



**Nova Southeastern University
Standard Operating Procedure for GCP**

Title: <u>Audits – Sponsor and/or Regulatory (FDA)</u>		Version # 1
SOP Number: OCR-AUD-001	Effective Date: August 2013	Page 1 of 3

PURPOSE: This SOP will describe the types of audits that can be expected and the preparations and procedures for those audits. There are generally two types of audits that a site can expect. One is an audit conducted by the Sponsor or Sponsor's agent and one is an audit conducted by a Regulatory Agency such as the US FDA.

POLICIES:

Sponsor Audit

1. A Sponsor's audit can be conducted for a number of reasons as follows:
 - 1.1 In preparation for a Regulatory audit at a site that is likely to be audited by a Regulatory Agency.
 - 1.2 High enrolling site.
 - 1.3 A site that has had a large ratio of protocol violations/deviations.
 - 1.4 A "for cause" audit in which the site has been found to be conducting incorrect or fraudulent clinical research or is suspected of such.
 - 1.5 To evaluate the work habits or performance of the Sponsor's representative.
 - 1.6 To assess the performance of the Investigators and staff.
 - 1.7 To assure quality of the data.

Regulatory Audit (FDA)

1. A Regulatory audit will usually take place after the Sponsor has filed an NDA or NDS to have the test product approved for sale but can happen at any point during or after study closure. A Regulatory audit is conducted for the following reasons
 - 1.1 To assure compliance with FDA and/or TPD regulations and guidelines.
 - 1.2 To assure compliance with ICH cGCPs.

- 1.3 To evaluate the accuracy of the data.
- 1.4 To detect and/or prevent fraud.

PROCEDURES

Sponsor's Audit:

- 1. Preparation:
 - 1.1 When notified by the Sponsor of a pending audit, agree upon a mutually acceptable date.
 - 1.1.1 Determine the time (number of days) the auditors will require to be at the site.
 - 1.1.2 Book a room with a large desk/work space.
 - 1.1.2.1 Climate controlled.
 - 1.1.2.2 Closing door.
 - 1.1.2.3 Telephone access.
 - 1.1.3 Assure that the required staff will be available.
 - 1.1.3.1 Principal Investigator.
 - 1.1.3.2 Study coordinator.
 - 1.2 Review the protocol.
 - 1.3 Review the Regulatory Binder.
 - 1.3.1 Assure organisation.
 - 1.3.2 Assure that all required signatures are present.
 - 1.3.3 Assure completeness.
 - 1.3.3.1 Request missing copies from the Sponsor.
 - 1.3.4 Assure the presence of all essential documents.
 - 1.4 Review CRFs and source documents.
 - 1.4.1 Assure completeness.
 - 1.4.1.1 Review all required signatures.
 - 1.4.2 Assure accuracy of information.
 - 1.4.2.1 Do not make changes on the CRFs that have already been pulled.
 - 1.4.3 All originally signed ICFs should be present and easily accessible.
 - 1.5 Review all study drug/device accountability and records of receipt.
- 2. The day(s) of the audit:
 - 2.1 Be on time.
 - 2.2 Ask for ID.
 - 2.3 Escort the auditor to prepared room.
 - 2.3.1 Do not give tour of facility unless asked.
 - 2.4 Provide the auditor with water/coffee/juice.
 - 2.5 Identify the location of the bathroom.
 - 2.6 Ask what materials the auditor needs to start and provide only those documents.

- 2.7 Bring new material and/or remove materials only when asked to do so by the auditor.
 - 2.8 Answer any questions directly and honestly, but do not offer extra information.
 - 2.8.1 If auxiliary staff is asked questions they should direct the auditors to the PI or Designee
 - 2.8.2 If you do not know the answer, offer to find the correct answer – DO NOT guess.
 - 2.9 Do not give the auditor original documents.
 - 2.9.1 Offer to make copies of documents if requested to do so.
 - 2.10 If the auditor asked the staff to make corrections, do so using correct cGCP guidelines and document the request appropriately.
3. Follow-up.
- 3.1 Ask for an exit interview.
 - 3.2 Ask for a copy of the auditors report.
 - 3.3 Review the auditors finding.
 - 3.3.1 Make appropriate revisions or corrections as requested in a timely manner.
 - 3.3.2 Use the audit as a learning tool to improve site practices in the future.

Regulatory Audits.

All of the above apply for a regulatory audit with the following additions:

- 1. When notified of a Regulatory audit notify the Principal Investigator, IRB, Office of Clinical Research and Sponsor **immediately**.
 - a. The Sponsor will usually try to send a team in to help prepare for the audit.
 - b. Never offer to take the auditors out for lunch, dinner or drinks.
 - i. Offer only the essentials.
 - c. Regulatory agency will not give a site a copy of the audit report but a follow-up letter will be sent.
 - i. A written response to the follow-up letter will be expected.
 - 1. This will include documentation of the corrections made in response to any findings.