

General Administration
GA – 101.01

STANDARD OPERATING PROCEDURE ON SOPs:
Preparing, Maintaining and Training

Approval: Nancy M. 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)

Issue Date: 01 June 2017

Effective Date: 01 June 2017

Expiration Date: 01 June 2019

Document Review Date: 01 January 2017

Reviewer: Joni Shortt, BSN, RN, CCRC

Primary Author: Anita Clavier, BSN, MPH

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

I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the preparation, review, approval, and maintenance of Georgia CORE's written procedures for clinical research to ensure compliance with all FDA regulations and guidelines. This SOP also describes procedures for training on SOPs and documentation of training.

2. SCOPE

This SOP applies to the written procedures followed by Georgia CORE as it facilitates the conduct of all clinical 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.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60 May 1997	General responsibilities of investigators International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
April 2011	2011 Code of Federal Regulations & ICH Guidelines

4. REFERENCES TO OTHER APPLICABLE SOPs

All SOPs are applicable to this SOP.

5. ATTACHMENT

- A. Title Page Template
- B. Training Compliance Form

6. RESPONSIBILITY

It is the responsibility of the Chief Medical Officer and President and CEO of Georgia CORE to review and approve SOPs. The President and CEO assume ultimate accountability for all SOPs. It is the responsibility of all Georgia CORE staff and consultants involved in supervising, managing, or conducting study-related activities to understand and follow the SOPs. This includes the following:

- President and CEO
- Chief Medical Officer (CMO)
- 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.

Standard Operating Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function.

8. PROCESS OVERVIEW

- A. Procedure for preparing new SOPs or revising previously issued SOPs
- B. Procedure for reviewing and approving SOPs
- C. Procedure for providing training on implementing SOPs

9. PROCEDURES

A. Procedure for preparing new SOPs or revising previously issued SOPs

Responsible Staff	Procedure:
<ul style="list-style-type: none"> • Designee 	<p>Based upon changes to the FDA regulations, guidelines, or to Georgia CORE policies and procedures, write a new SOP or revise a previously issued SOP that describes the new or revised procedures.</p> <p>Each SOP includes the following in the header:</p> <ul style="list-style-type: none"> • The title • The number for that SOP • The effective date of the new version • The date of the previous version <p>Each SOP includes the following on the title page (Attachment A):</p> <ul style="list-style-type: none"> • Georgia Center for Oncology Research and Education Georgia CORE • SOP category • SOP title • SOP number • Issue date of the new or revised SOP • Effective date of the new or revised SOP • Expiration date of the SOP • Approval name(s) and title(s) • Signature of the approver(s) and date • Name of the primary author <p>Each SOP includes the following in the footer:</p> <ul style="list-style-type: none"> • The Georgia Center for Oncology Research and Education name • If applicable, the statement: SOP adapted from Standard Operating Procedures For Good Clinical Practice At The Investigative Site, A Publication of The Center for Clinical Research Practice, Inc 2003 • The page number of total number of pages <p>New SOP numbers will be sequential within the appropriate category; the version number will start with .00 then proceed to .01, .02, etc.</p>

<ul style="list-style-type: none"> • Designee 	<p>Write the SOP, using the following format:</p> <ul style="list-style-type: none"> • Introduction and Purpose • Scope • Applicable Regulations and Guidelines • References to Other Applicable SOPs • Attachments • Responsibility • Definitions • Process Overview • Procedures • History of Changes <p>Maintain a Table of Contents by number and title of the SOPs.</p>
<ul style="list-style-type: none"> • CMO or Designee 	<p>Review draft SOP to ensure accuracy and completeness.</p>
<ul style="list-style-type: none"> • President and CEO and CMO 	<p>Approve, sign, and date each new SOP after it is finalized.</p>
<ul style="list-style-type: none"> • Contracts And Regulatory Administrator 	<p>Distribute the new/revised SOP to specified Georgia CORE staff members and consultants. The SOPs will be available online and in one controlled paper manual in the Georgia CORE headquarters office in Atlanta, Georgia. Collect the superseded SOP, if appropriate.</p>
<ul style="list-style-type: none"> • Contracts and Regulatory Administrator 	<p>Maintain an historical archive of copies of all previous versions of SOPs to be available in the event of an audit.</p>

B. Procedure for reviewing SOPs

<ul style="list-style-type: none"> • Designee 	<p>All SOPs will be reviewed for accuracy and/or obsolescence no less than once every two years from the approval date, and upon new issuance of federal or state regulation changes. If revisions or additions are required, follow the procedure described above.</p> <p>If no changes are required, document review date on the title page and note in History of Changes that no change was necessary, file appropriately.</p>
--	--

C. Procedure for providing training on implementing SOPs

• Designee	Provide training to all specified Georgia CORE staff members within 14 days prior to the effective date of a new or revised SOP.
• Designee	Ensure that each specified employee documents (Attachment A, Training Compliance Form) the date of training and the SOPs reviewed.
• Designee	Ensure that each new employee reviews all applicable SOPs prior to undertaking any responsibilities for which SOPs apply. Ensure that each new employee documents (Attachment B, Training Compliance Form) the date of review (<i>or training, if appropriate</i>) and the relevant SOPs.
• Designee	Maintain a record of SOP training and review for all employees at Georgia CORE.

10. History of Change

Version Number	Section Number	Modification	Approval Date
101.00	All	Original Version	
101.01	3	Updated Reference	09 March 2012
101.01		No changes necessary.	16 June 2014
101.01	All	No Changes necessary	01 January 2017

Attachment A

TITLE PAGE TEMPLATE

Category
SOP Number

STANDARD OPERATING PROCEDURE TITLE

Approval: Name and Title

(Signature and Date)

Approval: Name and Title

(Signature and Date)

Issue Date: DAY-MONTH-YEAR

Effective Date: DAY-MONTH-YEAR

Expiration Date: DAY-MONTH-YEAR

Primary Author:

