

TITLE: USES AND DISCLOSURES OF GENETIC INFORMATION

POLICY:

Columbia University Medical Center will use and disclose genetic information in accordance with its extremely confidential nature, but also as required by city, state, and federal laws and regulations, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

PURPOSE :

Genetic information is Protected Health Information (PHI) and, as such, is protected by city, state, and federal laws and regulations. However, because of its extremely sensitive nature, if genetic information is improperly used or released, the patient's privacy, healthcare, or other interests may be irreparably damaged. This Policy describes how, when, and by and to whom genetic information at Columbia University Medical Center will be collected, used, and disclosed.

PROCEDURES:

1. **Definitions..**

- a. "Genetic information" means any written or recorded individually identifiable health information resulting from genetic testing or medical evaluation to determine:
 1. the presence or absence of variations or mutations, including carrier status, in a patient's genetic material; or
 2. the presence or absence of genes that are scientifically or medically believed to cause a disease, disorder, or syndrome; or
 3. the presence or absence of genes that are associated with a statistically increased risk of developing a disease, disorder, or syndrome that is asymptomatic at the time of testing; and
 4. the findings or results of a genetic test; or
 5. documentation of counseling sessions to convey the genetic information to the subject individual.
- b. "Genetic testing" or "genetic test" means a test used to diagnose a pre-symptomatic genetic factor, including analysis of human DNA or RNA, mitochondrial DNA, chromosomes, proteins, or metabolites.
- c. "Protected Health Information" or "PHI" is information about a patient, including demographic information that may identify a patient, that relates to the patient's past, present or future physical or mental health or condition, related health care services or payment for health care services.

2. **Conducting genetic tests.** Prior to conducting any genetic testing of an individual patient, the patient's health care provider will:
 - . Notify the patient of the purpose for performing the test;
 - a. Disclose to the patient the proposed use of the resulting genetic information; and
 - b. Obtain the patient's written informed consent for the test prior to administering the test.

3. **Use of genetic information.** The patient's genetic information may be used only:
 - . for assessing or managing the patient's health;
 - a. for providing treatment; or
 - b. if the patient has signed an informed written consent to participate in an approved research study, for research.

4. **Disclosure of genetic information.** A patient's genetic information will not be disclosed without obtaining a written authorization from the patient unless:

the genetic test is required by law for reasons including but not limited to the following:

 1. to establish parentage;
 2. to determine the presence of metabolic disorders in a newborn by testing conducted pursuant to newborn screening and protocols;
 3. to furnish genetic information relating to a decedent to the blood relatives of the decedent for the purpose of medical diagnosis;
 4. in connection with a criminal investigation or prosecution;
 5. required under a specific order of a state or federal court;
 6. for identification of the individual; or
 7. for identification of human remains; or
 - a. the patient's genetic information disclosed will be used only as confidential research information in an approved research protocol; or
 - b. the disclosure has been approved by the HIPAA Privacy Officer.

5. **Questions.** Questions about whether collection, use, or disclosure of genetic information is proper should be directed to the HIPAA Privacy Officer.

RESPONSIBILITY: Departments, HIPAA Privacy Officer

ISSUED:	December 2003
REVIEWED:	October 2007
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