General Administration
GA – 104.01

STANDARD OPERATING PROCEDURE FOR Document Development and Change Control

Approval: Lynn M. Durham, Ed.D.
President and CEO

04 Feb 2021

(Signature and Date)

Approval: Frederick M. Schnell, MD, FACP
Chief Medical Officer

04 Feb 2021

(Signature and Date)

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Document Review Date:	30 June 2020
Reviewer:	Jane Clark, PhD, RN, AOCN, OCN (2020)
Previous Reviewers:	Joni Shortt, BSN, RN, CCRC (2017) Alice Kerber, MN, APRN (2014)
Primary Author:	Anita Clavier, BSN, MPH (2013)

1. INTRODUCTION AND PURPOSE

Georgia CORE is responsible for reviewing, approving, distributing, rendering obsolete, and archiving study documents; maintaining an Index of Forms and other documents; and maintaining a History of Changes Table for recording all revisions to existing forms and documents.

2. SCOPE

This standard operating procedure (SOP) describes the steps to be followed for developing, revising, and approving study documents for studies subject to investigational new drug (IND) regulations for drugs and biologics or those eligible for investigational new drug (IND) exemption during all investigational phases of development.

This procedure is applicable for study documents originating at Georgia CORE and for external study documents that will be used by Georgia CORE that do not have document development and change control information.

Study documents covered by this SOP include the following:

- Any regulatory documents including study protocols, protocol amendments, informed consent forms, case report forms, investigator brochure and adverse event reporting forms.
- Any document that describes or guides study activities including SOPs.
- Any study document under development or revision by a collaborative effort such as the Research Concept Proposal (RCP) form.

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. Document Control Form Template
B. Version Control Flow Chart
C. History of Changes Table
D. Document Training Documentation Form

6. RESPONSIBILITY

This SOP applies to Georgia CORE administration, staff, and consultants who participate in the development and modification of study documents. 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):

Clinical trial/study
Investigator
Subinvestigator

8. PROCESS OVERVIEW

A. Documentation Initiation and Approval Procedures
B. Documentation Change Procedures
C. Documentation of Training on New or Revised Documents

9. PROCEDURES

A. Documentation Initiation and Approval Procedures

President and CEO or Designee	Determine which documents are needed for developing regulatory submissions, collecting data or other study information, and/or performing any other study-related function. Determine who will draft the first version of a given document (the Primary Author). Determine who must review and approve the first and succeeding drafts in accordance with federal and Georgia CORE guidelines. The number of reviewers is determined on a case-by-case basis. Use templates or other available guidelines for developing new documents where available and initiate the document drafting process. Complete the Document Control Form (Attachment A: Document Control Form Template). If the document requires additional review, circulate the draft, with the Document Control Form as the cover. Secure signature/review date, comments and suggestions from all specified reviewers. Revise document per initial review process and if any revisions are not incorporated, notify the affected reviewer(s) of the reason(s) for not including the revision(s) and negotiate a resolution. Document any significant differences in the space provided on the Document Control Form. Continue to circulate the revised document to all signatories with the Document Control Form cover until the review process is complete. The document will have a version and draft number for each review and then a final version date (Attachment B Version Control Flow Chart). Ensure all required reviewed approvals are indicated by entries in the Signature and Approval Date boxes of the Document Control Form. Upon final signature of the last reviewer, sign, and date the Document Control Form in the space provided to indicate responsibility for this document.

	Following final approval, assign all newly approved documents a version number and effective date (Attachment B Version Control Flow Chart).
	Retain the original approved document and Document Control Form(s) in the appropriate archive or section of the Regulatory Master File.
	Update any related indices (e.g. List of Forms) to include the new or revised document.

B. Documentation Change Procedure

President and CEO/ Designee	Review study and study-related documents periodically or as needed by circumstances (e.g., new federal or state regulation, new organizational policy or procedure, or need to update obsolete information).
	When revisions are required, have the Author of the change (s) circulate the revised draft with a copy of the original, clearly noting the changes, using the Document Control Form as its cover.
	Continue to give updated and revised documents a new version number and a current effective date.
	Document periodic review and updating by maintaining an accurate History of Changes table for each document (Attachment C: History of Changes Table).
	Mark prior version of the document “Obsolete” and save a copy for the appropriate archive file or section of the Regulatory Master File.
	Update any related tables or indices, as appropriate.

C. Documentation of Training on New and Revised Documents

President and CEO/ Designee	Ensure that all appropriate staff are trained in the proper use of the new or revised documents. Document the training on the Document Training Documentation Form (Attachment D).
	Make a list of all affected parties and appropriate regulatory authorities (e.g., IRB, FDA) who must be notified of changes to the applicable documents and notify them in writing when the changes are implemented (or prior to implementing, if appropriate).

Provide the updated version of the document to affected parties.

10. History of Changes

Version Number	Section Number	Modifications	Approval Date
104.00	All	Original Version	
104.00	All	No change was necessary	09 March 2012
104.00	All	No change was necessary	01 July 2014
104.00	3	Update regulation	12 December 2016
104.00			01 June 2017
104.01	All	Edits for clarity	30 June 2020

ATTACHMENT A:
Document Control Form

Document Title/Version _____

Reason for Action:

___ Revision ___ Periodic Review

___ Existing document made obsolete ___ New document

Document Review:

Name of Reviewer	Review Date	Signature of Reviewer

***Note to Review:** Please track changes and insert your comments in the text of the attached document. Provide review date and signature (Reviewer must make certain that their user name is set in Word under tools/options/user information so that changes they make using "track changes" will be properly attributed to them).

Review Outcome:

___ No revision needed ___Revisions made ___ Revisions not made* ___New document created

*Summary of outstanding revision differences and rationale for final version:

_____

_____

_____

Approval Signatures:

Author: _____ Date: _____/_____/_____

President and CEO (Signature) _____ Date: _____/_____/_____

ATTACHMENT B:
Version Control Flow Chart

Document Date

Date the document is created or revised is incorporated in the header of each page.

Version Number

Current version number is identified on the first page and when possible, is incorporated in the header or footer of the document and appears on every succeeding page.

Draft Number

SOP document: 1st draft is XXX.00 Draft 1.0 - subsequent drafts will increase by 1.0.

All other study document (e.g., protocol, protocol amendment, informed consent form, CRF, Investigator Brochure, and adverse event reporting form); 1st draft is Version 0.1 – subsequent drafts will increase of 0.1.

First Final

SOP documents: 1st final version will be XXX.00.
All other study documents: 1st final version is 1.0.
All documents will have a version and effective date.

Subsequent Finals

SOP documents: Version number will increase by .01 above the version being revised e.g. XXX.01, XX, XXX.02, XXX.03.
Other final study documents: Version number will increase by 1.0 above the version being revised e.g., 1.x becomes 2.0, 2.x becomes 3.0.
All changes will be documented into a History of Changes Table.
All documents will have a version and effective date.

Previous Finals

Mark the previous final version of the document "Obsolete" and save a copy for the appropriate archive file or section of the appropriate file.
Update any related tables or indices, as appropriate.
Notify all appropriate Georgia CORE and Research Network staff members and consultants of the change and provide training as required.

ATTACHMENT C:
History of Changes Table

Title of Document_____

Version Number	Section Number	Modification	Approval Date

ATTACHMENT D:
Document Training Documentation Form

Name of Document(s):

_____
_____
_____
_____
_____

Date of Training: _____

Printed Name of Attendee	Attendee Signature