Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 118	
CHAPTER: Institutional Review Board	ISSUED: 9/2004	LATEST REVIEW/REVISION: 11/2018
POLICY: HIPAA for Researchers	PAGE 1 OF 5	

1. PURPOSE

This policy defines the standards and parameters for the use of Protected Health Information (PHI) in biomedical, behavioral, and social science research. The components of this institution that qualify as a HIPAA-covered entity will adhere to those regulations set forth in the HIPAA Privacy and Security Rules (45 CFR 160 and 164).

2. GENERAL

2.1. Federal privacy rules enacted under the Health Insurance Portability and Accountability Act (HIPAA) [Public Law 104-191, Sec. 264; 42 CFR Parts 160 and 164] restrict researchers' access to, use of, and disclosure of health information. Effective April 14, 2003, a Principal Investigator shall obtain a valid written HIPAA research authorization, approved by either the IRB or Privacy Officer, from a research subject or his/her legal representative (§14.2) in order to obtain, use, or disclose the subject's individually identifiable PHI, unless:

2.1.1. Written informed consent to participate in the research project was obtained from the research subject (or his/her authorized representative) prior to April 14, 2003

2.1.2. An exception to the written HIPAA authorization applies

2.1.3. The requirement for a written HIPAA authorization has been waived by Creighton's IRB

2.2. Health information that is de-identified, as defined under 42 CFR §164.514(a), is not PHI and therefore is not subject to the HIPAA requirements stated above (see IRB Document, "De-identified Health Information Under HIPAA," for elements of de-identified health information).

3. WRITTEN HIPAA RESEARCH AUTHORIZATION

3.1. Elements of a Valid HIPAA Research Authorization

A HIPAA research authorization shall be in writing and shall contain specific elements to be valid. The required elements are detailed in IRB Document, "Elements of a Valid HIPAA Authorization". The HIPAA research authorization may contain additional statements as long as they do not conflict with the required elements. The HIPAA research authorization may be combined with the

research informed consent document. However, the HIPAA research authorization shall not be combined with another HIPAA authorization if research-related treatment is conditioned on obtaining the HIPAA research authorization.

3.2. Approved HIPAA Research Authorization

3.2.1. In those instances, in which a written HIPAA research authorization is required, the researcher shall use the Creighton IRB-approved HIPAA Authorization of Use and Release of Health Information for Research Purposes; found within the IRB electronic system. Any deviations from the standard language shall be reviewed and approved by the University Privacy Officer prior to review by the IRB. The University Privacy Officer shall not approve a HIPAA research authorization that fails to contain one or more of the required elements. A copy of the University Privacy Officer's written approval shall be provided to the IRB before any IRB review will begin on the study.

3.3. Obtaining the HIPAA Research Authorization

3.3.1. When it is required, the Principal Investigator shall obtain a signed HIPAA research authorization from each research subject (or their authorized representative) before obtaining, using, or disclosing the research subject's PHI. The Principal Investigator shall provide the research subject (or his/her authorized representative) with a copy of each signed HIPAA research authorization. PHI shall be obtained, used, or disclosed only according to the provisions of the most recently signed HIPAA research authorization.

3.4. HIPAA Research Authorization – Substantive Changes

3.4.1. When a researcher has obtained written HIPAA authorization from a research subject, that authorization is effective for the entire study or as otherwise stated in the HIPAA authorization form, unless substantive changes occur in the study affecting the use, access, or disclosure of the PHI. Substantive changes would include, but not be limited to, adding entities to which the PHI will be disclosed or changes in the type of PHI to be used, accessed, or disclosed. Changes to only the study informed consent do not require re-execution of the HIPAA research authorization.

4. EXCEPTIONS TO WRITTEN HIPAA AUTHORIZATION

4.1. Researcher Reviews Preparatory to Research

4.1.1. A Principal Investigator is not required to obtain a written HIPAA research authorization when use or disclosure of PHI is sought solely to review the PHI to prepare a research protocol or other similar purposes preparatory to research (42 CFR §164.512(i)(1)(i)). Examples would include review of PHI to design a research study or to assess the feasibility of conducting a study. For reviews preparatory to research, the Principal Investigator shall follow any applicable policies of the entity from which the PHI is requested. The Principal Investigator shall not use any PHI to identify or recruit potential research subjects.

