General Administration
GA – 104.00

STANDARD OPERATING PROCEDURE FOR
Document Development and Change Control

Approval: Nancy Paris, MS, FACHE
President and CEO

24 May 2017
(Signature and Date)

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

30 May 2017
(Signature and Date)

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Previous Reviewer: Alice S. Kerber, MN, APRN (March 2014)

I. INTRODUCTION AND PURPOSE

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.

2. SCOPE

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. 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

01 April 2016	Federal Code of Regulations
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.61	Control of the investigational drug
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.66	Assurance of IRB review
21 CFR 312.68	Inspection of investigator's records and reports
45 CFR 46	46DHHS Part 46 Protection of Human Subjects
21 CFR 812	Subpart E Responsibilities of Investigators
January 1988	Guidelines for the Monitoring of Clinical Investigations
October 2009	Guidance for Industry Investigator Responsibilities--- Protecting the Rights, Safety, and Welfare of Study Subjects
FDA	Frequently Asked Questions, Continuing Review After Study Approval, Recruiting Study Subjects, Payment to Study Subjects, Screening Tests Prior to Study Enrollment, A Guide to Informed

May 1997 Consent, Investigator-IRB Interrelationship

ICH Good Clinical Practice: Consolidated Guideline (E6 4.2.4)

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. RESPONSBILITY

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

This includes the following:

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

7. DEFINITIONS

The following definitions from the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline apply to this SOP.

Clinical trial/study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Subinvestigator: Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

8. PROCESS OVERVIEW

A. Documentation Initiation and Approval Procedures
B. Document Change Procedures

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 numbers of reviewers is determined case-by-case). 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 its cover, securing 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, documenting 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 as its 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 reviewer 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 that 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 file or section of the Regulatory Master File. Update any related indices (e.g. List of Forms) to include the new or revised document.

B. Document Change Procedure

• Contracts and Regulatory Administrator	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 copy for the appropriate archive file or section of the Regulatory Master File. Update any related tables or indices, as appropriate

C. Documentation Training Document Form

• Contracts and Regulatory Administrator	Ensure that all appropriate staff are trained in the proper use of the new or revised document and document 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 appropriate documents to affected parties.

10. History of Changes

Version Number	Section Number	Modification	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	Updated regulation	12 Dec 2016

Attachment A

DOCUMENT CONTROL FORM

Routing Date:

Existing Document	New Document
Existing Document No.:	New Document No.:
Existing Document Title:	New Document Title:

Reason for Action:

☐ Revision
☐ Periodic Review
☐ Existing document made obsolete
☐ New document

Document Review:

Reviewer's Name*	Review Date	Reviewer's Signature

Note to Reviewer: 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.

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Draft Number
SOP documents: 1st draft is XXX.00 Draft 1.0 – subsequent drafts will increase by 1.0
All other study documents (e.g. protocol, protocol amendement, informed consent form, CRF, Investigator Brochure, and adverse event reporting form): 1st draft is Version 0.1 - subsequent drafts will increase by 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, 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 staff and consultants of the change; provide training as required

Attachment C

HISTORY OF CHANGES

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