Quality Assurance
QA – 601.02

STANDARD OPERATING PROCEDURE FOR FDA or Pharmaceutical-sponsored Audits

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04 Feb 2021

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1. INTRODUCTION AND PURPOSE

Georgia CORE is responsible for ensuring compliance with regulatory requirements and guidelines and standard operating procedures (SOPs) related to clinical research and responding to requests from third parties (e.g., sponsors/CROs or FDA) to review documentation and review of such compliance through an audit or inspection.

2. SCOPE

This standard operating procedure (SOP) describes the steps to be followed by Georgia CORE from the time an audit or inspection is scheduled until all follow-up activities associated with the audit or inspection has been completed. For the purposes of this document the terms “third party” addresses a sponsor/CRO or FDA, “audit” addresses

both audits and FDA inspections, and the term "auditor" includes both auditors and FDA inspectors.

3. APPLICABLE REGULATIONS AND GUIDELINES

The Code of Federal Regulations and the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline and selected program and guidance documents apply to this SOP (Appendix A).

4. REFERENCES TO OTHER APPLICABLE SOPs

All SOPS are applicable to this SOP.

5. ATTACHMENTS

A. Preparing for an Audit Checklist

6. RESPONSIBILITY

This SOP applies to Georgia CORE leadership, staff, and consultants responsible for arranging, managing, or participating in a third-party audit and/or monitoring a Research Network site that is being audited by a third party. Included are the following:

- President and CEO
- Chief Medical Officer
- Georgia CORE staff and consultants

7. DEFINITIONS

The following definitions apply to this SOP (Appendix B):
Audit
Audit Trail
Compliance
Direct Access
Documentation
Essential Documents
Good Clinical Practice (GCP)
Quality Assurance (QA)
Quality Control (QC)
Source Documents
Standard Operating Procedures (SOPs)

8. PROCESS OVERVIEW

A. Preparing for the audit
B. During the audit
C. Follow-up after the audit

9. PROCEDURES

A. Preparing for the Audit

President and CEO/ Designee

Notify the Principal Investigator of an Investigator-initiated study, when notified of a third- party audit as soon as possible.

Work with the auditor to develop a proposed scheduled (estimated number of days, times) for the audit and ensure that all key personnel will be available before confirming a date.

Ensure that records of staff qualifications and training are available for review by the auditor.

Review the following guidelines with Georgia CORE staff and consultants who will be involved in the audit:

- Documents that the FDA may not inspect, absent voluntary production by Georgia CORE, include but are not limited to:
  - Financial data
  - Personnel data (other than that needed to establish the qualifications of technical and professional personnel performing functions involved in the study)
  - Internal QA audit records
- Use of still or video cameras or voice recording apparatus on Georgia CORE premises by the auditor must be agree to by the President and CEO. It the decision is made to allow the use of the audiovisual equipment, the President and CEO will determine that the rights and privileges of Georgia CORE will not be waived, that Georgia CORE will be given equal opportunities to use the same equipment, and appropriate measure have been taken to ensure the protection of proprietary or confidential information of Georgia CORE and/or its staff, consultants, Research Network sites, and research subjects.
- The auditor may request to view electronic data files on a computer and to make copies of electronic data files on a memory device to be provided to the auditor as part of the audit document collection process. This request must

be reviewed and agreed to by the President and CEO of Georgia CORE in advance.

Review and approve all auditor requests for copies or documents and records before handing them to the auditor in order to be ensure that appropriate measures have been taken to ensure the protection of proprietary or confidential information contained in those documents and records.

Designate an individual to take notes of activities and discussions during the audit.

Designate an individual to make copies and obtain documents and records as requested.

Identify adequate space for the auditor(s) to use to review documents and records.

