Roswell Park Cancer Institute Policy and Procedure	Date Issued: 6/15/2006	Number: 206.2
Title: HIPAA and Research and De-Identification	Revision: 1	Effective Date: 8/25/2011
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A. STATEMENT OF POLICY

It is the policy of Roswell Park Cancer Institute to comply with the federal privacy requirements, known commonly as Health Insurance Portability and Accountability Act (HIPAA), when conducting human subject research (45 CFR 164.501,164.508, 164.512(i), 164.514 (e), 164.528, 164.532).

B. PURPOSE

Not Applicable.

C. DEFINITIONS

Protected Health Information (PHI) - individual's medical records and other personal health information or information that can, alone or in conjunction with other information, be used to identify the individual who is the subject of the information

Human Subject - living individual about whom an investigator conducting research obtains either data through intervention or interaction with the individual or identifiable private information.

Research - a systemic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 164.501)

De-identified health information - this is PHI that has all of the required identifying elements removed or, with respect to which, statistical assurance of de-identification has been obtained. The elements that are required removed for de-identification purposes are:

- Names
- All geographic subdivision smaller than a state
- Zip code (can retain the initial three digits if the zip code area has 20,000 or more people residing
- All dates except year
- Phone, fax numbers
- Electronic mail addresses, URLs, IP numbers
- Social security number
- Medical record number
- Health plan beneficiary number
- Patient Account number
- License number/motor vehicle numbers
- Device identifiers
- Biometric identifiers
- Full face photographic images
- Any other unique identifier

NOTE: can assign a code to re-identify if code is kept secure, if the code is not derived from information about the individual and the code is not used/disclosed for any other purpose and do not disclose the mechanism for re-identification (45 CFR 164.514 (c)

Limited Data Set - removal of direct identifiers and use of a data use agreement.
Direct Identifiers that must be excluded:

- Name
- Street/postal address - can retain city, state, zip code
- Phone/fax number
- E-mail address
- Social security number
- Certificate/license number
- Vehicle ID and serial number
- URL's and IP addresses
- Full face images and biometric identifiers
- Medical record number, health care plan number, other account numbers
- Device ID and serial numbers

Can include:

- Dates such as admission, discharge, service,
- date of birth, date of death
- city, state, five digit zip code
- age in years, months, days or hours as necessary for the research

D. POLICY

Policy:

a. Roswell Park Cancer Institute's Institutional Review Board, which is duly constituted and fulfills FDA and DHHS Office for Human Research Protections (OHRP) requirements defined in 21 CFR Parts 50, 56 and 312 and 45 CFR 46 (Code of Federal Regulations) and meets the requirements of HIPAA, serves as the entity that oversees the research use of PHI within the guidelines below. See also TABLE OF ACTIONS FOR USE OF PHI IN RESEARCH below.

b. Roswell Park Cancer Institute, as a covered entity under the HIPAA regulations, can use and disclose for research purposes health information which has been de-identified, in accordance with 45 CFR 164.502 (d) and 164.514 (a-c) without regard to the provisions below.

c. This policy defines the uses and disclosures of PHI for research purposes, ensuring access to the information necessary to conduct research and at the same time protecting the privacy of individually identifiable health information.

d. This policy and procedure applies to all research conducted regardless of funding.

Procedure:

In the process of conducting research, researchers may obtain, create, use and/or disclose PHI in accordance with the following:

a. Research Use/Disclosure WITHOUT Authorization:

i. WITH IRB approval of a WAIVER or Alteration of authorization for use and disclosure of information. (45 CFR 164.512(i)(1)(i). The Waiver application can be found on the Roswell Park Cancer Institute internal CRS/IRB website for use in the appropriate studies.

A waiver can be granted (for example, to conduct medical record research (EDR)), providing the research fulfills the following documented requirements for a waiver:

- Identification of the IRB and the date on which the waiver was approved
- Statement that the IRB has determined that the waiver, in whole or in part, satisfies the following three criteria:

  i. Involves no more than a minimal risk to the privacy of the individuals based on the following elements being present:

- Adequate plan to protect the identifiers from improper use and disclosure
- Adequate plan to destroy identifiers at 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 re-used 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 HIPAA

ii. The research could not be practically conducted without the waiver; and

iii. The research could not be practically conducted without access to and use of the PHI

- Brief description of the protected health information for which use or access has been determined to be necessary by the IRB
- Statement that the waiver has been reviewed and approved under either normal or expedited review procedures
- Signature of the chair of the IRB or designee

Preparatory to Research:

Written statement from the researcher that:

- the use or disclosure of the PHI is solely to prepare a research protocol or for similar purposes preparatory to research;
- the researcher will not remove any PHI from the institutes, and
- PHI for which access is sought is necessary for the research purpose (45 CFR 164.512 (i) (1) (ii).

Decedent Research:

Written representation that:

- the use or disclosure is solely for research on the PHI of decedents;
- the PHI is necessary for the research; and
- at the request of the Institute, documentation of the death of the individual (45 CFR 164.512 (i) (1) (iii).

Limited Data Sets with a Data Use Agreement:

A Data Use Agreement entered into by both the Institute and the researcher that enables the Institute to disclose a limited data set to the researcher for research, public health, or health care operations. (45 CFR 164.514 (e)).

A LIMITED DATA SET agreement excludes specific direct identifiers of the individual, relatives, employers, or household members of the individual.

