UC San Diego Senior Associate Vice Chancellor for Health Sciences Office of Clinical Research	SOP Number	OCR:008 Page 1 of 4
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SOP TITLE: DATA COLLECTION AND MANAGEMENT		

1 PURPOSE

1.1 This procedure establishes processes Principal Investigators (PIs) and study personnel under their supervision must follow when collecting, using, and storing data for research purposes to ensure that data is collected, managed, and secured in compliance with federal regulations, institutional policies, and IRB requirements.

2 REVISIONS FROM PREVIOUS VERSION

2.1 N/A

3 REQUIREMENTS

3.1 The PI or designee should formulate a written data management plan that addresses study database management, approved sources of study data, data collection and entry procedures, creation of data collection tools and case report forms, data security measures, and data storage from study inception through completion, and ensure the plan is updated during the study with any changes to the data capture and management process.

3.2 Data collection best practices include adherence to ALCOA-C principles as outlined by Good Clinical Practice,[1] meaning the data are **A**ttributable, **L**egible, **C**ontemporaneously documented, **O**riginal, **A**ccurate, and **C**omplete.

3.3 Procedures for generating study data and data collection tools, including questionnaires, surveys, or other measures, must be approved by the IRB prior to implementation.

3.4 The term source data refers to the primary source of information about a data point for a clinical study and is the original information recorded in clinical findings, observations, or other activities during a study.

4 RESPONSIBILITIES

4.1 The PI is responsible for complying with relevant federal regulations[2] and guidance, as applicable, regarding management of study data and records.

4.1.1 The sponsor's role involves broader oversight and compliance with regulatory and funding requirements, while the PI or designee's function focuses on specific operational responsibilities.

4.2 The PI ensures adequate delegation of authority[3] for data management tasks to qualified individuals under their supervision, but the PI retains ultimate responsibility for the quality, integrity, and security of research data.

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[1] ICH E6 Good Clinical Practice

[2] e.g., 21 CFR 312.62, 21 CFR 812.140, 21 CFR 312.68, 21 CFR 812.145, 21 CFR Part 11, 45 CFR Part 164

[3] OCR-011 Delegation of Authority

4.3 Designees of the PI, including study coordinators, data managers, or other research team members who have authority for data collection and management are responsible for following these procedures.

4.4 The PI is responsible for ensuring that the use of copyright protected forms or questionnaires are approved by the authors, and that relevant fees are paid when required.

5 PROCEDURE

5.1 Develop the data collection and management plan to meet requirements for data integrity, quality, confidentiality, and security.

5.1.1 21 CFR Part 11 applies to all FDA regulated studies. Confirm compliance of any electronic systems and databases with this regulation, if applicable.

5.1.1.1 Electronic systems may include study databases, regulatory databases, and systems for managing electronic signatures.

5.1.2 Prospectively identify the sources of data to be collected, captured, and stored.

5.1.2.1 Source data may include participant responses, clinical recordings such as ECG tracings, medical records, provider notes, surveys, questionnaires, or behavioral or physiological tests.

5.1.2.2 Study eligibility requirements must include a corresponding source document.

5.1.2.3 Data imported into the study database from other systems must be compatible and valid after import.

5.1.2.4 Use of identifiable data, data coding, and de-identification procedures must conform to the IRB-approved study application and protocol.

5.1.3 Develop data collection forms, as necessary, to ensure consistency with the study protocol and compliance with regulatory requirements.

5.1.3.1 Consult the study protocol; study operations manual; and laboratory, imaging, and pharmacy manuals, as applicable; to ensure that all relevant data are captured on the data collection forms.

5.1.4 Determine delegation of authority[4] for data access, collection, entry and security.

5.1.4.1 Implement physical security measures to restrict access to data storage locations, ensure password protection is in place on electronic devices, and use two-factor authentication, if indicated.

5.1.4.1.1 Individuals who have access to protected health information (PHI) must be approved by IRB and undergo appropriate

[4] OCR-011 Delegation of Authority

training on Health Insurance Portability and Accountability Act (HIPAA)[5] requirements.

5.1.4.2 Individuals who will perform data entry must be trained and provisioned on the appropriate data management software.

5.1.4.3 Data transmissions should be encrypted using current encrypted communication channels.

5.1.4.4 Electronic data should be backed up securely, with periodic verification of back data.

5.1.5 Develop a schedule for study data quality control review activities to ensure all data collected conforms to ALCOA-C principles.

5.1.5.1 Conduct periodic compliance reviews to verify data accuracy, completeness, and consistency.

5.1.5.2 Report findings and implement corrective actions as necessary.

5.1.6 Develop biospecimen tracking and management plan, including processes for labeling, storing and tracking biospecimens, with procedures to be followed when participants withdraw their permission for biospecimen use, if applicable.

5.1.7 Develop a quality control review plan for study data to include data validation and verification of a representative sample of the data at specified intervals.

5.1.8 Develop a plan for data retention in compliance with UC San Diego retention policies, applicable regulatory requirements, and sponsor contractual specifications.

5.1.8.1 Archived data must be secure yet retrievable for audit purposes.

5.1.9 Develop a plan for data destruction, when data is no longer needed.

5.1.9.1 Confirm data destruction with study sponsor prior to implementation.

5.1.9.2 Use approved data destruction methods when data are destroyed.

6 MATERIALS

6.1 N/A

7 REFERENCES

7.1 ICH E6 Good Clinical Practice

7.2 21 CFR 312.62

7.3 21 CFR 812.140

7.4 21 CFR 312.68

7.5 21 CFR 812.145

7.6 21 CFR Part 11

7.7 45 CFR Part 164

[5] 45 CFR Part 164