R-3 - Uses and Disclosures of Protected Health Information (PHI) for Research

Key Points

- Prior to using or disclosing PHI for research purposes, UH obtains a written authorization from each research subject or a waiver of the authorization requirement from the UHCMC Research Privacy Board (RPB).

- UH uses or discloses only the minimum amount of PHI necessary for any given research purpose.

- A patient’s signed general consent for treatment or informed consent for procedures does not constitute authorization to use or disclose PHI for research purposes.

Policy & Procedure

1. Prior to using or disclosing PHI for research purposes, UH obtains a written authorization from each research subject or a waiver of the authorization requirement from the UHCMC Research Privacy Board (RPB).

2. UH uses or discloses only the minimum amount of PHI necessary for any given research purpose.

3. UH investigators obtain prior approval from the RPB or the Institutional Review Board (IRB) prior to using or disclosing decedents' PHI, using or preparing limited data sets or de-identified health information for research purposes.

4. A patient’s signed general consent for treatment or informed consent for procedures does not constitute authorization to use or disclose PHI for research purposes.

5. Documentation of approval of use of PHI for research purposes (individual authorizations) is maintained by the researcher for a period of at least six (6) years after the research is complete.

6. Use and Disclosure of PHI for research purposes

6.1 This policy applies to PHI collected or obtained from individuals conducted at University Hospitals and all of its wholly-owned entities (collectively, “UH”).

6.2 The HIPAA Privacy Rule establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. UH is a covered entity and as such, complies with HIPAA requirements for the use and disclosure of PHI.
Under the HIPAA Privacy Rule, PHI may only be used and disclosed for research purposes under one or more of the following circumstances:

6.2.1 With the written permission of the individual (or the individual’s personal representative) in the form of an Authorization; OR

6.2.2 When the health information is de-identified; OR

6.2.3 When the RPB waives the requirement for Authorization or allows an alteration of the requirements; OR

6.2.4 When the information is collected preparatory to research (circumstances are limited); OR

6.2.5 When the information is from decedents (circumstances are limited); OR

6.2.6 When the information is part of a limited data set and UH has entered into a Data Use Agreement with a second party for the sharing of the information (circumstances are limited).

7. Obtaining Written Authorization for Use and Disclosure of PHI.

7.1 An investigator is required to obtain written HIPAA Authorization from each research participant prior to the use or disclosure of the participant’s individual PHI for research purposes. The purpose of the authorization is to inform individuals how their medical and research information (collected or created) is to be used; with whom the information is shared; and to inform individuals of the right to access information about them that is held by UH.

7.2 The UHCMC Research HIPAA Authorization Template is used. The language in the UHCMC template addresses the requirements of the HIPAA Privacy Rule.

7.2.1 The Research HIPAA Authorization template language may be included in the informed consent document OR may be used as a stand alone document.

7.2.2 Only designated sections in the Research HIPAA language (noted in red italics) may be revised to reflect the pertinent study information.

7.2.3 The remainder of the template text may not be deleted or altered in any way without prior RPB approval.

7.2.4 If the Research HIPAA Authorization is a stand alone document, the investigator receives a stamped copy of the document, when it is approved by the RPB that will designate an effective date.

7.2.5 If the Research HIPAA Authorization is included in the Research Informed Consent form, the Research HIPAA Authorization becomes a part of the stamped Informed Consent form and is re-approved as part of each IRB continuing review.

7.2.6 Investigators make sure that two copies of the signed HIPAA Authorization Form are obtained: one copy for the subject’s research file; and a second copy to be given to the subject.

7.2.7 The signed Authorization is retained by the covered entity for six (6) years from the date of creation or the date it was last in effect, whichever is later.
7.3 Written Authorization may be combined with any other type of written permission for the same or another research study.
7.3.1. This includes combining an authorization as part of a current IRB approved consent form, combining an authorization for a current IRB approved research study with an additional authorization for the creation or maintenance of an IRB approved research database or repository.
7.3.2. The compound authorization for the provision of research-related treatment must clearly differentiate between what the current authorization is for ("conditioned") and what future research will be conducted ("unconditioned") and must provide an individual with an opportunity to opt-in to the research activities described in the unconditioned authorization.