The LIMITED DATA SET must:

- Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which MAY NOT include any use or disclosure that would violate the rule if done by the covered entity.
- Limit who can receive the data
- Require the receiver of the data to agree to the following:

    - Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law.
    - Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the agreement
    - Report to the Institute any use or disclosure of the in-formation not provided for by the agreement, of which the receiver becomes aware
    - Ensure that any agents, including a subcontractor, to whom the receiver provides the information agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set, and
    - Not to identify or contact the individual.

WITH AUTHORIZATION:

The research participant/patient authorizes in writing the use and disclosure of PHI. This will apply to most clinical trials and some records research. (45 CFR 164.508) Authorization MUST satisfy all the requirements of the HIPAA regulations and contain:

- A specific identification of the study
- A description of the information to be used or disclosed that identifies the information in a specific and meaningful manner
- Name or other specific identification of the person or class of persons authorized to make the requested use or disclosure
- Name or other specific identification of the person or class of persons to whom the covered entity may make the requested use or disclosure
- Expiration date or event
- Statement regarding the individuals right to revoke the authorization in writing and the exceptions to the right to revoke
- A description of how the person may revoke the authorization
- A statement regarding redisclosure of the PI by a recipient who may not be covered by HIPAA provisions
- Signature of the individual and date
- If signed by a representative, the description of the other persons authority to act for the individual.

An authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the "end of the research study.
An authorization for the use or disclosure of PHI for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study.

Minimum Necessary:

HIPAA requires that no more than the minimum necessary PHI be disclosed for the intended purpose of the research.

Accounting for Research Disclosure:

In accordance with 45 CFR 164.528 an accounting must include disclosures of PHI that occurred during the six years prior to the request or since the compliance implementation date, and must include specified information regarding each disclosure.

Exemptions from accounting requirements:

- Disclosures made pursuant to an authorization
- Disclosures of the limited data set with a data use agreement
- Disclosures without authorization for research purposes that involve at least 50 records. Under this provision, the Institute may provide individuals with a list of all protocols for which the patient PHI may have been disclosed, as well as the researcher's name and authorization.

Transition Provisions:

PHI that was created and received for research purposes before or after the compliance date of April 14, 2003, may continue to be used/disclosed if obtained by use of any one of the following prior to April 14, 2003:

- An authorization or other express legal permission to use or disclose PHI for research
- An informed consent of the individual to participate in the research; or
- A waiver of informed consent by an IRB or an exception under the FDA regulations.

USE OF THE HIPAA AUTHORIZATION:

Roswell Park Cancer Institute, as a covered entity, will develop and publish for use an authorization for use and disclosure of PHI for research purposes that meets the requirements of HIPAA. Sponsors, pharmaceutical companies, CRO's and/or other entities that are not covered entities will not be permitted to change the authorization.

There will be posted on the internal Roswell Park Cancer Institute CRS/IRB website a therapeutic and non- therapeutic (NT) version of the authorization.

For all IRB approved informed consents that were approved BEFORE the compliance date of 4/14/2003 that will be used to enroll subjects on or after 4/14/2003, the appropriate HIPAA authorization should be attached to the end of the consent form. This authorization will require a separate signature and an indication of the protocol number for which it was obtained at the top.
For all consents submitted for IRB approval on or after 4/14/03, the appropriate HIPAA authorization should be incorporated into the consent document itself. This requires removal of any other confidentiality provision that may have been in the consent form. A separate signature is not required.

Participant's Right of Access to Research Records or Results:

A participant patient has the right to inspect and obtain a copy of PHI about him or her that is maintained by the Institute in a "designated data set". While unlikely that the researcher him or herself would be maintaining a designated record set, any research records or results that are actually maintained by the institute as part of a designated record set would be accessible to research participants unless one of the exceptions applies.

Exception:

The participant's right to access is suspended while the clinical trial is in progress, providing this was agreed to at the time the person consented to participate in the trial. Access will be reinstated after the trial is concluded.

Authorization Revocation:

Participants are allowed to revoke their authorization for use of PHI. This must be done in writing.

Exceptions:

- PHI already collected prior to the revocation may still be used.
- Mandated reporting of PHI, such as to the FDA, investigations of scientific misconduct, and/or adverse event reporting.

TABLE OF ACTIONS REQUIRED FOR USE OF PHI IN RESEARCH

NOTE: minimum necessary rule applies

There may be different and addition requirements under the regulations that the IRB must meet.

Type of information wanted for research	**RPCI IRB requirement**	**Researcher**	**Participant / Subject / Patient**	**Accounting**
PHI preparatory to research	Complete Medical record research form	Representation, in writing, that the use is solely and necessary for research and will not be removed from Institute None	N/A Info cannot be disclosed	
Deidentified Health Information	Approved research protocol	Removal of all the identifiers or a statistical assurance of deidentification	None	No
Limited Data Set	Approved research protocol	Removal of direct identifiers and a data use agreement	None	No
Decedents	Approved research protocol	Representation that use is solely and necessary for research on decedents and documentation of death upon request	None	No
PHI of Human Subjects (whether therapeutic, non-therapeutic or record review)	Can waive requirement for authorization IF meet the requirements for Waiver IF risk is minimal	Written representation that: 1. Risk to privacy is minimal based on: • Plan to protect identifiers • Plan to destroy identifiers unless there is a health, research or other legal reason to retain • Written assurance that the PHI will not be reused or redisclosed 2. Research requires use of	NONE	YES Fewer than 50 patients -record each disclosure More than 50 patients - keep a list of protocols

		specifically described PHI 3. Justify the waiver 4. Obtain IRB approval under normal or expedite review procedures		
	Approve research protocol ensuring that there is an authorization for use either combined with consent for and disclosure of PHI research or separate		Sign authorization	No