

OFFICE OF RESEARCH OVERSIGHT

**Examples and a Brief Guide for Reporting
Apparently Serious or Apparently Continuing Noncompliance in Human Research
That May Be Reportable to ORO under VHA Handbook 1058.01**

September 14, 2015

VHA Handbook 1058.01: Research Compliance Reporting Requirements

§4.c. Continuing Noncompliance. Continuing noncompliance is the **persistent failure** to adhere to the legal and policy requirements governing human research.

§4.s. Serious Noncompliance. Serious noncompliance is any failure to adhere to requirements for conducting human research that may reasonably be regarded as:

- (1) **Presenting a genuine risk of substantive harm** to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or
- (2) **Substantively compromising a facility's HRP** [Human Research Protection Program].

§6.f. Apparent Serious or Continuing Noncompliance. VA personnel, including WOC and IPA appointees, must ensure that the IRB is notified, in writing, **within 5 business days** after becoming aware of any apparent serious or continuing noncompliance with IRB or other human research protection requirements.

NOTE: HIPAA Privacy Rule deficiencies, including uses and disclosures of PHI for research without legal authority (e.g., without a valid authorization or waiver of authorization), are to be reported in accordance with paragraph 6.f. Such deficiencies should also be reported to the facility Privacy Officer (PO).

IMPORTANT NOTE: It is the role and responsibility of the Institutional Review Board (IRB) to determine whether a particular situation actually constitutes serious or continuing noncompliance in human research. However, VA personnel are required to report to the IRB any situation that appears to represent serious or continuing noncompliance. Examples are provided here to assist in identifying such noncompliance, but the examples should be not considered either exhaustive or definitive. ORO strongly recommends that IRBs clearly document case-specific determinations and justifications related to their evaluations of apparently serious or apparently continuing noncompliance.

A. Examples of Apparently Serious Noncompliance in Human Research That May Be Reportable to ORO under VHA Handbook 1058.01 §6.f:

- (1) Initiation of human research without required IRB approval.
- (2) Initiation of human research without R&D Committee approval.
- (3) Initiation of human research without ACOS/R notification that the research may begin.
- (4) Failure to obtain informed consent for one or more subjects (where required, unless waived by the IRB).
- (5) Failure to obtain documentation of informed consent (where required, unless waived by the IRB).
- (6) Failure to obtain HIPAA authorization for one or more subjects (where required, unless waived by the IRB).
- (7) Substantive informed consent or HIPAA authorization deficiencies.

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- (8) Substantive deviations from IRB-approved protocols, including substantive violations of inclusion or exclusion criteria.
- (9) Modification of a protocol without IRB approval (except to prevent immediate hazards to subjects).
- (10) Failure to implement, in a timely fashion, any protocol or informed consent modifications, or other changes required by the IRB.
- (11) Failure to notify the IRB of a death, SAE, or problem as required.
- (12) Unfounded labeling of a death, SAE, or problem as “anticipated” or “not related” to the research.
- (13) Conduct of research without required credentialing, privileging, or initial training.
- (14) Conduct of research involving women known to be pregnant, prisoners, or children, or of international research, without required approvals from the Facility Director or Chief Research and Development Officer, as applicable.
- (15) Continuation of human research beyond the specified IRB approval period (except where in subjects’ best interests as determined by the IRB Chair).
- (16) Any finding by any entity, including clinical trial monitors, of apparent serious noncompliance as listed here.
- (17) Substantive programmatic noncompliance (e.g., violation of IRB quorum requirements; improper approval or documentation of exemptions or waivers; failure to ensure review of proposed research sufficient to identify and address privacy or data security concerns). *NOTE: Apparent noncompliance on the part of the IRB should also be reported to the facility Research and Development (R&D) Committee and the Associate Chief of Staff for Research and Development (ACOS/R&D).*
- (18) Any combination of noncompliant actions that collectively present a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, or substantively compromise a facility’s HRPP.

B. Examples of Apparently Continuing Noncompliance in Human Research That May Be Reportable to ORO under VHA Handbook 1058.01 §6.f:

- (1) Persistent failure by the relevant investigator(s) to ensure timely remediation of any noncompliance, identified by or made known to the investigator(s), with requirements for the conduct of human research.
- (2) Persistent failure by the responsible official(s) to ensure timely remediation of any programmatic noncompliance, identified by or made known to the official(s), with requirements for the conduct or oversight of human research.
- (3) Any noncompliance that, due to its persistence over time, results in a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, or substantively compromises a facility’s HRPP.

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C. Brief Guide for Reporting Apparently Serious or Apparently Continuing Noncompliance in VA Research. For detailed requirements, see VHA Handbook 1058.01 §6.f.