7.4 An individual who has signed a written Research HIPAA Authorization to allow use and disclosure of PHI may revoke this authorization at any time by submitting a request in writing to the UH Privacy Officer. The covered entity is permitted to utilize the PHI previously collected under written authorization to preserve the integrity of the study; however, no additional PHI may be used or collected.

8. Waiver of Requirement for or Alteration of Written Research HIPAA Authorization for Use and Disclosure of PHI

8.1 An investigator may request a full or partial waiver of the requirement for written Research HIPAA Authorization in certain situations.
8.1.1 A partial waiver may be granted by the RPB in situations where the researcher needs to obtain PHI for the purpose of recruitment and/or to determine eligibility of potential research subjects.

8.2 Any request for waiver of written Research HIPAA Authorization is reviewed by the RPB.
8.2.1 In order to approve a request for waiver, the RPB determines and documents that the use meets each of the following three criteria:
8.2.1.1. The use or disclosure of the PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
8.2.1.1.1. An adequate plan to protect PHI identifiers from improper use and disclosure;
8.2.1.1.2. 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
8.2.1.1.3. Adequate written assurances that the PHI is not reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other
research for which the use or disclosure of the PHI is permitted by the HIPAA Privacy Rule.

8.2.1.2 The research could not practically be conducted without the waiver or alteration; AND
8.2.1.3 The research could not practically be conducted without access to and use of the PHI.

8.3 The RPB may also approve a request that removes some, but not all, required elements of a written Authorization (i.e., an alteration). For example, removing the element that describes the purpose of the requested use/disclosure of the PHI in cases where identification of the specific research study may affect the results of the study.

9. Activities Preparatory to Research

9.1 UH employees interested in using or disclosing PHI preparatory to research must comply with the Standard Operating Procedure (SOP) for Clinical Research: “Use and Disclosure of Protected Health Information Preparatory to Research.”

9.2 Non-UH personnel is permitted to use PHI preparatory to research only if first credentialed through the UHCMC Research Credentialing process and under the direction of a UH employee who has met the requirements of the SOP referenced in 9.1.

9.3 Activities considered “preparatory to research” include:
9.3.1 Preparing a research protocol;
9.3.2 Developing a research hypothesis; and
9.3.3 Identifying prospective research participants.

10. Use of De-identified Health Information

10.1 De-identified health information is not considered PHI. UH is permitted to use or disclose de-identified data for research purposes without obtaining a research authorization and without further restrictions on use or disclosure. Individuals utilizing this information for research purposes abide by federal regulations pertaining to human subject research as well as UHCMC IRB policies and procedures for human subject research. Information is considered “de-identified” if it meets one of following criteria:
10.1.1 All 18 identifiers of the individual; their relatives, employers, or household members are removed from the individual’s data set; and UHCMC does not have actual knowledge that the remaining information can be used alone or in combination with other data to identify the subject; or
10.1.2 The data is grouped in such a way that a qualified statistician using accepted analytic techniques, concludes that the risk is substantially limited and if the information is used alone or in combination with other reasonably available information, does not identify an individual subject (e.g., aggregate data);

10.2 PHI from UH cannot be sent to a third party for de-identification purposes to meet the above criteria without a Business Associates Agreement between UH and the third party.
11. Use of Decedents' PHI

11.1 An investigator may use or disclose PHI of deceased individuals for research purposes, under limited circumstances. Since the use of information from individuals who are deceased does not qualify as human subjects research according to the Office of Human Research Protection (OHRP), use of decedents' PHI for research purposes is noted as part of the submission of a UHCMC “Activity Determination Form” and the following points are affirmed in the submission:

11.1.1 That the use and disclosure is sought solely for research on the PHI of decedents; and
11.1.2 That the PHI for which use and disclosure is sought is necessary for the research purposes; and
11.1.3 At the request of the covered entity, documentation of the death of the individuals about whom PHI is being sought.

