

UBMD Policy for HIPAA Compliant Subject Recruitment

Approved by Executive Committee on December 5, 2016

I. Statement of Purpose

This policy is applicable in the situation where the Principle Researcher is determining the sufficiency of the number of potential research subjects prior to IRB protocol approval and after IRB Protocol approval when the Principal Investigator is ready to begin recruiting subjects into the research. It is the policy of UBMD to support research activities that have scientific merit and are compliant with all statutes and regulations pertaining to the release of Protected Health information (PHI) and access to patient medical records.

Protected Health Information obtained by UBMD may not be used internally or disclosed to any persons or organizations outside UBMD for research purposes without the use of a HIPAA research release mechanism. This includes the transfer of PHI from a practice plan to UB or a UB employee without the use of one of the mechanisms listed below:

II. Instructions

A. Definitions

1. **Research.** Research includes any systematic investigation (including research development, testing, and evaluation) that has as its primary purpose the development of or contribution to *generalizable knowledge*. This includes the development of research repositories and databases for research.
2. **Generalizable Knowledge.** Knowledge may be generalizable even if a research study only uses PHI held within UBMD and the results are generalizable only to the population served by UBMD. Research is not limited to clinical trials funded by government sponsors (such as the National Institutes of Health) or commercial sponsors. Quality assurance and utilization management activities do not typically result in generalizable knowledge and thus ordinarily would not be governed by this policy.
3. **Principal Investigator.** The individual responsible for the scientific, technical, and administrative aspects of the project (*e.g.*, for NIH-funded research, the person named at Item 3a, Form PHS 398).
4. **De-Identified Information.** Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual, as specified in the HIPAA Privacy Rule at 42 C.F.R. 164.514(b).
5. **Limited Data Set.** A limited data set is protected health information that excludes 18 direct identifiers of an individual or of relatives, employers or household members of such individual, as specified in the HIPAA Privacy Rule at 45 CFR §164.514(e)(1).

6. **UBMD.** UBMD means the practice plans created under New York Not-For-Profit Law section 1412 to support the Jacobs School of Medicine and Biological Sciences and UB Associates, Inc.
7. **UBMD Workforce.** The UBMD Workforce refers to physicians, mid-level providers, nurses and all other staff, including employees, students, interns, residents, fellows and volunteers.
8. **External Researcher.** Any individual who is not a member of the UBMD Workforce and performs activities defined in this policy as Research.

B. **Use and Disclosure of PHI for Research**

1. **General Rule**

- a. Certain requirements apply to the use and disclosure of PHI in connection with all research involving human subjects. As a general rule, UBMD may *not* authorize the use or disclosure of PHI for research purposes except:
 - 1) For reviews preparatory to research;
 - 2) For research on the PHI of a decedent;
 - 3) If the Principal Investigator for a study has obtained the informed consent of the individual to participate in the research, or a waiver of such informed consent, prior to April 14, 2003 (this exception ceases to apply if informed consent is sought from the individual after April 14, 2003);
 - 4) If the information is “completely de-identified;”
 - 5) If the information is partially de-identified into a “limited data set” and the recipient of the information signs a data use agreement to protect the privacy of such information;
 - 6) If the Principal Investigator has obtained a valid authorization from the individual subject of the information; or
 - 7) If an Institutional Review Board (an “IRB”) or a Privacy Board approves a waiver of the individual authorization requirement.
- b. The specific requirements for each of these exceptions are discussed below. One of the exceptions described above must apply before permitting the use or disclosure of any PHI for research purposes. All research activities must also comply with the Common Rule and FDA requirements for research and with any additional requirements that apply to the specific types of information identified below as having special rules.

2. **Special Rules for Sensitive Information**

Special rules apply to the use and/or disclosure for research purposes of the following types of information:

- a. Genetic tests and results from genetic tests;
- b. HIV-related information;

- c. Alcohol and substance abuse treatment information;
- d. Psychotherapy notes; and
- e. Mental health information.

