General Administration
GA – 101.02

STANDARD OPERATING PROCEDURE FOR Preparing, Maintaining, and Training for SOPs

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04 Feb 2021

(Signature and Date)

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04 Feb 2021

(Signature and Date)

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1. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) described the preparation, review, approval, and maintenance of written procedures for clinical research for Georgia CORE 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) exemptions during all investigational phases of development.

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. Title Page Template
B. Training Compliance Form

6. RESPONSIBILITY

The President and CEO of Georgia CORE and the Chief Medical Officer are responsible for reviewing and approving SOPs. The President and CEO assumes ultimate accountability for the preparation, maintenance, and training for the 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
- Georgia CORE staff and consultants
- Site Investigator/Subinvestigators and research team members conducting clinical trials

7. DEFINITIONS

The following definitions apply to this SOP (Appendix B):
Clinical Trial/Study
Standard Operating Procedures (SOPs)

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

President and CEO/ Designee	Based on changes to the FDA regulations, guidelines, or to Georgia CORE policies and procedures, write a new SOP or revise a previously issued SOP that described the new or revised procedures. Each SOP includes the following in the header: • The title

	• The number for that SOP • The effective date of the new version • The date of the previous version Each SOP includes the following on the title page (Attachment A). • Georgia Center for Oncology Research and Education (Georgia CORE) • SOP category • SOP title • SOP number • Issue date of the new or revised SOP • Expiration date of the SOP • Approved name(s) and title(s) • Signature of the approver(s) and date • Name of the primary author Each SOP includes the following in the footer: • The Georgia Center for Oncology Research and Education • Page number of total number of pages New SOP numbers will be sequential within the appropriate category, the version number will start with .00 then proceed to .01, .02, etc. Write the SOP using the following format: • Introduction • Purpose • Scope • Applicable Regulations and Guidelines • References to Other Applicable SOPs • Attachments • Responsibility • Definitions • Process Overview • Procedures • Historical Changes
Chief Medical Officer/ Designee	Review draft SOP to ensure accuracy and completeness.
President and CEO Chief Medical Officer	Approve, sign, and date each SOP once finalized.
President and CEO/ Designee	Distribute the new/revised SOP to specified Georgia CORE staff members and consultants for review.

President and CEO/ Designee	Collect all superseded SOPs, as appropriate. Maintain all current SOPs online and in one controlled paper manual in the Georgia CORE office in Atlanta, Georgia. Maintain a historical archive of copies of all previous versions of SOPs to be available in case of an audit.

B. Procedure for reviewing SOPs

President and CEO/ Designee	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. If no changes are required, document the review date on the title page and note in History of Changes that no change was necessary and file appropriately.

C. Procedure for providing training on implementing SOPs

President and CEO/ Designee	Provide training to each specified Georgia CORE staff member and consultants within 14 days prior to the effective date of a new or revised SOP. Ensure that each specified Georgia CORE staff member and consultant document the date of training and the SOPs reviewed on the Training Compliance Form (Attachment A). Ensure that each new employee documents the date of review or training, if appropriate, and the relevant SOPs on the Training Compliance Form (Attachment A). Maintain a record of SOP training and review for all staff members and consultants at Georgia CORE.

10. HISTORY OF CHANGES

Version Number	Section Number	Modifications	Approval Date
101.00	All	Original Version	
101.01	3	Updated reference	09 March 2012
101.01	All	No changes necessary	16 July 2014
101.01	All	No changes necessary	01 January 2017
101.02	All	Edits for clarity and consistency, removal of reference	30 June 2020

ATTACHMENT A: Title Page Template

Category
SOP Number
STANDARD OPERATING PROCEDURE TITLE

Approval: Signature _____ _____
Name and Title Date

Approval: Signature _____ _____
Name and Title Date

Issue Date: Day Month Year

Effective Date: Day Month Year

Expiration Date: Day Month Year

Document Review Date: Day Month Year

Reviewer: Name and Credentials (Year)

Previous Reviewers: Name and Credentials (Year)

Primary Author: Name and Credentials (Year)

1. INTRODUCTION AND PURPOSE

2. SCOPE

3. APPLICABLE REGULATIONS AND GUIDELINES

4. RFERENCES TO OTHER APPLICABLE SOPs

5. ATTACHMENT(S)

6. RESPONSIBILITY

7. DEFINITIONS

8. PROCESS OVERVIEW

9. PROCEDURES

10. HISTORY OF CHANGES

(Added for completeness and consistency)

ATTACHMENT B: Training Compliance Form

Form for: _____ Staff Member/Consultant

SOP #	Standard Operating Procedure Title	Initials	Date Reviewed