POLICY

1. Purpose

Ensure that University of Rochester research activities comply with the national standards for the protection of certain health information that apply to the use and disclosure of individuals' health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 CFR 160 and 164).

2. Scope

This policy applies to all human subject research conducted or supported by employees or agents under the covered entity (see the *URMC and Affiliates Notice of Privacy Practices* for a list of all applicable facilities) of the University of Rochester (UR) Medical Center and Affiliates.

3. Definitions

3.1. *Authorization* – An individual's written permission to allow the use or disclosure of specified protected health information for specified purposes, the contents of which comply with the required elements and statements under the HIPAA Privacy Rule [45 CFR 164.508(c)].

3.2. *Covered Entity* – A health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a standard transaction. See the University of Rochester Medical Center and Affiliates Notice of Privacy Practices for a list of all applicable facilities.

3.3. *Health Information* – Any information including genetic information, whether oral or recorded in any form or medium, that:

3.3.1. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

3.3.2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

3.4. *Individually Identifiable Health Information* – Information that is a subset of health information, including demographic information collected from an individual, and:

3.4.1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and,

3.4.2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and,

- That identifies the individual; or,

- With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

3.5. *Protected Health Information (PHI)* – Includes but is not limited to any information that is created or received by a health care provider that relates to:

- The past, present, or future physical or mental health or condition of an individual; or
- Provision of health care to an individual; or,
- The past, present, or future payment for the provision of health care to an individual.

3.6. *Use and Disclosure of Data*

3.6.1. *Use of Data* - Use involves the sharing, employment, application, use, examination or analysis of such information within URMC and Affiliates. For example, a clinical trial coordinator in the School of Medicine and Dentistry analyzing a research subject's individually identifiable health information is using PHI.

3.6.2. *Disclosure of Data* - Disclosure occurs when individually identifiable health information is given to someone who is not an employee, student, volunteer or otherwise under the direction and control of the URMC and Affiliates covered entity. For example, showing source documentation to a representative of a clinical trial's sponsor is a disclosure even if the representative does not physically remove any PHI from the research site.

4. References

4.1. HHS 45 CFR 160; HHS 45 CFR 164

4.2. Policy 403 Notification of RSRB Determinations;
Policy 404 Criteria for RSRB Approval of Research

4.3. Guideline for Exempt Status Determination

4.4. URMC and Affiliates Notice of Privacy Practices;
URMC and Affiliates 0P7.1 Uses and Disclosures of PHI Requiring Authorization Policy;
URMC and Affiliates 0P7.1 Uses and Disclosures of PHI Requiring Authorization Procedure;
URMC and Affiliates 0P25 Uses and Disclosures of PHI for Research Activities;
URMC and Affiliates 0P25 Uses and Disclosures of PHI for Research Procedure

4.5. RSRB Consent Form Templates

5. Responsibilities

5.1. Investigators are responsible for identifying and complying with the requirements of the HIPAA Privacy Rule according to the federal regulations, policies, and procedures referenced under Section 4 above, when applicable.

5.1.1. HIPAA policies and procedures referenced above are available in the HIPAA Policy and Training Manual.

5.2. The RSRB is responsible for reviewing and approving research that is in compliance with the requirements of the HIPAA Privacy Rule for the use or disclosure of protected health information (PHI) according to the federal regulations, policies, and procedures referenced under Section 4 above, when applicable.

5.2.1. When the RSRB is the Reviewing IRB, this will be included as part of the RSRB review.

5.2.2. When the RSRB is the Relying IRB, he responsible party will be determined in the agreement, and if necessary the RSRB will review the HIPAA authorization.

6. Requirements

6.1. Investigators will identify in the protocol all proposed access to PHI which will occur during the course of the research, and describe the PHI to be collected. This includes access to paper medical records and electronic health records (EHR) for the purpose of subject identification (recruitment) or screening, collection of PHI for the purposes of the research, and collection or use of human biospecimens with individually identifiable health information attached. Investigators will specify the HIPAA identifiers that will be collected when the research indicates that Authorization will not be obtained.

