



Policy/Procedure Title	Health Information Portability and Accountability Act
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**DEFINITIONS**

*Protected health information* is defined as the medical records maintained by a covered entity through which the identity of an individual may be determined. It consists of the following 18 elements: names, addresses, employers' name or addresses, relatives names or addresses, dates (other than year), telephone or fax numbers, electronic addresses (email), social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate numbers (including device serial numbers for implants or other test articles), vehicle identifiers and serial numbers, including license plate numbers, web universal resource indicators (URLs), internet protocol (IP) address numbers, voiceprints, fingerprints, member or account numbers or any other unique identifying number, characteristic or code.

*Covered entity* is defined as a health care provider, including those involved in incidental and billing services, that receives payment from insurance, Medicare or Medicaid. These activities are categorized as treatment, payment and the health care operations.

**PURPOSE**

The Privacy Rule of the Health Information Portability and Accountability Act of 1996 (HIPAA) became effective on April 14, 2003. For purposes of HIPAA, Charleston Area Medical Center (CAMC) and the Robert C. Byrd Health Sciences Center of West Virginia University – Charleston Division (WVU-Charleston Division) are “Covered Entities.” The Privacy Rule outlines the conditions under which a covered entity may use or disclose protected health information (PHI).

Where research is concerned, the Privacy Rule protects the privacy of health records containing individually identifiable health information, while at the same time providing researchers access to medical information necessary to conduct research.

**SCOPE**

This policy covers Protected Health Information (PHI) that is contained in existing records or which may be created through or during research activity. This policy applies to all CAMC Health Education and Research Institute (CAMC Institute), CAMC, WVU researchers and staff that conduct research, assist in the performance of research or likewise use or disclose PHI. The CAMC/WVU-Charleston IRB will review a proposed research activity performed at CAMC, WVU-Charleston Division and/or the CAMC Health Education and Research Institute and the accompanying HIPAA forms.

**POLICY**

**I. Research Use or Disclosure of PHI**

A. **Authorization by the Patient (prospective subject)**

When feasible, a researcher **must obtain an Authorization from all research subjects** prior to the intended use or external disclosure of PHI for any research-related purposes. When the researcher and the subject are face-to-face, authorization is considered feasible. The researcher must complete an authorization form at the same time he/she

completes a research consent form and submit it to the IRB for prior review and approval. The authorization form must be paginated with the consent form.

**a. Elements of Authorization:**

An authorization for Research must contain all of the following elements:

- 1) A description of the information to be used or disclosed.
- 2) The name or identification of the persons or class of persons authorized to make disclosures of PHI and to use the PHI for research-related purposes.
- 3) The name or identification of the persons or class of persons authorized to receive disclosures of PHI and to use the PHI for research-related purposes.
- 4) A description of each purpose for the use or disclosure.
- 5) An expiration date or the statement “end of research study” or “none” when appropriate (i.e. for research database).
- 6) The individual’s signature (or that of his/her authorized representative as determined by West Virginia law) and the date.
- 7) A statement that the individual may revoke the authorization, if done in writing to principal investigator.
- 8) A statement that the information may be disclosed to others not subject to the privacy rule (Sponsors, Federal or State agencies).
- 9) A statement that the individual’s clinical treatment may not be conditioned upon whether or not the individual signs the Authorization form. However, participation in research may be conditioned on a signed authorization as well as a signed consent form.
- 10) The individual must be provided with a copy of the signed Authorization form.

**b. Procedure for Signing an Authorization Form**

- 1) Adults: A competent individual, 18 years of age or older, should always sign the Authorization to use or disclose his/her PHI. A person is competent if he/she has the general ability to understand the concept of release of his/her medical information.
- 2) In the individual is competent, but unable to sign the Authorization form, the person witnessing the consent and authorization interview may write in “Patient unable to sign due to \_\_\_\_\_ (insert reasons). Patient gave verbal permission.” The Authorization form must be signed. [by whom?]
- 3) If the patient (subject) is not conscious, coherent, or not competent for whatever reason, a legally recognized representative must sign the Authorization form.
- 4) Minors: Any parent or legally authorized adult may sign for a minor child in his/her legal custody.

