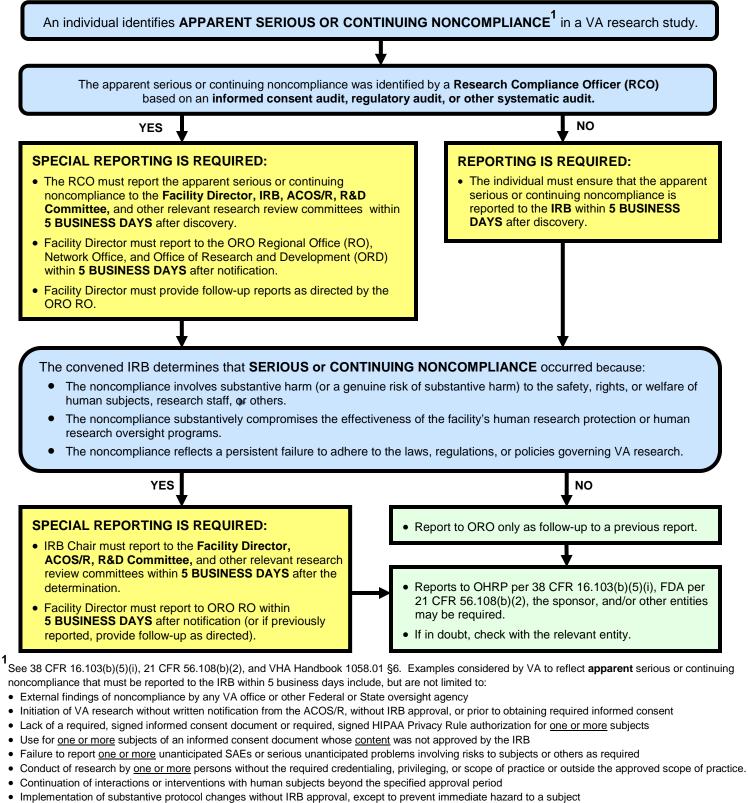
REPORTING NONCOMPLIANCE IN VA HUMAN RESEARCH



- · 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