# TITLE: RESEARCH AND HIPAA CLINICAL AND MEDICAL RECORDS POLICY:

Columbia University Medical Center will administer and conduct medical records research activities in accordance with city, state, and federal laws and regulations, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

#### **PURPOSE**

The purpose of this policy is to describe how Columbia University Medical Center will protect the privacy of an individual's Protected Health Information (PHI) when preparing for, prior to, during, and after medical records research activities.

## **PROCEDURES:**

## 1. Adherence to existing HIPAA Policies and Procedures

Individuals conducting or assisting with research activities will follow existing Columbia University Medical Center HIPAA Policies and Procedures. Individuals will also address and/or implement the additional requirements related to collecting, creating, storing, using, and disclosing PHI in human subjects research activities described in this Policy and in the HIPAA Clinical Research Activities Policy.

# 2. Scope of the PHI protected

HIPAA requires that Columbia University Medical Center protect all health information that is individually identifiable or which could be used to identify the individual. For a list of the identifiers that make health information individually identifiable, refer to Form G (Investigator's Certification for Research with De-Identified Data) available on Rascal.

#### 3. Oversight Board

- a. The Institutional Review Board (IRB). governs research involving human subjects and is responsible along with the researchers and for ensuring appropriate safeguards exist and are implemented to protect PHI used in research.
- b. The HIPAA Privacy Officer provides review, support and oversight for the HIPAA research requirements for protocols submitted to the IRB.

# 4. Medical record research activities

- Submit a Form D (Investigator's Certification for Reviews Preparatory to Research) to the Privacy Board prior to initiating any research activities.
  - 1. If the IRB has questions or requires further information about the research.
    - Submit a completed Form B (HIPAA Application for Waiver of Authorization) to the IRB prior to conducting any pre-screening of subjects.
    - b. If the Researcher has already identified the patients who will be recruited for or whose PHI will be used in the study, the researcher must:
      - . submit a completed Form A (HIPAA Clinical Research Authorization) for the purposes of obtaining authorization

from each study participant prior to initiating any further research activities.

- 2. If the study participant is not a patient of the researcher, the researcher must obtain permission from the patient's physician to communicate initially with the patient.
  - a. Generally, the Researcher should not contact any study participant prior to receiving approval to do so from the patient's physician.
  - b. The patient's physician is responsible for reviewing the study protocol and informing the patient of the risks and benefits that may inure to the patient if he / she participates in the study.
  - c. The patient's physician is responsible for communicating the names of the patients who are interested in participating in the study to the Researcher.
- 3. Form B is used typically for retrospective chart reviews and for other medical records research where subjects will not be contacted by a Researcher.
- 4. If the IRB does not approve the submitted Form B, the Researcher will be required to obtain a written authorization from each subject authorizing the Researcher to access and use the subject's PHI.
- b. Preparing a research protocol;
  - If not already done, submit a completed Form D (Investigator's Certification for Reviews Preparatory to Research) for purposes of:
  - ii. developing a research hypothesis; or
  - iii. Identifying the subjects whose records will be required as part of the research.
- c. The information being sought is solely for research on
  - i. If the medical records research involves the use of medical records of a decedent, the Researcher must provide the holder of the medical record with assurances that:
  - ii. The information being sought on the decedents is necessary for research purposes.

## 5. Clinical Research HIPAA Requirements

- . If the Researcher is engaging in "activities preparatory to research," he / she must submit a completed Form D (Investigator's Certification for Reviews Preparatory to Research) to Rascal prior to initiating any research activities.
  - 1. "Activities preparatory to research" are activities that are conducted:
    - a. for the purpose of preparing a research protocol;
    - b. developing a hypothesis;
    - c. writing a grant application; or
    - d. identifying subjects for recruitment.

#### 6. Using de-identified health information or a Limited Data Set

- . When the Researcher plans to use de-identified health information in his/her research activities the health information must qualify as de-identified, as defined in the HIPAA Privacy Regulations. (All identifiers have been removed).
  - a. In lieu of completely de-identifying health information, the Researcher may be able to use a limited data set.
  - b. Using either de-identified health information or a Limited Data Set eliminates the need to obtain authorizations from each of the subjects whose PHI is used or a waiver of authorization from the IRB.
- 7. **Questions.** Questions about clinical or medical records research activities that involve PHI or the procedural requirements should be directed to the HIPAA Privacy Officer.

#### 8. **Definitions**.

**Activities preparatory to research** - activities conducted for the purpose of (1) preparing a research protocol, (2) developing a hypothesis, (3) writing a grant application, or (4) for identifying subjects or records of subjects that will be recruited for the research.

Clinical Research - research in which clinical services are provided to patients.

**De-identified Health Information** means health information without any of the following identifiers:

- 1. Names;
- Account numbers;
- 3. Medical record numbers;
- Social Security Number;
- All elements of dates (except years) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89;
- 6. Telephone numbers;
- 7. Fax numbers:
- 8. All geographic subdivisions smaller than a state including, street address, city, county, precinct, and zip code (except for the initial three digits if the population exceeds 20,000);
- 9. Health plan beneficiary numbers;
- 10. Email addresses;
- 11. Internet Protocol Address Numbers (IP addresses);
- 12. Web Universal Resource Locators (URLs);
- 13. Device identifiers and serial numbers;
- 14. Certificate/License numbers;
- 15. Vehicle identification numbers and serial numbers:
- 16. Full face photographic images and any comparable images;
- 17. Biometric identifiers such as finger and voice prints;
- 18. Any other unique identifying number, characteristic, or code.

**Limited Data Set** - health information that contains only a limited number of identifiers that, combined, carry little risk of allowing identification of the individual. A limited data set may include only the following specific identifiers:

- 19. Zip code;
- 20. Age;
- 21. Dates (admission, discharge, enrollment, procedure, etc.)

**Medical Records Research** - research in which no clinical services are provided to patients. All PHI collected, created, used, stored, and disclosed comes from documentation or databases.

*Medical Records Researcher* or *Researcher* - an individual who conducts, assists with, or is involved in medical records research activities.

**Protected Health Information (PHI)** - information, including demographic information that may identify the patient, that 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 identifies or could reasonably be used to identify the individual.

**RASCAL** – Refer to the CUMC online research tool for a comprehensive HIPAA and Research manual.

**Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**RESPONSIBILITY:** Departments, HIPAA Privacy Officer

Institutional Review Board, Researchers

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