**B. Waiver of Authorization by the CAMC/WVU-Charleston IRB**

In certain circumstances, Research Authorizations otherwise required under this Policy may be waived, in whole or in part, by the CAMC/WVU-Charleston IRB, provide the following criteria are satisfied and documented:

- 1) The use or disclosure of PHI involves no more than a *minimal risk to the privacy* of individuals based on the presence of at least the following elements:
  - An adequate plan to protect the identifiers from improper use and disclosure;
  - An adequate plan to destroy the identifiers at the earliest opportunity consistent with the 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
  - 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 Policy.

- 2) A request for Waiver of Authorization must be completed by the researcher and submitted to the IRB (on a HIPAA waiver application) for prior review and approval.
- 3) The IRB shall maintain the following documentation about the waiver:
  - A statement identifying the IRB and the date on which the waiver request was approved.
  - A statement that the IRB determined that the waiver satisfied the criteria for waiver.
  - A statement that the waiver has been reviewed and approved under either quorum or expedited review procedure; and
  - The IRB Chairperson or his/her designee has signed the document.
- 4) Uses or disclosures of PHI using a waiver are subject to accounting of disclosures procedures (see section IV below).

#### C. Use and Disclosure of PHI for the Purpose of Contacting and/or Recruiting Potential Research Subjects

- 1) Physicians, and other health care providers, may contact their own patients for purposes of informing them about a research study without an Authorization form.
- 2) Individuals responding to an advertisement regarding participation in a research study may be given an explanation of the study (including, but not limited to, the name of the principal investigator and description of the study) prior to signing an Authorization.
- 3) An Authorization must be obtained from an individual who has indicated interest in participating in a research study prior to asking the individual any screening questions that involve PHI. The IRB may determine that some of the elements of authorization may be waived (a partial waiver) until the time of the informed consent interview, The IRB may also waive the requirement to have a signed authorization.
- 4) All other uses and disclosures of PHI for the purpose of contacting and/or recruiting potential research participants may require an Authorization or Waiver.

#### D. Use Preparatory to Research

- 1) Researchers may use or disclose PHI without an Authorization or IRB waiver for the development of a research protocol, provided that the researcher documents that all the following criteria are satisfied:
  - The use of PHI is solely to prepare a research protocol, or to identify prospective research participants for the purposes of seeking an Authorization;
  - The PHI shall not be removed from CAMC, WVU-Charleston Division and/or CAMC Institute and
  - The PHI sought is necessary for the purposes of the research.
  - The PHI may be removed from the covered entity if it is first De-identified (all 18 identifiers removed).
- 2) The researcher will complete a Preparatory to Research Application prior to commencing the data review. *This* application will be reviewed and approved by the CAMC Institute's Research and Grants Administration Office. Documentation of approval will be given to the researcher in writing.
- 3) The researcher will provide approval documentation to the medical records or the data collection custodian before accessing individual medical records.
- 4) Use or disclosure of PHI for preparatory to research purposes is subject to accounting disclosure procedures (See section IV below).

#### E. Use and Disclosure of Decedent's PHI

- 1) Researchers may use or disclose a decedent's PHI for research without an Authorization or IRB waiver, provided that the researcher documents that all of the following criteria are satisfied:
  - The use will be solely for research on the PHI of decedent(s) and

- The researcher has documentation of the death of the individual(s) about whom information is being sought, and
  - The PHI sought is necessary for the purposes of the research.
- 2) The researcher will document that these criteria have been met by submitting a letter to the Research and Grants Administration Office. Documentation of approval will be given to the researcher in writing.
  - 3) The researcher will then provide IRB approval documentation to medical records or the data collection custodian that all of the above criteria are satisfied.
  - 4) Use or Disclosure of decedent's PHI for research purposes is subject to accounting disclosure procedures (See section IV below).

#### F. Use or Disclosure of "De-identified" Health Information

- 1) De-identified health information is exempt from HIPAA and may be used or disclosed for research purposes without an Authorization or IRB waiver.
- 2) Researchers must provide documentation through a "de-identified application" to the IRB certifying that the health information has been de-identified by one of two methods:

**Method 1:** The IRB determines that the health information is de-identified for research purposes, in writing, by an **independent**, qualified statistician either by determining that the risk of re-identification of the data, alone or in combination with other data, is very small; and further documents the methods and results by which the health information is de-identified, and the expert makes his/her determination of risk. Note: the expert may not be the researcher or anyone directly involved in the research study including the data collection and/or analysis.

