REPORTING NONCOMPLIANCE IN VA HUMAN RESEARCH

An individual identifies **APPARENT SERIOUS OR CONTINUING NONCOMPLIANCE**[1] in a VA research study.

The apparent serious or continuing noncompliance was identified by a **Research Compliance Officer (RCO)** based on an **informed consent audit, regulatory audit, or other systematic audit.**

YES

SPECIAL REPORTING IS REQUIRED:

- The RCO must report the apparent serious or continuing noncompliance to the **Facility Director, IRB, ACOS/R, R&D Committee,** and other relevant research review committees within **5 BUSINESS DAYS** after discovery.
- Facility Director must report to the ORO Regional Office (RO), Network Office, and Office of Research and Development (ORD) within **5 BUSINESS DAYS** after notification.
- Facility Director must provide follow-up reports as directed by the ORO RO.

NO

REPORTING IS REQUIRED:

- The individual must ensure that the apparent serious or continuing noncompliance is reported to the **IRB** within **5 BUSINESS DAYS** after discovery.

The convened IRB determines that **SERIOUS or CONTINUING NONCOMPLIANCE** occurred because:

- The noncompliance involves substantive harm (or a genuine risk of substantive harm) to the safety, rights, or welfare of human subjects, research staff, or others.
- The noncompliance substantively compromises the effectiveness of the facility's human research protection or human research oversight programs.
- The noncompliance reflects a persistent failure to adhere to the laws, regulations, or policies governing VA research.

YES

SPECIAL REPORTING IS REQUIRED:

- IRB Chair must report to the **Facility Director, ACOS/R, R&D Committee,** and other relevant research review committees within **5 BUSINESS DAYS** after the determination.
- Facility Director must report to ORO RO within **5 BUSINESS DAYS** after notification (or if previously reported, provide follow-up as directed).

NO

- Report to ORO only as follow-up to a previous report.

- Reports to OHRP per 38 CFR 16.103(b)(5)(i), FDA per 21 CFR 56.108(b)(2), the sponsor, and/or other entities may be required.
- If in doubt, check with the relevant entity.

[1] See 38 CFR 16.103(b)(5)(i), 21 CFR 56.108(b)(2), and VHA Handbook 1058.01 §6. Examples considered by VA to reflect **apparent** serious or continuing noncompliance that must be reported to the IRB within 5 business days include, but are not limited to:

- External findings of noncompliance by any VA office or other Federal or State oversight agency
- Initiation of VA research without written notification from the ACOS/R, without IRB approval, or prior to obtaining required informed consent
- Lack of a required, signed informed consent document or required, signed HIPAA Privacy Rule authorization for one or more subjects
- Use for one or more subjects of an informed consent document whose content was not approved by the IRB
- Failure to report one or more unanticipated SAEs or serious unanticipated problems involving risks to subjects or others as required
- Conduct of research by one or more persons without the required credentialing, privileging, or scope of practice or outside the approved scope of practice.
- Continuation of interactions or interventions with human subjects beyond the specified approval period
- Implementation of substantive protocol changes without IRB approval, except to prevent immediate hazard to a subject
- Failure to obtain CRADO approval for VA research involving prisoners or children or for international VA research
- Serious programmatic noncompliance, eg, conduct of IRB business by an improperly constituted IRB or with less than a quorum of voting members, improper designation of research as exempt, noncompliant approval or noncompliant documentation by the IRB of an informed consent waiver, documentation waiver, or HIPAA authorization waiver, failure to provide for PO and ISO review of proposed research
- Failure to implement IRB-required changes within the IRB-specified time period
- Deficiencies in informed consent or HIPAA authorization procedures or documentation for 10 or more subjects
- Failure to maintain documentation required by the IRB or the IRB-approved protocol
- Failure to implement remedial actions within the time periods specified by VA policy without acceptable justification

[ORO: 12/01/2011]