C. **Requirements for Each Exception**

UBMD may **not** authorize the use or disclosure of PHI for research purposes unless at least one of the following exceptions applies:

1. **Reviews Preparatory to Research.**

- a. UBMD may permit the use and disclosure of PHI to develop a research protocol or for similar purposes preparatory to research (*e.g.*, to determine whether UBMD has information about prospective research participants that would meet the eligibility criteria for enrollment in a research study). It is not necessary for a researcher to obtain patient authorization or an IRB waiver of authorization to conduct a review preparatory to research. In order to permit a use or disclosure of PHI under this exception, the Principal Investigator must be able to represent that:
 - 1) The use or disclosure is sought solely to prepare a research protocol or for similar purposes preparatory to research;
 - 2) No researcher will remove any PHI from UBMD's premises or systems in the course of the review; and
 - 3) The PHI for which use or access is sought is necessary for the research purposes.
- b. External Researchers should be aware that they are *not* permitted to continue to use or disclose the PHI once they have decided to go forward with the study. For example, using PHI to contact eligible subjects for recruitment purposes would *not* be permitted by an External Researcher under this exception unless they obtain a partial IRB waiver of authorization. If the researcher is a member of the Workforce, a partial IRB waiver of authorization is not required for recruitment purposes but the researcher must contact the prospective subject's treating practitioner before contacting the patient about participation in a research study.

2. **Research on the PHI of a Decedent.**

It is permitted to use and disclose the PHI of a decedent for research purposes if the Principal Investigator represents that the use or disclosure is sought *solely* for research on the PHI of a decedent (*e.g.*, researchers may not request a decedent's medical history to obtain health information about a decedent's living relative) *and* that the information for which use or disclosure is sought is necessary for the research purposes. Moreover, the Principal Investigator must provide, at UBMD's request, documentation of the death of any individuals about whom information is sought.

3. **Informed Consents or Waivers of Informed Consent Obtained Prior to April 14, 2003.**

The use or disclosure of PHI for a specific research project is permitted provided that one of the three following requirements is met:

- a. Express Legal Permission For Use And Disclosure Of PHI. If the researcher has obtained, prior to April 14, 2003, express legal permission from the individual that *specifically authorizes* a use or disclosure of PHI for purposes of the research project. However, any restrictions on the use and disclosure of health information provided in such express legal permission must be honored.
- b. General Informed Consent. If the researcher has obtained, prior to April 14, 2003, the individual's *informed consent* to participate in a specific research project, it is permitted to use or disclose for purposes of that project even though the informed consent *does not* specifically authorize the use or disclosure of PHI for purposes of the research project. However, any restrictions on the use and disclosure of health information provided in such informed consent must be honored.
- c. Waiver of Informed Consent. If the researcher has obtained, prior to April 14, 2003, an IRB waiver of the informed consent requirement (in accordance with the Common Rule) for a specific research project, it is permitted to use or disclose the individual's PHI for purposes of that project. However, if the researcher obtains an individual subject's informed consent at any time after April 14, 2003, the researcher will also be required to obtain the individual's Research Authorization.

4. **Completely De-identified Information.**

- a. If PHI is de-identified to HIPAA standards, it may be used for research purposes. PHI is de-identified to HIPAA standards when the following elements are deleted

- 1) Names;

- 2) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

- (A) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(B) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

3) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

4) Telephone numbers;

5) Fax numbers;

6) Electronic mail addresses;

7) Social security numbers;

8) Medical record numbers;

9) Health plan beneficiary numbers;

10) Account numbers;

11) Certificate/license numbers;

12) Vehicle identifiers and serial numbers, including license plate numbers;

13) Device identifiers and serial numbers;

14) Web Universal Resource Locators (URLs);

15) Internet Protocol (IP) address numbers;

16) Biometric identifiers, including finger and voice prints;

17) Full face photographic images and any comparable images; and

18) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

5. **Limited Data Set.**

- a. A limited data set ("LDS") is protected health information that **excludes** the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- 1) Names;
- 2) Postal address information, **other than** town or city, State, and zip codes;
- 3) Telephone numbers;
- 4) Fax numbers;
- 5) Electronic mail addresses;
- 6) Social security numbers;
- 7) Medical record numbers;
- 8) Health plan beneficiary numbers;
- 9) Account numbers;
- 10) Certificate/license numbers;
- 11) Vehicle identifiers and serial numbers, including license plate numbers;
- 12) Device identifiers and serial numbers;
- 13) Web Universal Resource Locators (URLs);
- 14) Internet Protocol (IP) address numbers;
- 15) Biometric identifiers, including finger and voice prints; and
- 16) Full face photographic images and any comparable images.

- b. UBMD may allow the disclosure of a LDS for research purposes, as permitted under 45 CFR §164.514(e)(1), provided that a data use agreement (“DUA”) is executed between UBA or the practice plan controlling the LDS and the LDS recipient.
- c. Protected Health Information may be disclosed to a third party for the purpose of creating a LDS on behalf of UBMD provided that a Business Associate Agreement is executed between the third party and UBMD.

