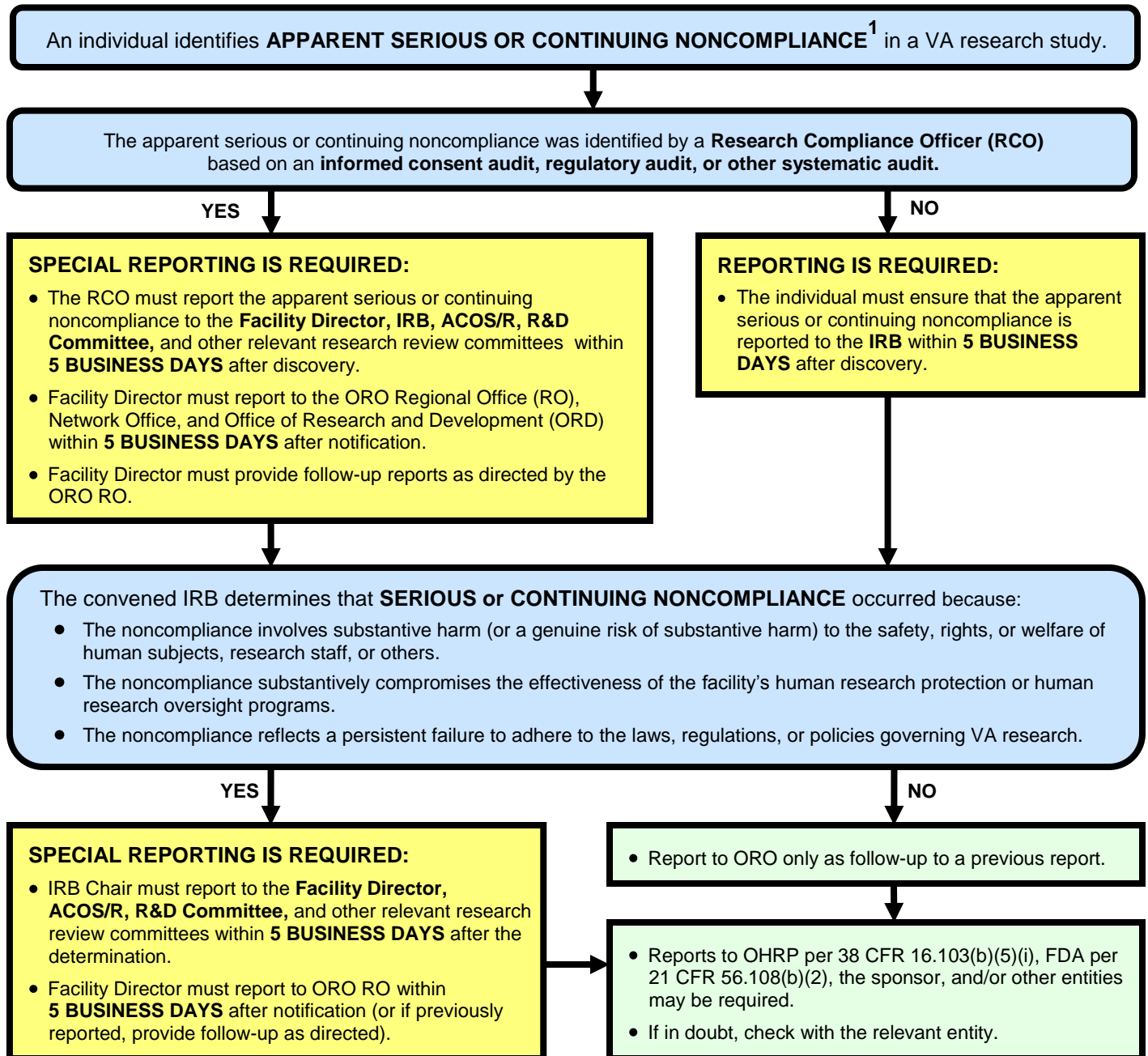


REPORTING NONCOMPLIANCE IN VA HUMAN RESEARCH



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