4.2. Decedent's Information

4.2.1. A Principal Investigator is not required to obtain a written HIPAA research authorization for requests to use or disclose a decedent's PHI for research purposes (42 CFR §164.512(i)(1)(iii)). The Principal Investigator must follow any applicable policies of the entity from which the decedent's PHI is requested.

4.3. Limited Data Sets with a Data Use Agreement

4.3.1. A Principal Investigator is not required to obtain a written HIPAA research authorization for research on PHI contained in a limited data set and subject to a written data use agreement (42 CFR §164.514(e)). Contact the University Privacy Officer for further information regarding Limited Data Sets with a Data Use Agreement.

5. IRB WAIVER/ALTERATION OF HIPAA RESEARCH AUTHORIZATION

5.1. Submission Requirements

5.1.1. Principal Investigators who seek a waiver or alteration of the written HIPAA research authorization from the IRB shall submit:

5.1.1.1. The Application for Waiver of HIPAA Privacy Authorization or if the project may be determined to be exempt the completed Application for Determination of Exempt Status Medical Record Review (114.1 C);

both found within the IRB electronic system, and;

5.1.1.2. The protocol or study design (if it has not already been submitted to the IRB)

5.1.2. The submission may be made with any other IRB application for approval of the research study under which the HIPAA research authorization waiver is being requested, or it may be made as a separate application

5.2. IRB Review Process

5.2.1. A waiver shall be granted only if the IRB determines that:

5.2.1.1. Disclosure of the PHI involves no more than minimal risk to the privacy of the individuals;

5.2.1.2. The research could not practicably be conducted without the alternation or waiver; and

5.2.1.3. The research could not practicably be conducted without the PHI

5.2.2. After the Application for Waiver of HIPAA Privacy Authorization has been submitted, the submission shall be reviewed by the IRB Chair/Vice Chair. Once reviewed, one of the following determinations shall be made:

5.2.2.1. Approved (with or without instructions)

5.2.2.2. Denied

5.2.2.3. Forward for full IRB review

5.2.3. The researcher shall be notified in writing of the IRB's determination. If full board review is required, the application shall be reviewed at the next regularly scheduled IRB meeting. The researcher shall be notified in writing of the full IRB's decision.

6. OTHER ISSUES

6.1. Suspension of Research Subject's Right to Access PHI

6.1.1. Unless otherwise provided herein, a research subject has the right, under HIPAA, to access his/her PHI created or obtained during the research study. A research subject's right under HIPAA to access PHI created or obtained during the research may be suspended provided that information regarding the suspension, and when it will be reinstated, is included either in the HIPAA research authorization or informed consent document

6.1.2. A research subject shall have access to his/her PHI upon completion of the research study or as provided in the HIPAA research authorization or informed consent, whichever occurs first

6.2. Research Subject's Right of Revocation of HIPAA Research Authorization

6.2.1. A research subject has the right to revoke his/her HIPAA research authorization at any time during or after the research study. However, the following applies:

6.2.1.1. The research subject's revocation DOES NOT defeat any access limitation agreed to under the HIPAA research authorization or informed consent; and

6.2.1.2. The Principal Investigator may continue using and disclosing PHI that was obtained prior to the revocation as necessary to maintain the integrity of the research study (i.e., accounting for subject withdrawal, information necessary for marketing application submitted to the FDA, to report adverse events)

6.3. Retention and Maintenance of HIPAA Documents

6.3.1. The IRB shall retain all documents relating to IRB Waivers of HIPAA Research Authorizations for at least six years from the date of closure.

6.3.2. The Principal Investigator shall retain all HIPAA documents, including, but not limited to, HIPAA research authorizations and written attestations for HIPAA exemption, for at least six years from the date of closure, as applicable.