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 URMC & Affiliates Notice of Privacy Practices) 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.

   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](#);

4.3. [Policy 404 Criteria for RSRB Approval of Research](#);

4.4. [URMC and Affiliates Notice of Privacy Practices](#);

4.5. [URMC and Affiliates 0P7.1 Uses and Disclosures of PHI Requiring Authorization Policy](#);

4.6. [URMC and Affiliates 0P7.1 Uses and Disclosures of PHI Requiring Authorization Procedure](#);

4.7. [URMC and Affiliates 0P25 Uses and Disclosures of PHI for Research Activities](#);

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 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, this requirement 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 and Research Subjects Review Board on-line submission system (ROSS) all proposed access to protected health information (PHI) which will occur during the course of the research. 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.

6.2. Investigators must indicate how they will comply with requirements of HIPAA Authorization when the protocol requires the collection of PHI. This includes a description in the protocol, delineation in the ROSS application, and authorization language included in the consent form. 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 HIPAA Authorization (e.g., Authorization will be obtained, or justification for an alteration or waiver of such Authorization requirements).

6.4. When the RSRB is responsible for determining compliance with HIPAA Authorization, the RSRB will follow the procedures under Policy 404 Criteria for RSRB Approval of Research.

6.4.1. RSRB approval of written Authorization, or an RSRB approved waiver or alteration of such Authorization requirements, 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 whether any 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., recruitment purposes).

7.2. Investigators must provide adequate justification that the use and disclosure of PHI involves no more than minimal risk to the privacy of the individuals.

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

7.4. Investigators must confirm 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.

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

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10/28/2014

Approved By:

Kelley A. O'Donoghue
Director, OHSP

Date

Tiffany L. Gommel
Director, RSRB

Date