**Method 2: Removal of all PHI identifiers.** All 18 elements of individual PHI concerning the individual, the individual's employer, relatives and household members are removed.

- 3) **Re-identification Code.** The de-identified information may be assigned a code that can be affixed to the research record that will permit the information to be re-identified if necessary, **provided that**, the code is randomly selected and neither the key to the code nor the method for re-identification are disclosed **to the researcher**.

#### G. Limited Data Set

- 1) A researcher may use or disclose a Limited Data Set for any research purpose without an Authorization or Waiver of Authorization.
- 2) A "limited data set" is defined as PHI that **may include** any of the following direct identifiers:
  - Town, city, State and zip code.
  - All elements of dates directly related to an individual, including birth date, admission date, discharge data and date of death.
- 3) A limited data set must **exclude all** other direct identifiers of the individual or of the individual's relatives, employers, or household members of the individual including names; postal address information other than town or city, State and zip code; telephone numbers; health plan beneficiary identifiers; account numbers; certificate/license numbers; vehicle identifiers; device identifiers and serial numbers; URLs; internet protocol; email addresses; biometric identifiers; including finger and voice prints; full face photographic images; and any other number, characteristic or code that could be used to identify the individual.
- 4) A limited data set may be used or disclosed only if there is a **Data Use Agreement** between CAMC and the recipient of the limited data set. Data Use Agreement applications must be submitted to and approved by the CAMC Institute's Research and Grants Administration. A copy of the Data Use Agreement will be sent to the CAMC Privacy Office.
- 5) Limited data sets are not subject to Accounting of Disclosure as outlined in Section I of this policy.

## II. Individual's Access to Research Information

- 1) As a general rule, individuals who participate in research have a *right* to access their own PHI.
- 2) However, individuals participating in research protocols that include treatment (i.e. clinical trials) may be denied access to their PHI obtained in connection with a research protocol, **provided that**:
  - The PHI was obtained in the course of the research;
  - The individual agreed to the denial of access in the Research Authorization;
  - The research remains in process, and
  - The individual's rights to access to PHI are re-instated once the research study has ended and the Research Authorization has expired.

## III. Individual's Revocation of Research Authorization

- 1) As a general rule, an individual may revoke his/her Authorization, in writing to the Principal Investigator, at any time.
- 2) The revocation will be applicable to the protocol or protocols specified by the individual. However, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected about the individual pursuant to a valid Authorization **before** it was revoked.
- 3) The Principal Investigator shall forward a copy of the written revocation to the CAMC Privacy Officer. The Principal Investigator shall also keep copies of all revocations of Authorizations for a specific protocol and report them to the IRB at the time of continuing review.

## IV. Accounting of Disclosures

- 1) As a general rule, upon request, an individual must be provided with an accounting of all disclosures of his/her PHI for research purposes made in the **past 6 years**, unless such disclosure was made pursuant to an Authorization, or is part of a Limited Data Set.
- 2) The researcher or data custodian must keep records of all disclosures of PHI in the following circumstances:
  - Disclosures pursuant to IRB waiver;
  - Disclosures of PHI used in preparation of a research protocol
- 3) A simplified accounting procedure may be used if the research use or disclosure involves the PHI of more than 50 people. Under the simplified accounting procedure:
  - The individual must be provided a list of research protocols in which the individual's PHI **may have been used**.
  - The list must provide the following: the name of the protocol or research activity; a description of the purpose of the study and the type of PHI disclosed and the timeframe during which such disclosures occurred.
  - Upon request, the CAMC Privacy Officer, or his/her designee, will assist the individual in contacting those researchers to whom it is likely that the individual's PHI was actually disclosed.

## V. Notice of Privacy Practices

A notice of Privacy Practices should be provided to a research participant when an Authorization is signed.

## VI. Transition Provisions

Researchers may continue to use and disclose PHI created or received before and after April 14, 2003, if the researcher has obtained any one of the following prior to such date:

- An authorization or other express legal permission from an individual to use or disclose the PHI for research;
- The individuals' informed consent to participate in the research; or
- An IRB waiver of informed consent for the research.