# Clinical Research Record Management

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

| SOP No.: CR-CO-510.3 | Status: Final | Version Date: 07/22/2025<br>Effective Date: 08/04/2025 |
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## 1. PURPOSE

This Standard Operating Procedure describes standards by which VCU/VCU Health research personnel will maintain participant-specific information created or collected during the conduct of a clinical research project at VCU/VCU Health facility, affiliate, or participating site.

## 2. REQUIREMENTS

Research personnel employed by VCU/VCU Health and affiliated entities shall abide by VCU/VCU Health policies regarding medical records and maintenance, and security of Protected Health Information (PHI). A research record will be maintained for all participants in research projects and be housed in a secure area as designated by the Principal Investigator (PI) or their designee. These procedures ensure the confidentiality of research participants and contribute to the scientific integrity of data created and collected during the conduct of the research project as well as allow for any requested compliance reviews and/or audits.

## 3. DEFINITIONS

Research Record- A research record is any data, document, computer file, compact disc, external computer storage (i.e., compact disc, USB drive, etc.), or any other electronic (i.e.; digital capture, recordings, eDiaries, etc.) or hard copy information regarding proposed, conducted, or reported research. Documentation that comprises a research record includes but is not limited to: laboratory notes, correspondence, videos, photographs, X-ray film, slides, biological materials, computer files and printouts, manuscripts and publications, equipment use logs, laboratory procurement records, human subject protocols, consent forms, medical charts, and participant research files.

Identifiable Information- Information that may identify an individual, or of relatives, employers, or household members of the individual. Identifiers may include, but, are not limited to: Names; all geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes; all elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89; telephone numbers; fax numbers; electronic mail

addresses; Social Security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web URLs; IP addresses; biometric identifiers, including finger and voice prints; full-face photographic images and any comparable images; and any other unique identifying number, characteristic, or code.

De-identified Data:
Data, including health information, from which all personally identifiable information has been removed to protect individual identities and privacy.

**4. PROCESS**

The maintenance of research-related information in the research record should adhere to the following procedures:

A. Research Records are required to be housed in a secure location and is the responsibility of the PI to designate the secured area and designate research personnel to whom access has been granted (reference VCU/ VCU Health SOP CR-CO-525: Delegation of Authority).

B. A research record shall be maintained for every individual who is screened and/or consented, whether enrolled or found ineligible, in accordance with applicable sponsor guidelines, federal, state, and local regulations, and institutional guidance.

C. The research record contents may be maintained in paper (hardcopy) and/or electronic formats, including digital images, and may include PHI and/or patient identifiable source information such as photographs, films, digital images, and fetal monitor strips and/or a written or dictated summary or interpretation of findings. Research records that fall under FDA regulations are required to be maintained following 21 CFR 11.

D. The research record may include, but is not limited to, source documentation, including medical records, physician progress notes, nursing notes, and other information required to document subject treatment, response, and other study-specific outcomes. The record must include a signed and dated consent form(s) and HIPAA Authorization (Health Insurance Portability and Accountability Act of 1996), except when these requirements are waived by the IRB of record. HIPAA is a United States legislation that provides data privacy and security provisions for safeguarding medical information.

E. During the course of a clinical research study, use of a participant's medical record, source documents, and the information contained therein are restricted only as consented to or authorized by the participant.

F. In the event that a research project involves the gathering, documentation, analysis, or review of genetic information, the informed consent and data should remain exclusively in the research record. This includes any research-informed consent document and/or test results that may be associated with a research project that includes, as a provision of the protocol, the gathering, documentation, analysis, or review of genetic information.

G. Case report forms and supporting documentation containing the participant's protected health information that are sent to sponsors by mail, fax, or electronic communication must be de-identified prior to sending.

H. Research records will be available to non-research VCU/VCU Health personnel and non-VCU/VCU Health entities upon request in accordance with VCU/VCU Health Compliance Policies.

I. Results of tests conducted for research purposes only, which are analyzed at reference laboratories external to VCU/VCU Health, will be maintained only in the participant-specific research record.

**5. REFERENCES**

A. US Code of Federal Regulations
- 21 CRF 11: Electronic Records; Electronic Signatures
- 45 CFR 46: Basic HHS Policy for Protection of Human Research Subjects

B. VCU HRPP Policies and Guidance; HRPP Toolkit
  - HRP-103-Investigator Manual

C. VCU Health Policies related to clinical research
- Documentation- Entries in the Medical Record
- Protected Health Information, Administrative, Technical, and Physical Safeguards
- Protected Health Information Release
- Protected Health Information, Uses & Disclosures for Research

D. VCU/VCU Health Standard Operating Procedure (SOP)
- CR-CO-525: Delegation of Authority

| Review/Revision History CR-CO-510 | | |
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| **Version No.** | **Effective Date** | **Description** |
| CR-CO-510.3 | 08/04/2025 | ● Updated identifiable information examples<br>● Aligned with HRPP toolkit<br>● Aligned with ICG E6(R3)<br>● Biennial review performed<br>● Minor formatting edits<br>● Reference links updated |
| CR-CO-510.2 | 06-01-2021 | ● Biennial review performed<br>● Minor formatting edits<br>● Reference links updated |
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