


Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	WRITING AND MAINTAINING SOPs		
SOP#: 101	Effective Date:01/01/2015	Version: 1.0	Page 1 of 3

**PURPOSE:** This Standard Operating Procedure (SOP) describes the standard format, and the method for writing and maintaining the SOPs for clinical trials conducted at the USF Health Morsani Clinical Research Center (CRC), hereafter referred to as the “CRC.” This procedure is intended to meet Food and Drug Administration (FDA) Federal Regulations, International Conference on Harmonization (ICH) Good Clinical Practices (GCPs) as well as the requirements for the USF Institutional Review Board (IRB).

**SCOPE:** This SOP describes systematic processes and functions for USF Health Morsani CRC in compliance with Good Clinical Practices (GCP) requirements for the management and coordination of clinical trial operations. It applies to all personnel engaged in clinical trial research, administration or management for clinical trials conducted in the CRC.

**RESPONSIBILITY:** The clinical research staff is responsible for preparing and complying with all SOPs at this site. Each SOP will designate who is responsible for oversight of the SOP, performing the activities, or other procedural responsibilities.

#### DEFINITIONS:

**Standard Operating Procedure (SOP):** The International Conference on Harmonization (ICH) defines a SOP as “detailed written instructions to achieve uniformity of the performance of a specific function.” (ICH GCP 1.55). In simple terms, a SOP is a written process for a clinical site to perform a task the same way each time it is completed.


**Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

**International Conference on Harmonization (ICH):** A joint initiative by the European Union (EU), Japan and the United States that established the ICH GCP Guideline to provide a unified standard to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

#### PROCEDURE:

##### 1. Writing the SOP:

- 1.1 This includes a step-by-step task listing of the activity including who will perform the activity.
- 1.2 Forms, templates, and checklists are designed to be used with the SOP.
- 1.3 When the first draft of SOP is completed, each one is reviewed for accuracy.

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SOP#: 101	Effective Date:01/01/2015	Version: 1.0	Page 2 of 3

#### PROCEDURE (cont.):

- 1.4 After the procedure, all comments and revisions are evaluated and are included in the final version.
- 1.5 The final version is available for all research employees on the OCR SharePoint

#### 2. SOP Format:

- 2.1 Title: The title should be descriptive and accurate.
- 2.2 Purpose: The purpose describes why the activity is being performed.
- 2.3 Scope: The scope of the SOP describes the range of activities for which the SOP applies.
- 2.4 Responsibilities: This describes individuals accountable for oversight of the SOP, performing the activities, or other procedural responsibilities.
- 2.5 Procedures: This includes a list of described tasks or step-by-step procedures necessary for completion of the activity.
- 2.6 Appendix: Attached reference materials such as forms, checklists, or other additional information are included in this section.

#### 3. SOP Implementation:

- 3.1 Each SOP will be prepared and implemented (See Appendix A: SOP flow diagram).
- 3.2 When the SOP is finalized and approved, a hard copy will be available in the CRC work area and online at the OCR SharePoint site for all research employees to access when needed.
- 3.3 The Investigator, and other designated members of the research staff (e.g.: Clinical Research Coordinator, Clinical Research Associate, etc.), ensures that the site procedures, and activities detailed in the SOP accurately reflect how the tasks are performed at the site.
- 3.4 All staff supervisors are responsible for having new employees and staff members sign the SOP Acknowledgement form (Appendix B) stating they have acknowledged, read, and understood the CRC's SOPs. The Acknowledgement form will be scanned into OCR SharePoint site and the hard copy will be maintained in the hard copy SOP binder in the CRC.

#### 4. SOP Revisions:

- 4.1 Each SOP will be systematically reviewed every 2 years, unless changes in regulations or site procedures occur.
- 4.2 Each revision will be labeled as a revision with an effective date listed.
- 4.3 Previous versions of the SOP will be archived on the OCR SharePoint site
- 4.4 In the event of an FDA audit, the FDA may audit a study against the SOP that was in effect at the time of study conduct.

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**SOP#: 101**

**Effective Date:01/01/2015**

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**Page 3 of 3**

<b>REFERENCES:</b>	21 CFR 50, 21 CFR 54 Financial Disclosure by clinical investigators 56, 312, 314, 600, 601, 812 and 814; ICH GCP 1.55; ICH GCP 2.13	
<b>RELATED POLICIES:</b>		
<b>APPENDICES:</b>	Appendix A: SOP Flow Diagram; Appendix B: SOP Acknowledgement Form	
<b>REVISION HISTORY:</b> Keep a running history of all revision dates		
<b>Approval Date</b>	<b>Effective Date</b>	<b>Review/Revision Date</b>
01/01/2015	01/01/2015	