[SITE NAME]

STANDARD OPERATING PROCEDURE

Title:		No.: ISCORE-RC-105.00	
Clinical Research Personnel Responsibilities and Training Program		Page 1 of 4	
		Date of Issuance: dd, month, yyyy	Date Effective: dd, month, yyyy
		Supersedes:	
Prepared by:	Reviewed by:	Approved by:	

Purpose:

This standard operating procedure (SOP) describes the responsibilities and training requirements for clinical research personnel at the [Site location] and affiliated health systems engaged in clinical research.

Scope:

This SOP describes the responsibilities and training requirements for the clinical research staff to ensure compliance with the regulatory requirements, ICH E6 Good Clinical Practices (GCP), investigational plan and institutional policies.

Materials:
Attachment 1: Site Training Record

Responsibility:

The Principal Investigator (PI) and all members of the research team are responsible for having a clear working knowledge about their specific duties. The PI may delegate authority to trained and/or licensed members of the research team; however, the PI is ultimately responsible for the conduct of the study.

Procedure

1. Responsibilities for all research team members:
    a. Protect the rights, safety, and welfare of subjects.

b. Conduct the clinical study in accordance with the approved study protocol, all applicable federal and state laws, regulatory requirements, institutional policies, including but not limited to protection of confidentiality of all clinical research related information, as well as Good Clinical Practice (GCP) guidance.

c. Comply with federal regulations governing disclosure of personal, professional or financial interests in a research study that may impact upon its conduct, evaluation or outcome.

d. Maintain confidentiality of all clinical trial related information.

e. Fulfill position requirements specific to the job title and in accordance with the delegation by the PI and according to appropriate regulations.

f. Ensure the integrity of the trial-related duties and functions performed and any data generated.

2. Principal Investigator (PI)

Sponsor-Investigator or Investigator Initiated Trials:

For Investigator-Initiated Trials, both Investigator and Sponsor responsibilities apply, including requirements for safety reporting to regulatory agencies and quality management by establishing monitoring and auditing plans as needed.

The Principal Investigator (PI) is the individual of record who is qualified by education, experience and appropriate licensure or certification and assumes the authority and overall responsibility for the conduct of a clinical study in accordance with all applicable federal and state laws, regulatory requirements, institutional policies and Good Clinical Practice (GCP).

a. Must ensure all study team members delegated are qualified by education, training and experience.
b. Ensure that the informed consent process is being conducted according to regulations and that study participants understand the nature of their participation and their risks.
c. Documents the delegation of responsibilities. The PI has the authority to delegate responsibility to qualified and trained members of the research team; however, the PI is ultimately responsible for the overall conduct of the study.
d. Ensure adequate resources are available to conduct the study.
e. Ensures proper use and storage of the investigational product, as applicable.
f. Ensures the integrity of the trial-related duties and functions performed and any data generated.
g. Ensures accurate and prompt safety reporting (e.g. adverse events, unanticipated problems) as required by sponsor and/or Institutional Review Board (IRB).
h. Meets with sponsors' representatives (e.g. monitors) and the research team as appropriate to discuss planned and ongoing studies.
i. Meet with auditors (internal, sponsor and regulatory agency) at the conclusion of their audits to review findings.

3. Co-Investigator/Sub-Investigator

An individual member of the clinical trial team, qualified by education, experience and appropriate licensure or certification to perform trial related procedures or to make trial-related decisions as delegated by the PI, however the PI is ultimately responsible for the overall conduct of the study.

4. Investigational Pharmacist

Duties delegated by the Principal Investigator that may include:

a. Investigational Product (IP) receipt, storage, preparation and distribution
b. Maintenance of IP accountability, inventory and study related documentation.

5. Research Nurse/Coordinator
   a. Participates in the development and/or organize sponsor provided aids and checklists to facilitate patient recruitment and enrollment as well as the collection of complete and accurate study data.
   b. Enrolls subjects in studies and manages their participation according to ethical, regulatory, and protocol-specific requirements.
   c. In conjunction with Regulatory Staff, maintains the regulatory and study files for each research project.
   d. Participates in quality assurance activities (monitoring visits, internal audits, sponsor audits, FDA audits).

6. Regulatory Staff
   a. Maintains essential documents according to federal regulations, Good Clinical Practice (GCP) guidelines and internal processes.
   b. Serves as the point of contact for Institutional Review Board (IRB) of record.

Training

Research studies will be conducted according to the approved protocol, Good Clinical Practices (GCP) and regulatory requirements to protect the safety and welfare of study subjects and ensure data integrity by providing initial and ongoing training regarding the responsible conduct of research.

Requirements include:
a. Current curriculum vitae (CV) – A current (signed and dated at least annually) CV and licensure (if applicable) will be maintained and expiry dates tracked and updated in [Site's CTMS System] for all delegates members of the study team who are involved in key study activities..
b. Maintenance of licensing and continuing education is required for all licensed professionals (RNs, LPNs, etc.) per state requirements. Continuing education is expected for all licensed professionals.

Training requirements for personnel conducting human subject research shall include:
a. Good Clinical Practices (GCP)
b. Human Subject Protection
c. Safe Handling of Hazardous Materials (if applicable)
d. Health Insurance Portability and Accountability Act (HIPAA)
e. Information technology (IT) Security
f. Protocol specific training (for clinical trials)

Additional training may also be required depending on the role and the department.

Certification through either The Society of Clinical Research Associates (SoCRA) or The Association of Clinical Research Professionals (ACRP) is encouraged.

As needed, the Site Training Record can be used to document site-specific training.

References
International Conference on Harmonisation (ICH), Good Clinical Practice (GCP)
FDA Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects

SOP No. ISCORE-RC 105.00

History of Revisions to SOP

Effective Date	Nature of Revision