Work with Research Network sites to prepare for a study-related audit by a third-party at their site by:

- Ensuring that the Research Network site Investigator, Subinvestigator(s), and site staff are instructed to notify Georgia CORE if a third party requests an audit at their site
- Research Network Investigator/ Subinvestigator(s) and key study personnel and Georgia CORE staff and consultants will be available for the audit before the audit is confirmed.
- Review Information Sheet Guidance For IRBs, consultants Clinical Investigators, and Sponsors FDA Inspections of Clinical Investigators https://www.fda.gov/media/75185/download if a FDA inspection is requested.
- Review the following with the Research Network site staff prior to a scheduled to ensure that:
  - Records of key research personnel qualifications and training are available.
  - All study documents, including informed consent forms, source documents, electronic records, CRFs, the regulatory binder for the study identified as the focus of the audit are complete, accurate, and available for review

by the auditor (Attachment A, Preparing for an Audit Checklist.)
- Research Network site SOPs are available.
- Study drug accountability records, including study drug ordering, receipt, dispensing, disposal, and instances of emergency breaking the blind were required are complete, accurate, and available for review.

Georgia CORE staff and consultants	Review Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors FDA Inspections of Clinical Investigators https://www.fda.gov/media/75185/download Ensure that all study documentation, including the regulatory binder, study templates, study communications records, and electronic records maintained by Georgia CORE for the study identified as the focus of the audit are accurate, complete, and available for review by the auditor (Attachment A, Preparing for an Audit Checklist). Ensure that Georgia CORE Standard Operating Procedures are available.
B. During the Audit	
President and CEO/ Designee	Meet with the auditor(s). Request to see identification, - **Note:** If an FDA audit, request FDA Form 482c, Notice of Inspection and ascertain the purpose of the inspection. Review the policies and guidelines for the conduct of the audit with the auditor. Provide an orientation to the facilities, site and access to the site for the audit, and access to the study records and files. Ensure that the auditor(s) is not left unattended and arrange for appropriate staff to be available to answer questions, retrieve documents, and facilitate completion of the audit. Ensure that questions posed by the auditor are answered by the appropriate personnel and request additional time to respond if necessary. Document all relevant discussion and requests.

		Provide copies of requested study-related documents; ensuring a second copy of each document is made and kept in the Georgia CORE audit file. Ensure that the auditor does not make any copies, make marks on original documents and records, nor remove an original document or record from the premises of Georgia CORE or Research Network site. Request that a summary of audit finding be provided at the end of each day. Notify key Georgia CORE and Research Network Site personnel of the time, location, and teleconference/telephone access of the exit interview (summary audit) meeting. Participate in the exit interview (summary audit) meeting (in person or by teleconference) with the auditor, Investigator and/or Subinvestigator(s) and relevant Research Network site staff for audit of Research Network sites when the audited study is sponsored by Georgia CORE or Georgia CORE is serving as the Site Management Organization (SMO). Record comments. **Note:** If an FDA audit, obtain a signed FDA Form 483, Inspectional Observations from the auditor, if a FDA Form 483 is required. Request an opportunity to correct objectionable observations immediately. Ask the auditor to clarify any items and provide as much detail as appropriate for items that need clarification. Review the copies to redact any proprietary or confidential information before the copy is given to the auditor.
C.	**Follow-up After the Audit**	
	President and CEO/ Designee	Meet with Investigators and/or Subinvestigator(s) and all relevant Research Network site staff after the exit interview (summary audit) meeting to discuss the audit summary and next steps.

Request that the site send draft responses to audit reports and or/form FDA 482c to Georgia CORE prior to formal submission to the auditor or FDA.

Review draft documents and provide feedback to the appropriate Research Network staff members within one business day.

Ensure that the Georgia CORE Chief Medical Officer is notified of all audit findings and follow-up, as applicable.

Ensure that the Georgia CORE President and CEO has reviewed and signed the final response to the audit results prior to submitting to the sponsor or regulatory organization.

Determine, in consultation with the Georgia CORE Chief Medical Officer, regarding the need to report audit results to other relevant regulatory authorities or funding sponsors.

