

<b>Altman Clinical and Translational Research Institute Center for Clinical Research</b>	<b>SOP Number</b>	<b>CCR:004</b>  Page 1 of 3
	<b>Date:</b>	<b>10/06/2025</b>
	<b>Author:</b>	<b>T. Graham</b>
	<b>Approved by:</b>	<b>B. Cale, RN</b>
<b>SOP TITLE: CENTER FOR CLINICAL RESEARCH RECORDS</b>		

## 1 PURPOSE

- 1.1 This procedure establishes the process to manage Altman Clinical and Translational Research Institute (ACTRI) Center for Clinical Research (CCR) records.
- 1.2 The process begins when records are received or created.
- 1.3 The process ends when records have been filed.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3 REQUIREMENTS

- 3.1 The study principal investigator (PI) remains responsible for the overall conduct of the research and for delegating authority for study tasks to individuals who have appropriate skill and training to complete them.
- 3.2 The scope of the PI's delegation to the CCR and the clinical research coordinator (CRC) team must be addressed in the delegation log.
- 3.3 Records covered by this procedure include:
  - 3.3.1 CCR administrative records
    - 3.3.1.1 Training records
      - 3.3.1.1.1 Training records for CCR personnel, including good clinical practice (GCP) training records
      - 3.3.1.1.2 Certification records for CCR personnel
    - 3.3.1.2 CCR study submission documentation
  - 3.3.2 Study regulatory records and essential documents as required by applicable regulations.<sup>1</sup>
  - 3.3.3 Study participant records as required by applicable regulations,<sup>1</sup> to include:
    - 3.3.3.1 Appointment records
    - 3.3.3.2 Study source documents,<sup>2</sup> including:
      - 3.3.3.2.1 Nursing notes, including details of adverse events
      - 3.3.3.2.2 Checklists

<sup>1</sup> [21 CFR 312.62](#) Investigator recordkeeping and record retention; [21 CFR Part 812 Subpart G](#) Records and Reports; [45 CFR Part 46](#) Protection of Human Subjects; [Integrated Addendum to ICH E6 \(R1\): Guideline for Good Clinical Practice E6\(R2\)](#)

<sup>2</sup> Source documentation is the first documentation of the primary data point(s) for a study participant and is important in a clinical trial to reconstruct the trial as it happened (<https://pmc.ncbi.nlm.nih.gov/articles/PMC3121265/>). Source documentation may be defined as any information in original records and also certified copies of original records of clinical findings, observations, or other activities in a clinical investigation that may be used for the reconstruction and evaluation of the study. This typically refers to the first place that a data point is recorded (<https://www.med.upenn.edu/clinicalresearch/source-documentation.html>)

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- 3.3.3.2.3 Physician orders
- 3.3.3.2.4 Participant logs
- 3.3.3.2.5 Coordinator notes
- 3.3.3.2.6 Study-specific questionnaires, diaries, scales, or other instruments
- 3.3.3.2.7 Laboratory, x-rays, ECG and other clinical reports
- 3.3.3.2.8 IRB correspondence
- 3.3.3.2.9 Correspondence and communications between study team and study participant
- 3.3.3.2.10 Copy of informed consent, HIPAA, and California Bill of Rights

3.4 Study documentation must follow the principles of ALCOA-C as defined by Good Clinical Practice (GCP) section 4.9.0.<sup>3, 4</sup> All study record entries must be:

- 3.4.1 Attributable
- 3.4.2 Legible
- 3.4.3 Contemporaneous
- 3.4.4 Original
- 3.4.5 Accurate
- 3.4.6 Complete

#### 4 RESPONSIBILITIES

- 4.1 CCR and clinical research coordinator (CRC) personnel are responsible for carrying out these procedures.
- 4.2 The study PI is responsible for ensuring that relevant study records are generated and maintained in accordance with applicable regulations.<sup>1</sup>
- 4.3 The study PI ensures adequate delegation of authority for study record management tasks to qualified individuals under their supervision, but the PI retains ultimate responsibility for the integrity and security of the research records.
- 4.4 The study PI is responsible for ensuring that study records are retained in compliance with UC San Diego retention policies, applicable regulatory requirements, and sponsor contractual specifications.
  - 4.4.1 Archived study records and data must be secure yet retrievable for audit purposes.
  - 4.4.2 The study PI is responsible for developing a plan for study record destruction, when records and data are no longer needed.
    - 4.4.2.1 The PI or designee will confirm approval for data and record destruction with study sponsor prior to implementation.

<sup>3</sup> [E6\(R2\) Good Clinical Practice Section 1.52 Source Document](#)

<sup>4</sup> [UC San Diego Research Compliance and Integrity: ALCOA](#)

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4.4.2.2 The PI or designee will ensure that approved destruction methods are employed when data and records are destroyed.

## 5 PROCEDURE

- 5.1 For each clinical study conducted within the ACTRI, a study master file will be maintained. The CRC supervisor will ensure that the master file includes:
- 5.1.1 Copies of communications between the PI and the CRC team
  - 5.1.2 Documents provided by the PI to the CRC team, including relevant regulatory documents
- 5.2 For each participant encounter, the PI or designee will generate and maintain the appropriate source documents.
- 5.2.1 CCR source documents will include, but are not limited to:
    - 5.2.1.1 Nurses notes and flowsheets
    - 5.2.1.2 Physician orders
    - 5.2.1.3 Appointment records
    - 5.2.1.4 Other notes and documentation, as required by protocol
  - 5.2.2 CRC team source documents will include, but not be limited to, all applicable study source documents as described in 3.3.3 above.
- 5.3 Records will be retained as follows:
- 5.3.1 Copies of relevant CCR documentation will be provided to the CRC at the conclusion of the study visit. CCR original source records will be filed in the study participant's paper CCR chart and maintained in the CCR file room until archival.
  - 5.3.2 CRC original source records and copies of the CCR documentation will be retained for the duration of the participant's study activity.
- 5.4 Record Archival
- 5.4.1 CCR records will be archived as needed to accommodate storage requirements.
    - 5.4.1.1 The CCR assistant clinical director will ensure that a complete record of archived documents that permits timely record retrieval is available.
  - 5.4.2 CRC records will be returned to the PI for storage and archival at the end of the study.

## 6 MATERIALS

- 6.1 CCR-101: Sample Delegation Log

## 7 REFERENCES

- 7.1 CCR-001 Definitions
- 7.2 [21 CFR 312.62](#) Investigator recordkeeping and record retention
- 7.3 [21 CFR Part 812 Subpart G](#) Records and Reports
- 7.4 [45 CFR Part 46](#) Protection of Human Subjects
- 7.5 [Integrated Addendum to ICH E6 \(R1\): Guideline for Good Clinical Practice E6\(R2\)](#)
- 7.6 [UC San Diego Research Compliance and Integrity: ALCOA](#)