12. Use of a Limited Data Set

12.1 Prior to a limited data set being used or disclosed outside of the covered entity, the investigator (recipient) enters into a Data Use Agreement (DUA) with the covered entity. The DUA establishes who is permitted to use or receive the limited data set; and the limited purposes under which the recipient of the data may use or disclose the PHI.

12.2 A DUA:

12.2.1 Establishes the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and the agreement does not include any use or disclosure that would violate the HIPAA Privacy Rule if done by the covered entity;
12.2.2 Limits who can use or receive the data; and
12.2.3 Requires the recipient to agree to the following:
   12.2.3.1 Not to use or disclose the information other than as permitted by the DUA or as otherwise required by law;
   12.2.3.2 Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the DUA;
   12.2.3.3 Report to the covered entity any use or disclosure of the information, in violation of the DUA, of which the recipient becomes aware;
   12.2.3.4 Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
   12.2.3.5 Not to re-identify the information or contact the individuals who are the subjects of the limited data set.

12.3 Researchers execute a DUA prior to the receipt and/or disclosure of any PHI for research purposes. This DUA may be executed with the assistance of the UHCMC Center for Clinical Research and Technology (CCRT).
12.4 If UH learns that a violation of the executed DUA has occurred, reasonable steps are taken to end or repair the violation. If such steps are unsuccessful, the UH Privacy Office reports the investigator to the DHHS Office of Civil Rights.

13. Research Started Prior to April 14, 2003
   13.1 Investigators are permitted to use and disclose PHI that was created or received for research, either before or after April 14, 2003, if one of the following occurred prior to April 14, 2003:
   13.1.1 An Authorization or other express legal permission from an individual to use or disclose PHI for the research; or
   13.1.2 The informed consent of the individual to participate in the research; or
   13.1.3 A waiver of informed consent by an IRB in accordance with the Common Rule, or an exception under the Food and Drug Administration's (FDA) human subject protection regulations.
   13.1.3.1 If a waiver of informed consent was obtained prior to the compliance date, but informed consent is subsequently sought after the compliance date, the investigator obtains the individual's authorization or waiver of the authorization requirement, as discussed in Sections 7 and 8 above.

14. International Research
   14.1 Identifiable health information collected in a foreign country as part of a research protocol is not bound by the requirements set forth in the United States' HIPAA Privacy Rule unless:
   14.1.1 A U.S. investigator uses or discloses identifiable health information that qualifies as PHI by a U.S. institution that is considered a “covered entity”.
   14.1.2 If the HIPAA Privacy Rule applies, a modified shortened form of the required Research HIPAA language is utilized in both the English version and all translated versions of the Informed Consent forms.
   14.1.3 When appropriate, a waiver may be requested and is subject to the criteria outlined in Section 8 above.

15. Violations of the HIPAA Privacy Rule as It Pertains to Use and Disclosure of PHI
   15.1 Any violations of the HIPAA Privacy Rule related to research use and disclosure of PHI are referred to the UHCMC Center for Clinical Research and Technology (CCRT) and the UH Privacy Officer for further investigation.
   15.2 Allegations of non-compliance and results of any investigations are reviewed with the RPB either at a fully convened meeting of the RPB or administratively by designated members of the RPB.

16. Use or Disclosure of PHI by or to Non-UH Employees
   16.1 In accordance with Standard Operating Procedure for Clinical Research: Research Credentialing, non-UH employees must be research credentialed prior to accessing UH PHI.
16.2 Non-UH employees who request use of PHI for research purposes may receive this information provided that a Business Associate Agreement (BAA) has been executed.

See Also:

Standard Operating Procedure for Clinical Research “Use and Disclosure of Protected Health Information Preparatory to Research.”

