**[Site Name]**

[Site Logo]

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| **SOP Number:** | Version Number: | **Effective Date:** | Page **1** of X |

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| --- | --- | --- |
| **Originated by:**  **[NAME(S)], [tiTLE(S)]** | **Signature:** | **Date:** |
| **Reviewed by:**  **[NAME(S)], [tiTLE(S)]** | Signature | **Date** |
| **Approved by:**  **[NAME(S)], [tiTLE(S)]** | Signature | **Date** |

**Title: SOP for GCP Training, Education and Certification**

1. **SCOPE**

The scope of this SOP applies to all research personnel conducting clinical trials that involve human subjects**.**

1. **PURPOSE**

## The purpose of this Standard Operating Procedure (SOP) is to describe the training required to conduct clinical trials in accordance with federal regulations and Institutional policies that ensure that the rights, safety and welfare of human subjects are protected.

1. **DEFINITIONS/ABBREVIATIONS**
   1. CFR - The Code of Federal Regulations
   2. ICH-GCP - International Council on Harmonization-Good Clinical Practice
   3. FDA - Food and Drug Administration
   4. IATA/DOT - International Air Transport Association/Department of Transportation
2. CRC - Clinical Research Coordinator
3. Investigator - An individual who conducts a clinical investigation, under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.
4. **GENERAL STANDARDS**

## This SOP should be read and documented in the site training log by any new Investigator or CRC prior to starting any study-related activity.

## This SOP should be read and documented in the site training log by current Investigators and CRC every 3 years.

1. **PROCESS AND PROCEDURES**
2. Mandatory training:
3. Human Subject Protection: The Collaborative Institutional Training Initiative Program (CITI program) offered through CITIprogram.org, has two options based on the type of research:
4. Biomedical Researchers
5. Social-Behavorial-Educational Researchers

*Add instructions for your institutional qualifications.*

1. Good Clinical Practice: Offered through CITIprogram.org, the ICH-GCP for Clinical Trials

with Investigational Drugs and Medical Devices (U.S. FDA Focus)

1. IATA/DOT Regulations for the Shipment of 6.2 Biologicals, Infectious Substances and Class 9, Dry Ice Dangerous Goods Training
2. Institution-specific training for transporting study specimens by research staff, if applicable
3. Protocol-specific training:
   * 1. After completing protocol-specific training, complete the sponsor training log.
4. Institutional guidelines/policies:

*Add instructions on who to contact regarding what additional CITI training your site requires, such as COI training.*

*Add instructions on whom to call at your institution if help is needed with the CITI website.*

1. Optional training:
2. Study specific investigator meetings
3. Association of Clinical Research Professionals (ACRP)
4. Society of Clinical Research Associates (SOCRA)
5. Refresher training
   * 1. Complete CITI training every *(enter your institutional guidelines for the number of years).*
     2. Complete GCP training every *(enter your institutional guidelines for number of years).*
     3. IATA/DOT training is completed every two or three years.
     4. *Add your institutional training for transporting specimens by staff members between institutions/facilities.*
6. **Documentation of training**

All team members should file their required mandatory training certificates electronically and sign and date the GCP SOP training log.

**VII. SUPPORTING DOCUMENTS**

International Council on Harmonization E6 (R2)

*Insert your institutional supporting documents*

1. **ATTACHMENTS**

Attachment 1-Attachment Title: Staff GCP Training Log

1. **REVISION HISTORY**

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Summary of Changes** | **Replaces**  **(Document Number,**  **Version Number)** |
|  |  | *Document Number, Revision Number* |
| 2.0 | *Enter the summary of change in a bulleted list, highlighting the major changes* | SOP XXX-###, 1.0 |
| 1.0 | *Original Document* | New Document |

*Major changes should be identified. Show history in descending order of versions.*

**Attachment 1:** **Staff Training Log for GCP Training**

|  |  |  |
| --- | --- | --- |
|  | **GCP Training Name and Number with Current Date** | |
| **Type of GCP Training Completed** | **Date Completed by Staff** | **Staff Signatures** |
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