6. Subject Signs Authorization Research Form.

- a. It is permissible to use and disclose PHI pursuant to a properly completed and signed Research Authorization form. Permissible uses and disclosures are limited to those described in the authorization, even though those permissible

uses and disclosures may be more limited than what UBMD's Notice of Privacy Practices describes.

- b. The Research Authorization form must be completed by the Principal Investigator for the research subject's review and signature. It is the responsibility of the Principal Investigator to ensure that the Research Authorization form covers the uses and disclosures necessary for the research study.
- c. When obtaining a Research Authorization, an individual's ability to receive research-related treatment as part of a research study may be conditioned upon the individual's agreement to sign the Research Authorization form. However, in presenting the Research Authorization form to prospective subjects, researchers should never suggest that failure to sign the form will limit access to any treatment that may be available *outside* the study. Any questions about the availability of such treatment outside the study should be referred to the prospective research subject's physician(s).
- d. Any original documentation relied upon for the disclosure of PHI for research purposes will be maintained by the Principal Investigator and will be made available to UBMD upon request.

7. IRB Approval of Waiver.

It is permitted to use and disclose PHI for research purposes if the IRB grants a partial or total waiver of the patient authorization requirement. UBMD may rely on a request for disclosure made by a researcher pursuant to total or partial IRB waiver of authorization for purposes of the minimum necessary requirement.

- a. **Partial Waiver.** If the IRB grants only a *partial waiver* – that is, if it modifies or waives only some elements of the Research Authorization form – the use of PHI must be conditioned on the partial waiver and compliance with any authorization requirements not waived and as modified. For example, if an IRB grants a partial waiver of authorization to allow a researcher to obtain PHI to recruit potential research participants, the researcher would still have to obtain authorizations from the subjects to use or disclose PHI for the study itself.
- b. **Total Waiver.** The Principal Investigator must maintain the following documentation of a total waiver:
 - 1) The name of the IRB (not the names of individual members of the board);

- 2) The date on which the waiver was approved;
- 3) The signature of the IRB chair, or other member designated by the chair;
- 4) A statement that the IRB has determined that the waiver satisfies the required criteria;
- 5) A brief description of the PHI that the IRB has determined is necessary for research purposes; and
- 6) A statement that the waiver has been reviewed and approved under either normal or expedited review procedures and that all applicable procedures were followed.

****Keypoint:** A waiver of individual authorization under this policy is *not* a waiver of the requirements of informed consent for the project or of any other consent required by UBMD. The IRB may waive or alter informed consent requirements, but the IRB must review a request to waive or alter informed consent requirements *separately* under criteria set forth in the Common Rule.

C. **Release of Medical Records**

1. If the patient Authorization or IRB waiver of authorization permits disclosure of the subject's *entire* medical record, the disclosure of such complete record will occur.

If the patient authorization or IRB waiver authorizes disclosure of a *portion* of the subject's medical records, (i.e. only data relating to treatment of asthma), the research data set to be disclosed by UBMD will be created by one of two mechanisms:

- a. If the researcher is a member of the UBMD Workforce, he or she may extract the data on behalf of UBMD and then disclose it to the researcher (i.e. to themselves). The Workforce member is responsible for ensuring that only the data identified in the Authorization Form or waiver of authorization is disclosed.
- b. If the researcher is not a member of the Workforce (i.e. an External Researcher), a UBMD business associate agreement must be signed by that person or the organization that employs the person before data extraction can occur. Furthermore, an External Researcher will request the medical records and pay any retrieval fees. Once the data has been extracted by the business associate on behalf of UBMD under the terms of the business associate agreement, the data can be disclosed to the External Researcher as long as only the data identified in the Authorization Form or IRB waiver is disclosed.

D. Research Subject Recruitment

- a. Prior to attempting to recruit a patient treated by UBMD provider(s), researchers will ask that patient's treating physician (for the condition under study) if the treating physician has any objection to requesting the patient's participation in the research as a subject. The treating physician will have seven days to reply to the request. If no reply is received at the end of the seven days, the researcher may contact the patient to request participation. If the treating physician objects to the recruitment of the patient into the study, the Principal Investigator will ensure the patient is not contacted.
- b. If the patient is not recruited while being seen during an appointment with a UBMD healthcare provider, the patient must be initially recruited by letter. The letter will have all UBMD Practice Plans listed on the letterhead and will state that the patient's UBMD provider agreed to the patient's recruitment as a research subject. If the patient does not respond to the initial letter, the researcher may attempt to contact the patient by telephone one time with one follow up call if the patient does not respond. If the patient expresses his or her desire to not be a research subject at any time, no follow-up is permitted.