.

2. CDU IRB will report to federal department or agency head(s), which regulates the research (i.e., DHHS, FDA).

3. CDU IRB will not report to the federal department or agency head(s) that have been notified through other mechanisms, such as the investigator, sponsor or external site.

4. The report will be sent to institutional official(s), federal department or agency head(s), and other appropriate entities within 30 days of the receipt of the report from the investigator.

PROCEDURES

1. Once the convened IRB (1) determines that unanticipated problems involving risks to subjects or others has occurred, (2) determines that serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB has occurred, or (3) suspends or terminates IRB approval, IRB Chair and IRB staff will prepare a notification report, which includes the following, but not limited to:

   a. Name of the institution conducting the research
   b. Title of the research project
   c. Name of the Principal Investigator (PI)
   d. IRB number, sponsor protocol number, federal grant award number, and IND or IDE number for FDA-regulated studies, if applicable
   e. Nature of the event
   f. IRB determination (e.g., unanticipated problems, serious and/or continuing noncompliance, suspension or termination of IRB approval)
   g. Description of the findings and the reason for the determination
   h. Actions taken or planned to be taken to address the problem and the reason for the action
   i. Plans for continued investigation or action as necessary
2. The ORIC Director and the institutional official(s) reviews and approves the final written report to be sent to the appropriate regulatory agency.

3. The ORIC Director signs the written report and sends it within 30 days of the receipt of the report from the investigator. If a full resolution was not achieved, an initial report will be forwarded within 30 days, and the final report within 30 days of final resolution. If ORIC Director is not available, the report is signed and sent by the institutional official.

4. If the institution takes further action in addition to the IRB, the institution’s findings, determination, reasons for the determination, and actions planned will also be included in the initial report and/or in the final report.

5. A copy of the report will be sent to the following:
   a. DHHS/Office for Human Research Protections (OHRP)
   b. Food and Drug Administration, if the study involves FDA-regulated product
   c. Western IRB, if the study is an industry-sponsored, multi-center study and WIRB is the IRB of Record
   d. Study sponsor, if the study was sponsored (e.g., National Institutes of Health-NIH, Health Resources and Service Administration-HRSA, industry sponsors)
   e. Other Common Rule agencies (e.g., Department of Energy, Department of Defense, Department of Homeland Security, Department of Education, Department of Justice) that is conducting or supporting research or has regulatory oversight
   f. Principal Investigator (PI)
   g. IRB Chair
   h. Federal-Wide Assurance (FWA) Signatory Official
   i. Executive Vice President of Academic Affairs/Provost
   j. Dean
   k. Vice President of Research and Health Affairs
   l. Director of Office of Sponsored Programs (OSP), if the study was externally funded
   m. Other university committees (e.g., Institutional Biosafety Committee, Radiation Safety Committee, Conflict of Interest Committee), as applicable
   n. Institutional official of any other site involved in the research for which the CDU is the IRB of Record
   o. Any other individuals within the university or external entities as determined by the Institutional official(s), ORIC Director, or IRB Chair

6. No additional reporting will be made to the regulatory agencies if they have been notified already by other collaborating institutions, who may be serving as the IRB of Record.
7. Any follow up reports will be written using the same procedures as above.

8. IRB Chair, ORIC Director and the institutional official will notify each other of any correspondences from the federal agencies, sponsors, and other entities which may have monitoring or oversight function.

9. ORIC Director and the institutional official will maintain all correspondences with regards to, and including, the initial and final report.

DEFINITIONS

**Continuing non-compliance**: A continuing non-compliance is a pattern of recurring non-compliance by the same investigator or research staff support. This pattern includes the number of non-compliant incidences during the entire study, and whether the same or different action was repeated. Continuing non-compliance might involve lack of attention, knowledge, or understanding about the applicable regulations and IRB requirements or willingness to follow them.

**Non-compliance**: Any action or activity that does not comply with applicable federal, state, or local laws and regulations or the IRB requirements or determinations, including IRB and institutional policies governing human participant research. Non-compliant actions or activities might be unintentional or deliberate.

**Related**: An event is “related” if there is a possibility that the event was caused by the research procedures.

**Serious event**: An event is “serious” if participants or others experience serious harm or requires intervention to prevent participants or others from potential serious harm.

**Serious non-compliance**: An action or omission by the investigator or the research staff support that affects the rights or welfare of the participants and places them at greater risk or causes harm. Serious non-compliance includes deliberate compromise of the integrity or validity of the research.

**Suspension of previously approved research**: Temporary stop of some or all research activities. This includes suspension of (1) some or all research activities from a single study or (2) other active studies involving human participants.

**Termination of previously approved research**: Permanent stop of all research activities. This includes termination of (1) some or all research activities from a single study or (2) other active studies involving human participants.
**Unanticipated**: An event is “unanticipated” if the event was unforeseeable at the time of its occurrence. All unanticipated problems are unexpected, but not vice-versa.

**Unanticipated problems involving risk to participants or others**: Any event that meets the following: (1) unexpected, (2) serious, and (3) related or possibly related.

**Unexpected**: An event is “unexpected” when the specificity, nature, severity, or incident are not accurately reflected in the protocol approved by the IRB.

**REGULATIONS**

45CFR46.103(b)(5)  
21CFR56.108(b)

**REFERENCES**


FDA, IRB Information Sheet – Continuing Review after Study Approval, October 18, 2010.

Accessed February 29, 2012