**PURPOSE:** This Standard Operating Procedure (SOP) describes the standard format, and the method for writing and maintaining the SOPs for clinical trials conducted at Kent State University, hereafter referred to as the “KSU.” 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 KSU Institutional Review Board (IRB).

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

**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.

**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 Office of Research Compliance website.

1. **SOP Format:**

2.1 Title: The title should be descriptive and accurate.

* 1. Purpose: The purpose describes why the activity is being performed.
	2. Scope: The scope of the SOP describes the range of activities for which the

 SOP applies.

* 1. Responsibilities: This describes individuals accountable for oversight of the

 SOP, performing the activities, or other procedural responsibilities.

* 1. Procedures: This includes a list of described tasks or step-by-step procedures

 necessary for completion of the activity.

* 1. Appendix: Attached reference materials such as forms, checklists, or other

 additional information are included in this section.

1. **SOP Implementation:**

3.1 Each SOP will be prepared and implemented.

3.2 When the SOP is finalized and approved, a hard copy will be available in the

research work area and online 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 SOPs. The Acknowledgement form will be scanned and stored on secure department server and the hard copy will be maintained in the SOP binder.

1. **SOP Revisions:**
	1. Each SOP will be systematically reviewed every 2 years, unless changes in

 regulations or site procedures occur.

* 1. Each revision will be labeled as a revision with an effective date listed.
	2. Previous versions of the SOP will be archived on the Office of Research Compliance server.
	3. 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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| **REFERENCES:** | 21 CFR 50, 21 CFR 54 Financial Disclosure by clinical investigators56, 312, 314, 600, 601, 812 and 814; ICH GCP 1.55; ICHGCP 2.13 |
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| **RELATED POLICIES:** |  |
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| **APPENDICES:** |  |
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| **REVISION HISTORY:** Keep a running history of all revision dates |
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| **Approval Date** | **Effective Date** | **Review/Revision Date** |
|  | **01/29/2017** |  |
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