Note: If a FDA audit, respond to the form FDA 483c and the audit report as soon as possible after receipt and within required deadlines. Reply to each item in the form and report including:

- An evaluation of the extent of the problem
- Assessment of the root cause of the problem and if the problem is systemic
- Any corrective action: What was or will be corrected, when it was or will be completed.
- Actions to prevent recurrence of the problem in future studies
- Time frame for training
- Supportive documentation

Note: Contact the FDA office and request the state of a letter from the FDA officially classifying the inspection as either No Action Indicated, Voluntary Action Indicated, Official Action Indicated) is not received within 45 days of the inspection.

Retain copies of all audit documents in the appropriate, secured file at Georgia CORE.

10. HISTORY OF CHANGES

Version Number	Section Number	Modifications	Approval Date
601.00	All	Original Version	
601.01	Section 3	Addition of June, 2010 Regulations for Clinical Investigator Inspections	09 March 2012
601.01	All	No change was necessary	01 July 2014
601.01	All	Modification of Title	01 March 2017
601.02	All	Reorganization of content for clarity and demarcation of sponsor and FDA audit requirements Remove expired FDA forms Clarification of titles and responsibilities of Georgia CORE staff	30 June 2020

ATTACHMENT A:
Preparing for an Audit Checklist

I. ORGANIZATION		Completed	N/A	COMMENTS
	Industry Sponsor (if an FDA audit)			
	IRB			
Notify all parties involved with the study	Investigator, Subinvestigators Research Network site staff			
	Pharmacy			
	Laboratories			
	Medical records			
	Administration			
	Legal counsel			
	Reserve secured space for the audit~~or~~			
General overview of the study	Prepare a general overview of the study			
	List all personnel and responsibilities delegated (Delegation of Tasks)			
List of subjects	List all subjects enrolled including name, address, and/or phone number, date enrolled and completed, medical record number (to be kept as a reference for Research Network site staff			
	List all subjects screened			
Standard Operating Procedures (SOPs)	Georgia CORE and Research Network site SOPs			

2. FILES MANAGEMENT		YES	N/A	COMMENTS
Organize all regulatory files by general heading arranged in chronological order	Protocol (all versions)			
	Investigator's Brochure (all versions)			
	Protocol amendments			
	Form FDA 1572 (all versions)			
	CVs for Investigator and Subinvestigators listed on all versions of Form FDA 1572			
	Training records for all key study staff			
IRB files	Approval letter (initial) for initial protocol with original informed consent(s)			
	Amendment approval(s) with approved informed consent(s) (if applicable)			
	Informed consent forms (originals) for enrolled subjects			
	Informed consents for screened subjects			
	Status reports for:			
	· Yearly renewal(s)			
	· Adverse events			
	· Deaths			
	· Study termination			
	· Final summary			
Communications	Sponsor correspondence			
	CRO correspondence			
	IRB correspondence			
	Other study correspondence			
	Monitoring log			
Laboratory	Laboratory certifications and normal ranges			
	Drug log to include:			
Drug accountability	· Receipt of drug			
	· Dispensing			
	· Return/Destruction			
Equipment accountability	Equipment log including:			
	· Receipt of equipment			
	· Dispensing			
	· Return			

3. REVIEW OF DOCUMENTATION		YES	N/A	COMMENTS
Collect and review for each subject enrolled	CRFs completed for each subject enrolled			
	Data correction forms for CRFs			
	Source documents for each subject enrolled that document the following:			
Medical records and/or study files	· Condition of subject at time of entry into the study (i.e., all inclusion/exclusion criteria are met)			
	· Case history documents including that informed consent process was charted and obtained prior to start of study procedures			
	· Exposure to test article			
	· Concomitant medications			
	· Clinical assessments of the subject during the course of the study			
	· Laboratory reports			
	· Diagnostic tests			
	· Dose modifications			
	· Adverse events/death			
	· Protocol exemptions			
	· Early termination			

4. SITE SPECIFIC		YES	N/A	COMMENTS
Temperature Logs	· Refrigeration			
	· Drug			
Equipment	· Name of equipment: _____			
	· Calibration logs			
	· Inspection reports			
	· Permits			
	· Licensure			