

University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 5.1
Protocol Audits

Policy

The IRB has the authority to observe, or have a third party observe, the consent process and the research it has approved, and to verify that the study is being conducted as required by the IRB. When the IRB opts to assess the conduct of the study or the consent process as part of providing adequate oversight, an audit is conducted by the IRB Chair, a member of the IRB, a member of another IRB or an unaffiliated party. An audit may be study-oriented (focused on a specific study) or investigator-oriented (focused on all the studies of a particular investigator). An audit may be also be classified as routine (part of the normal oversight process) or “for cause.” A “for cause” audit may be initiated in response to any of the following findings:

1. An allegation of or evidence suggesting noncompliance with applicable regulations or institutional policies
2. Noncompliance with policies of the IRB as outlined in this document
3. Expressed concerns by the sponsor regarding the investigator’s work
4. A complaint by a subject in a study about protocol or subject's rights violations
5. A potential high risk to subjects
6. Recruitment of vulnerable populations
7. Studies that involve large numbers of subjects
8. Investigators who are conducting multiple studies under IRB jurisdiction
9. Research by an investigator outside of their specialty areas
10. Safety or effectiveness findings that are inconsistent with other investigators studying the same test article
11. Too many subjects with a specific disease given the locale of the investigation are claimed
12. Laboratory results that are outside the range of expected biological variation
13. Studies selected at the discretion of the IRB
14. An allegation of or evidence suggesting abuse of research subjects
15. An allegation of or evidence suggesting scientific misconduct
16. Associated with unexpected serious harm to participants

Audit Procedures

In order to determine the facts surrounding the conduct of the study, the auditor may review the protocol and any modifications, investigational drug brochure, the informed consent, the investigator’s and the IRB files, subject’s medical and/or research records, case report forms, literature and other documents that could serve to provide factual information regarding the conduct of the study. Although not generally recommended, the auditor may conduct interviews with the Investigator, members of the study team, or research subjects. A written

report of findings will be provided to the IRB for further review. If the audit report documents substantial issues of noncompliance, the IRB may take action as outlined in the section, “Communications, Sanctions, Appeals and Disciplinary Actions.”

Third Party Verification

Third party verification of information provided by an Investigator may be necessary to ensure protection of subjects. The IRB may require verification of any information provided by an investigator as part of an initial application or as part of a re-approval, interim or completion report. The IRB also has the authority to observe, or have a third party observe, the consent process and the research it has approved. The need to verify any information, the information that needs verification and the extent to which the information will be verified will be determined by the IRB at a convened meeting. Methods of third party verification include:

1. Direct observation of research procedures by an IRB member
2. Direct request to sponsor for information
3. Direct request to Data Safety Monitoring Board (DSMB) for information

Procedures

1. Auditors complete audit report within 10 working days of completing the audit, review all documents for could provide factual information regarding conduct of the study, conform that the study is being conducted in compliance with the documents provided, by observation if possible, especially a) methods of subject recruitment, and or safeguards for subjects vulnerable to coercion or undue influence; b) process for obtaining informed consent; c) version of informed consent used; d) facilities available in an emergency; e)adherence to inclusion/exclusion criteria, confirmation information about any adverse events that may be reported, obtain information about any adverse events that may not have been reported, and confirm status of project (enrolling, inactive, etc.).
2. IRB members will review the audit report, assess the need for additional information, determine audit conclusion, and vote on remedial action imposed on investigator, as necessary.
3. IRB Administrator will provide auditor with a copy of the protocol and any modifications, investigational drug brochure, informed consent, IRB files and any other documents that could provide factual information regarding the conduct of the study, provide audit with audit checklist and contact investigator to arrange audit logistics.

Applicable Regulations, References and Forms

[21 CFR 56.108\(a\)\(2\)](#)

[21 CFR 56.109 \(f\)](#)

[38 CFR 16.103\(b\) \(4\)\(ii\)](#)

[38 CFR 16.109\(e\)](#)

[45 CFR 46.103 \(b\)\(4\)\(ii\)](#)

[45 CFR 46.109\(e\)](#)

[VHA Handbook 1200.05](#)

UCSD On Site Audit Checklist

FDA GCP Audit Guidelines