

<i>EVENT TYPE</i>	<i>IRB Involvement</i>	<i>Follow up and Documentation</i>
Minor Protocol Deviation/Protocol Noncompliance (examples below):	Not Reportable to the IRB	Track Issue and CAPA in Regulatory Binder Log Sheet
Consents not scanned into CPRS but note is entered (under 10 per protocol)		
Unstamped HIPAA document		
Wrong date/time for POC		
Subject date on ICD or HIPAA present, just the wrong date (and the date in CPRS is correct)		
POC writing in date and/or time for subject on ICD and/or HIPAA		

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Protocol Deviation/Protocol Noncompliance (examples below):	Reportable to the IRB (via eIRB) within 10 business days	CAPA to be approved by the IRB CoRE Team
No consent notes in CPRS (under 10 per protocol)		
No signature and/or date/time for POC on ICD/HIPAA		
POC fully credentialed through VA Research Office, just not added to the study in eIRB		
Incorrect or expired version of the ICD/HIPAA used, regardless of content		

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Apparent Serious/Continuing Noncompliance (examples below):	Reportable to the IRB (via eIRB) within 10 business days	CAPA to be approved by the IRB CoRE Team/Committee Q/ (R&D Committee if Serious/Continuing NC)
Initiation of VA human subject research, regardless of level of risk or number of subjects, without IRB approval OR written notification from the ACOS for Research that the project may begin		
Initiation of research interactions or interventions with one or more subjects prior to obtaining required informed consent		
Lack of a required, signed informed consent document or lack of a required, signed HIPAA authorization for one or more subjects		
Failure to report one or more unanticipated SAEs or unanticipated serious problems involving risks to subjects or others as required		
Participation by one or more members of the research team in the conduct of an active protocol without the required credentialing, privileging, or scope of practice, or engaging in activities outside the approved scope of practice		
Continuation of interactions or interventions with human subjects beyond the specified IRB approval period		
Deficiencies in informed consent or HIPAA authorization procedures or documentation for ten or more subjects		
Failure to maintain documentation required by the IRB or by the IRB-approved protocol for ten or more subjects (ex. inadequate CPRS documentation)		