[SITE NAME]

STANDARD OPERATING PROCEDURE

<table>
<tr><td colspan="2">Title:</td><td colspan="2">No.: ISCORE-RC-113.00</td></tr>
<tr><td colspan="2" rowspan="2">Data Management: Security, Confidentiality, Sharing, Transmission, and Archiving</td><td colspan="2">Page 1 of 4</td></tr>
<tr><td>Date of Issuance:
dd, month, year</td><td>Date Effective:
dd, month, year</td></tr>
<tr><td colspan="2"></td><td colspan="2">Supersedes:</td></tr>
<tr><td>Prepared by:</td><td>Reviewed by:</td><td colspan="2">Approved by:</td></tr>
</table>

Purpose:

This standard operating procedure (SOP) describes the operations followed by the [SITE LOCATION] [SITE] and affiliated health systems for the management of clinical research data.

Scope:

This SOP describes procedural pathways utilized at this site for the maintenance of clinical research data by describing the steps for the security, confidentiality, sharing, transmission, and archiving of clinical research data to ensure data integrity, compliance with the ICH E6 Good Clinical Practices (GCP), institutional policies, and regulatory guidelines. This procedure applies to electronic systems for which the site holds responsibility.

Materials:
N/A

Responsibility:

This SOP applies to the [SITE] Institutions and associated clinical departments involved in clinical research involving human subjects and is responsible to adhere to this SOP.

Definitions

Essential documents: Documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the

investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements.

Source data/documents: All information in original records or certified copies of original records, with clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data provides verification for existence of the subjects and confirms the integrity of trial data.

Case Report Form: Data reporting (electronic or paper) document used in clinical research.

Procedure

During the conduct of clinical trials, essential study-related documentation is generated, collected, and maintained. These documents serve to demonstrate the compliance of data management with the standards of GCP and with all applicable regulatory requirements. It is important for study documentation to be maintained in order to serve as a reference guide during the project and as a historical record at the conclusion of the study.

Documents, whether paper or electronic, should be recorded, handled and maintained in a manner that allows accurate reporting, interpretation and verification. Changes to source data and case report forms should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail). Trial information is then recorded in the case report form.

Direct access should be provided for source data/documents for trial-related monitoring, audits, IRB/IEC review, and regulatory inspection.

Source data should be attributable, legible, contemporaneous, original, accurate, and complete.

1. Data Security

   Note: Security methods should be in place to prevent unauthorized access to the data in any format, which may include paper or electronic computerized systems.

   a. Electronic Records
      - All electronic technology used to enter, or access trial data shall have appropriate security measures installed. Refer to [SITE] Information Technology ([SITE] IT) Security Policies.
      - Electronic data shall only be stored on secure systems or servers that meet security guidelines, have access limited to authorized personnel and are backed up.
      - Study databases shall have an audit trail for any revisions made to the electronic data after the initial data entry.

   b. Paper Records
      - Documents shall be maintained in a secure location with limited access throughout the conduct of the clinical trial.

2. Confidentiality
   a. All source documents containing protected health information (PHI) shall be kept confidential per institutional policies. This includes but not limited to:
      - Medical Records (electronic or paper)
      - Subject Diaries
      - Lab reports
      - Progress Notes

- Signed Informed Consents

3. Sharing
   Due to the sensitive and personal information regarding the research subject, data shall be shared in a manner that protects the subject's privacy and confidentiality.
   - Manage access to PHI
   - Details related to PHI sharing must be included within the IRB approved informed consent
   - Each subject has consented, to direct access to his/her medical records or trial-related records for monitoring, audits, IRB/IEC review, and regulatory inspection.
   - Prior to transferring PHI off site, data should be redacted to remove all of the subject's personal identifiers

4. Transmission
   To protect the confidentiality of the research subject, a secured process shall be used for both internal and external data transfer.

5. Archiving

   An investigator is responsible for securely maintaining all essential documents, including the research data, in accordance with the [SITE] Record Retention Policies for Human Subject Research. It is the responsibility of the sponsor to inform the investigator/institution in writing of the requirements for retention and when the documents no longer need to be retained. However, prior to destroying the records, a confirmation for destruction of records must be received from the study sponsor.

   For FDA regulated studies with a [SITE] Sponsor-investigator, note, unless specified otherwise in a written agreement:

   Drugs/Biologics: An investigator shall retain records for a period of 2 years following the date a marketing application is approved for the drug indication being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

   Device: An investigator or sponsor shall maintain the records for a period of 2 years after the latter of the following two dates:
   a. The date on which the investigation is terminated or completed, or
   b. The date that the records are no longer required for purposes of supporting a premarket approval application

   or a notice of completion of a product development protocol.

For federally funded (e.g. NIH) investigator-initiated research not under regulatory agency approval, study documents will be maintained for a minimum of 3 years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report.

References

International Conference on Harmonisation; Good Clinical Practice Consolidated Guidelines, ICH E6
21 CFR 312.60/812.00 General Responsibilities of Investigators

History of Revisions to SOP

Effective Date	Nature of Revision