Standard Operating Procedure for Clinical Research “Research Credentialing”

UH Policy PH-15, De-Identifying Protected Health Information (PHI)

UH Policy PH-16, Limited Data Set: Permitted Purposes for Use/Disclosure

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1 Use means sharing, employing, applying, utilizing, examining or analyzing PHI within UH.
2 Disclose means the release, transfer, provision of, access to, or divulgence of PHI to a person or entity outside UH.
3 **Protected Health Information (PHI)** is individually identifiable health information, including demographic data that is collected from an individual, and:
   1. is created or received by a health care provider, health plan, public health authority, employer, life insurer, school/university, or health care clearing house; AND
   2. relates to past, present or future physical or mental health or condition of the individual; or 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
   3. identifies the individual or where there is a reasonable basis to believe the information can be used to identify the individual; AND
   4. is transmitted or maintained in any form or medium, whether electronic, paper or oral. Individually identifiable health information regarding a person who has been deceased for more than 50 years is not PHI.
4 The HIPAA Privacy Rule defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”
5 **Research Privacy Board (RPB)** is a review body which acts upon the HIPAA Privacy Rule’s authorization requirements for use or disclosure of PHI for a specific research protocol. The RPB’s authority is limited to approval of privacy language; approval of requests for a waiver or alteration of the HIPAA Privacy authorization requirements; approval for the use of PHI from deceased individuals; and review of HIPAA compliance allegations. For UHCMC, the RPB consists of representatives from the IRB, the UH Compliance and Ethics Department, UH Legal Department and the UH Center for Clinical Research and Technology. See UH Policy R-7 - Research Privacy Board.
6 **Covered Entity** is a health plan, a health care clearinghouse, or health care provider that transmits health information in electronic form in connection with a transaction for which DHHS has adopted a standard. A covered entity can be an institution, organization, or person. The covered entity is responsible for implementing HIPAA Privacy Rule protections of Protected Health Information collected, generated, or stored under its
University Hospitals Case Medical Center (UHCMC) and all its related divisions, employees, and medical staff constitute a covered entity.

7 **Authorization** is permission to gain access to PHI. At UHCMC, Authorization for use and disclosure of PHI for research purposes is provided by signing a Research HIPAA Authorization Form, which provides clear descriptions of how privacy will be protected and confidentiality of the information will be maintained, exactly who will have access, and for how long.

8 **Informed Consent Document** is a form that will be used to document an individual's agreement to participate in the research study. This document contains a description of the study, anticipated risks and/or benefits, voluntariness and how the confidentiality of records and subject privacy will be protected.

9 **Subject Identifiers under HIPAA include:** (1) Names (including the patient's name and names of other individuals connected to the patient); (2) Geographic subdivisions smaller than a state (zip-code, street address, etc); (3) All elements of a date (except year) including birth date, admission date, discharge date, date of death, and all ages over 89; (4) Telephone numbers; (5) Fax numbers; (6) Email address; (7) Social Security number; (8) Medical record number; (9) Health plan beneficiary numbers; (10) Account numbers; (11) Certificate/license numbers; (12) Vehicle identifiers and serial numbers; (13) Device identifiers and serial numbers; (14) Web universal resource locators (URLs); (15) Internet protocol (IP) address numbers; (16) Biometric identifiers including fingerprints and voice prints; (17) Full face photographic (or comparable) images; (18) Any other unique identifying number, characteristic, or code unless otherwise permitted by the HIPAA Privacy Rule for re-identification.

10 **Limited data sets** refers to PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with an appropriately executed DUA.

11 **Business Associate** is a person or entity who, on behalf of a covered entity, performs or assists in performance of a function or activity involving the use or disclosure of individually identifiable health information, such as data analysis, claims processing or administration, utilization review, and quality assurance reviews, or any other function or activity regulated by the HIPAA Administrative Simplification Rules, including the HIPAA Privacy Rule.