

Protected Health Information, Uses & Disclosures for Research

VCU Health System Authority and Affiliates Policy

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Privacy Officer

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This policy applies to Virginia Commonwealth University Health System Authority and all of its wholly owned or controlled affiliates (collectively referred to herein as VCUHS or VCU Health System).

This policy applies to the facilities marked below:

- | | | |
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| <input checked="" type="checkbox"/> VCU Medical Center | <input checked="" type="checkbox"/> Community Memorial Hospital | <input type="checkbox"/> VCU Health Children's Services at Brook Road |
| <input checked="" type="checkbox"/> VCU Health Ambulatory Surgery Center L.L.C | <input checked="" type="checkbox"/> Community Memorial Hospital (Hundley Center) | <input checked="" type="checkbox"/> VCU Health Tappahannock Hospital |
| <input checked="" type="checkbox"/> MCV Associated Physicians d/b/a MCV Physicians | <input checked="" type="checkbox"/> CMH Physician Services, LLC | |

General Description

Purpose:

To provide guidance for VCU Health System (VCUHS) Team Members for the use and disclosure of Protected Health Information (PHI) for research purposes.

Policy

- A. VCUHS may, for research purposes, use and disclose health information that has been de-identified according to methods established in Health Insurance Portability and Accountability Act (HIPAA) regulations
- B. VCUHS may use and disclose identifiable PHI for research purposes with individual authorization, or without individual authorization under limited circumstances meeting the procedures below.
- C. In order for VCUHS to meet HIPAA regulations for our patients regarding accounting of disclosures, data retention, and data destruction requirements for PHI data obtained without patient authorization, members of the study team (including principal investigators) are directed to consult with VCU Informatics or other approved method by the VCUHS Privacy Office to obtain data. This does not include obtaining data for which the study team has patient authorization.

Procedures

1. For data requests, including preparatory to research, contact informatics@vcu.edu to request the desired PHI or for a consultation on alternate methods to obtain the data. VCU Informatics will maintain and provide requested Accounting of Disclosures for research purposes to VCUHS as patient requested. See <https://informatics.vcu.edu> for more information.
2. Research disclosures with individual authorization
 - 2.1. VCUHS may use or disclose PHI for research if the subject of the PHI has granted specific written permission through an authorization.
 - 2.1.1. For specific requirements of a research authorization, consult VCU Policy, WPP XII-3, Health Insurance Portability and Accountability Act (HIPAA) Information and the Conduct of Research.
3. Research disclosures without individual authorization
 - 3.1. VCUHS may use or disclose PHI for research purposes without authorization of the research participant provided one of the following situations applies:
 - 3.1.1. Documented Institutional Review Board (IRB) or Privacy Board approval of an alteration or waiver of authorization
 - 3.1.2. Information sought is preparatory to research;
 - 3.1.3. Research is on PHI of decedents; or
 - 3.1.4. Information is provided by Limited Data Set with a signed Data Use Agreement.
4. A Waiver of Authorization under Section 3.1.1 above must include:
 - 4.1. Identification of the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;
 - 4.2. A statement that the authorization satisfies the following three (3) criteria:
 - 4.2.1. The use or disclosure involves no more than a minimal risk to the privacy of the individual(s), based on, at least the presence of the following:
 - 4.2.1.1. An adequate plan to protect the identifiers from improper use or disclosure;
 - 4.2.1.2. A plan to destroy the identifiers at the earliest opportunity with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

- 4.2.1.3. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this section.
 - 4.2.2. The research could not be conducted without access to and use of the PHI; and
 - 4.2.3. The research could not practicably be conducted without the waiver or alteration.
- 4.3. A brief description of the PHI for which use and access has been determined to be necessary by the IRB or Privacy Board;
- 4.4. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, and
- 4.5. The signature of the chair or other member designated by the chair of the IRB or Privacy Board, as applicable.
5. If request is preparatory to research, the following assurance must be obtained from the researcher by completing the Redcap form, [VCU Review Preparatory to Research Form](#):
 - 5.1. Use and disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
 - 5.2. No PHI will be removed from VCUHS; and
 - 5.3. The PHI is necessary for the research purpose.
6. Decedent's information may be disclosed if the researcher provides the following:
 - 6.1. Assurance that use and disclosure is sought solely for research on the PHI of decedents;
 - 6.2. Documentation of the death of such individuals; and
 - 6.3. Assurance that the PHI is necessary for research purposes.
7. A Data Use Agreement must be reviewed by Compliance Services to ensure the agreement:
 - 7.1. Establishes the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research;
 - 7.2. Does not include any use or disclosure that would violate the HIPAA Privacy Rule, if done by VCU Health System;

7.3. Limits who can use or receive the data; and

7.4. Requires the recipient to agree to the following:

- 7.4.1. Not use or disclose the information other than as permitted by the agreement or otherwise required by law;
- 7.4.2. Use appropriate safeguards to prevent the use or disclosure of the information not provided for by the agreement;
- 7.4.3. Report any use or disclosure of the information not provided for by the agreement of which the recipient becomes aware to VCU Health System;
- 7.4.4. Ensure that any agents, including subcontractors, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and
- 7.4.5. Not to identify the information or contact the individual.

Definitions

Term:	Definition:
Accounting of Disclosures	Information that describes a covered entity's disclosures of PHI other than for treatment, payment, and health care operations; disclosures made with Authorization; and certain other limited disclosures. For those categories of disclosures that need to be in the accounting, the accounting must include disclosures that have occurred during the 6 years (or a shorter time period at the request of the individual) prior to the date of the request for an accounting.
Institutional Review Board (IRB)	Any specifically constituted body that has been formally designated to review and monitor research involving humans as subjects. IRBs have the authority to approve, require modification to, or disapprove all research activities covered by the HHS and FDA Protection of Human Subjects Regulations.
Limited Data Set	Protected health information that excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual.

Privacy Board	A review body established to act upon requests for a waiver of an alteration of the authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study. Membership must satisfy the criterion at 164.512(i)(1)(i)(B)
Privacy Rule	HIPAA Administrative Simplification Regulations located at 45 CFR Part 160 and Subparts A and E of Part 164. Establishes national standards to protect individuals' medical record and other personal health information; requires appropriate safeguards to protect the privacy of personal health information and sets limits and conditions on the uses and disclosures that may be made of such information; gives patients rights over their health information.
Team Member	Any person, whether compensated or not, who performs some function for, on behalf of, and under the supervision of the VCU Health System, and who has access to health system premises, information and/or electronic information systems including, but not limited to: salaried or hourly team members, medical staff, credentialed providers, faculty, researchers, VCU employees, students, volunteers, contractors, consultants and agency or temporary employees.