

TITLE: STANDARD OPERATING PROCEDURE FOR SOPs

1.0 OBJECTIVE:

- 1.1 This Standard Operating Procedure (SOP) describes the standard format and method which the Office of Human Research Protection (OHRP) uses in writing and maintaining the Clinical Research SOPs for the Medical College of Georgia (MCG), and also describes how research groups may use these SOPs as guidelines and examples in developing their own SOPs
- 1.2 This procedure is intended to meet the following regulations while recognizing that these regulations may override the procedure:
 - Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814)
 - Department of Health and Human Services (DHHS) Regulations (45 CFR Subparts A, B, C, and D)
 - International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines
 - Medical College of Georgia (MCG), Medical College of Georgia Health, Inc. (MCGHI), and Medical College of Georgia Research Institute (MCGRI) guidelines.

2.0 RESPONSIBILITIES:

- 2.1 The Clinical Research SOP Workgroup is responsible for preparing, revising and implementing the SOPs at this site.
- 2.2 The Office of Human Research Protection (OHRP) is responsible for monitoring compliance with Clinical Research SOPs at the Medical College of Georgia and Medical College of Georgia Health, Inc.
- 2.3 The Office of Human Research Protection is responsible for training research team members on implementing Clinical Research SOPs in their particular research area.
- 2.4 The Office of Human Research Protection (OHRP) is responsible for posting these SOPs on their website as a reference material.

3.0 PROCEDURES:

- 3.1 Writing the SOP:
 - 3.1.1 After designating an activity, the Clinical Research Workgroup determines the level of detail for the SOP.

- 3.1.2 The Workgroup prepares a step-by-step task listing of the activity including which research team member (listed by job title only) is responsible for performing the activity.
 - 3.1.3 Each activity is evaluated for efficiency, effectiveness, and compliance with regulations specified in part 1.2.
 - 3.1.4 Tools are designed to be used with the SOP such as forms, templates, checklists, etc.
 - 3.1.5 The first draft of the SOP is completed. Each SOP is reviewed for accuracy and ability to follow.
 - 3.1.6 After the procedure is reviewed, all comments and revisions are evaluated and are included in the final version as appropriate.
 - 3.1.7 The final version is completed and distributed throughout the organization.
- 3.2 Format:
- 3.2.1 Title of SOP:

The wording should be descriptive but not too long.
 - 3.2.2 Objective of SOP:

The writer describes the purpose of the SOP.
 - 3.2.3 Reference:

This section notes why the activity is being performed. For example, the activity may be performed in order to meet regulations or hospital requirements. This reason for the performance of the activity should be included as part of the SOP objective.
 - 3.2.4 Definitions:

This section will define all terms and acronyms used within the SOP.
 - 3.2.5 Responsibilities:

The writer lists here who is responsible for oversight of the SOP, performing the activities, or other procedure responsibilities.
 - 3.2.6 Procedures:

The writer describes the tasks or step-by-step procedures necessary for completion of the activity. Include definitions as necessary.
 - 3.2.7 Appendix

The writer attaches reference materials such as forms, checklists, or other additional information in this section.

3.3 Implementation:

3.3.1 After the SOP is final, the writer posts the SOP on the OHRP website.

3.3.2 An initial training session is conducted to ensure understanding of the requirements of the Clinical Research SOPs, and the activities necessary for adherence to the SOPs.

3.3.3 Each research area ensures that the site procedures, and activities detailed in the SOP, accurately reflect how the tasks are performed within their research area.

3.3.3.1 If revisions are required to reflect how the tasks are performed within each research area, the Principle Investigator must ensure these revisions are made to the SOP and implemented within the research area.

3.4 SOP revisions:

3.4.1 Each SOP is reviewed annually for possible revisions due to changes in regulations or procedures.

3.4.2 Each revision is labeled as a revision with an effective date listed.

3.4.3 A copy of the revised SOP is posted on the OHRP website. Research areas will be instructed to destroy their copy of the previous version of the SOP.

3.4.4 A central records area (for each research area) must maintain all old versions of SOPs. In the event of a regulatory audit, the regulatory agency may audit a study against the SOP that was in effect at the time of study conduct.