6.2. Investigators must indicate how they will comply with the HIPAA Privacy Rule when the protocol requires the collection of PHI. This includes a description in the protocol and authorization language included in the consent form, when applicable. Requests to waive or alter the HIPAA Authorization requirements should be made according to Section 7 below.

6.2.1. When the RSRB is the Reviewing IRB, authorization for use and disclosure of PHI is combined with the informed consent document (see *Consent Form Templates* for standard language).

6.3. The RSRB will determine if there are adequate provisions to comply with the requirements for the HIPAA Privacy Rule (e.g., Authorization will be obtained or there is justification in the protocol for alteration or waiver of HIPAA Authorization), or that Authorization is not required (e.g., Limited Data Set or de-identified information).

6.4. When the RSRB is responsible for determining compliance with the HIPAA Privacy Rule, the RSRB will follow the procedures under *Policy 404 Criteria for RSRB Approval of Research*, or the *Guideline for Exempt Status Determination*, when appropriate.

6.4.1. RSRB approval/confirmation of written Authorization, waiver or alteration of such Authorization, or Limited Data Set with Data Use Agreement, must be obtained by the Investigator prior to implementation of any research activities.

7. Requirements for a Request to Waive or Alter Authorization to Use or Disclose PHI

7.1. Investigators must indicate which of the following apply when requesting a waiver or alteration of HIPAA Authorization:

7.1.1. Waiver of written authorization requirements to conduct the research, meaning that the elements of the HIPAA Privacy Rule will not be included as pertain to the authorization; however, some elements of the Privacy Rule may still apply (e.g., logging disclosures, maintaining records, etc.).

7.1.2. Alteration of written authorization requirements to conduct the research, meaning that some of the elements of the HIPAA Privacy Rule will not be included, as pertain to the authorization; however, some elements of the Privacy Rule may still apply (e.g., logging disclosures, maintaining records, etc.).

7.1.3. Partial waiver of written authorization requirements to conduct the research, meaning that authorization will not be obtained for part of the study (e.g., the Investigator needs to disclose information outside of the URMC & Affiliates covered entity for the purposes of recruitment).

7.2. Investigators must provide adequate justification in the protocol that the use and disclosure of PHI involves no more than minimal risk to the privacy of the individuals based on the following:

7.2.1. An adequate plan to protect the identifiers from improper use and disclosure;

7.2.2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research; and

7.2.3. Assurance that the PHI will not be reused or disclosed to any other person or entity except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.

7.3. Investigators must explain why the research cannot practicably be conducted without the requested waiver or alteration, and without access to and use of PHI.

7.4. The RSRB must review any request to waive or alter written Authorization and will communicate such review determinations according to *Policy 403 Notification of RSRB Determinations*.

7.4.1. For research requiring expedited or convened board review, the Chair or an Experienced Member will approve the request.

7.4.2. For research that meets the criteria for exemption, an RSRB Specialist, as determined in *Policy 401 Functions of RSRB Office*, will confirm that the requirements for the HIPAA Privacy Rule are met.

Originator/Authors:
Emily Flagg, Senior Regulatory Specialist

Appendices:
None

Revision History:
01/2018: Sect 4 hyperlinks added to references; Sect 5.2.1 and 5.2.2 added for Reviewing and Relying IRB language; Sect 6.2 and 6.4 language to clarify Reviewing IRB added; editorial and administrative changes.
03/2019: Sect 4.3 addition of guideline reference; Sect 7.4.1 and 7.4.2 added to clarify process for HIPAA determinations; remove T. Gommel and add N. Tabone as signatory; editorial and administrative changes

Supersedes Date:
01/29/2018

Approved By:

Kelley A. O'Donoghue
Director, OHSP

4/12/2019
Date

Nora Tabone
Chief Privacy Officer

4/12/19
Date