General Administration
GA – 101.02

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

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)

Issue Date: 01 June 2017
Effective Date: 01 September 2020
Expiration Date: 01 September 2022
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

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/ Review draft SOP to ensure accuracy and Designee completeness.
President and CEO Approve, sign, and date each SOP once finalized.
Chief Medical Officer

President and CEO/ Distribute the new/revised SOP to specified Georgia Designee CORE staff members and consultants for review.

Georgia Center for Oncology Research and Education
Page 3 of 7
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

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Section Number</th>
<th>Modifications</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>101.00</td>
<td>All</td>
<td>Original Version</td>
<td></td>
</tr>
<tr>
<td>101.01</td>
<td>3</td>
<td>Updated reference</td>
<td>09 March 2012</td>
</tr>
<tr>
<td>101.01</td>
<td>All</td>
<td>No changes necessary</td>
<td>16 July 2014</td>
</tr>
<tr>
<td>101.01</td>
<td>All</td>
<td>No changes necessary</td>
<td>01 January 2017</td>
</tr>
<tr>
<td>101.02</td>
<td>All</td>
<td>Edits for clarity and consistency, removal of reference</td>
<td>30 June 2020</td>
</tr>
</tbody>
</table>
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. REFERENCES 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

<table>
<thead>
<tr>
<th>SOP #</th>
<th>Standard Operating Procedure Title</th>
<th>Initials</th>
<th>Date Reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>