

It's All Relative: Does HIPAA Permit Researchers to Identify Prospective Biobank Participants Based on Health Information Provided by Family Members?

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Analytical goals

- To understand the importance of recruiting family groups for a genetic research biobank
- To identify which provisions, if any, of the federal Health Information Portability and Accountability Act (HIPAA) apply to a research biobank at Mayo Clinic.
- To discuss whether HIPAA allows a covered entity (in this case, Mayo Clinic) to utilize personal health information obtained from a relative of the subject of the information.

Introduction

The ultimate clinical utility of a biobank - particularly a rare disease biobank like the Mitochondrial Disease Biobank at Mayo Clinic - increases in proportion to the number of family groups that enroll. Access to information from related individuals, whether or not they are directly affected by the disease in question, assists researchers with the potential discovery of unique genes responsible for disease. The Mitochondrial Disease Biobank collects medical records and biological samples from individuals with mitochondrial disease. Affected individuals can either volunteer to participate, be invited to enroll during appointments with participating physicians, or they can be identified via a focused search of Mayo Clinic medical records. Patients identified through a review of medical records signed a Minnesota Research Authorization prior to being identified as eligible for an invitation, which signaled their willingness to be contacted about research participation.¹ Individuals who enroll in the Biobank are also encouraged to invite first-degree family members to enroll. Ideally, enrollees directly contact family members to discuss participation, who then in turn contact the Biobank. A more complex situation arises when an enrollee provides protected health information about a family member, and requests that Biobank follow-up with that individual.

Background

Biobank participants affected by mitochondrial disease frequently ask whether their family members can participate in the project. Enrollment of first-degree relatives is both allowed and encouraged, but Biobank staff have expressed concerns about the use of personal information conveyed by a third party. The Health Information Portability and Accountability Act (HIPAA) protects the ways in which Mayo Clinic can use such information- does it violate HIPAA's privacy rules to utilize personal data absent a patient-provider relationship? What are the best practices to respond to the following circumstances encountered during this project?

Case examples

- **Case one:** A woman visits her physician and is invited to join the Biobank. She agrees but requests an extra enrollment packet that she can take to her sister.
- **Case two:** A man sends the Biobank an e-mail describing his struggle with mitochondrial disease. He attaches a list of family members, and includes details about each person's symptoms and diagnosis, as well as their names and addresses. He asks that each be sent an enrollment packet.
- **Case three:** A woman calls the Biobank, and requests enrollment information for herself and her asymptomatic adult son, who lives in another state. She provides his contact information.

1. Mn. Stat. § 144.295 (2011).
2. 45 CFR § 164.104 (2010).
3. 45 CFR § 164.501 (2010).
4. 45 CFR § 164.502(a)(1) (2010).
5. Beskow, LM et al. Ethical issues in identifying and recruiting participants for familial genetic research. Am J Med Genet A. 2004 Nov 1;130A(4):424-31.

Does HIPAA apply to information patients disclose about family members to the Mitochondrial Disease Biobank?

- Who does HIPAA regulate? **Covered entities:**
Except as otherwise provided, the provisions of this part apply to covered entities: health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with any transaction referred to in section 1173(a)(1) of the Act. Sec. 164.104.²

The Biobank is part of an institution that provides health care and stores and transmits medical records electronically. Therefore, the Biobank is a covered entity according to the statute.

- What does HIPAA regulate? **Protected health information**, also known as **individually identifiable health information:**
Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:
 - 1) *Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and*
 - 2) *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*
 - i. *That identifies the individual; or*
 - ii. *With respect to which there is a reasonable basis to believe the information can be used to identify the individual.³*

The details Biobank participants share about their family members are given to Biobank personnel, who are clinic employees; thus the information is received by a health care provider, satisfying (1) above. If and when that information relates to the past, present, or future medical status of a specific person, and contains information sufficient to identify that person (2), it is protected health information regulated by HIPAA.

Case examples: When does HIPAA apply?

- **Case one:** HIPAA does not apply to this circumstance, since the patient did not share demographic information about her sister with the Biobank. In order to fall under the purview of the HIPAA rules regulating information privacy, Mayo Clinic must know both demographic and medical information about the relative
- **Case two:** The man in this example has shared both demographic data as well as details about the current health conditions of each of his relatives. The data therefore qualifies as protected health information, so HIPAA regulations must be followed in regards to how the information is used and disclosed.
- **Case three:** It is unclear whether familial genetic information qualifies as health information referred to in HIPAA. Does knowing that a man has a mother (or any first-degree relative) with mitochondrial disease constitute information that relates to a "past, present, or future physical or mental health or condition of an individual"? HIPAA only applies if it does.

When HIPAA applies, what is the result?

- 1) *Permitted uses and disclosures. A covered entity is permitted to use or disclose protected health information as follows:*
 - i. *To the individual.⁴*

HIPAA allows covered entities to disclose protected medical information to the person the information is about.



Discussion

The Mitochondrial Disease Biobank may legally use patient and family information resulting from all three example cases. It is unclear if mitochondrial disease in a first-degree relative qualifies as medical information under HIPAA, but whether it does or not is a moot point here, as the Biobank can continue recruitment under the current protocol either way. Although information that can identify a specific person is considered protected when coupled with medical information, HIPAA allows such information to be disclosed to the person the information is about, which is how the Biobank uses it.

Obtaining information about first-degree relatives from Biobank participants is legally acceptable, but ethically complex. Genetic disorders and predispositions are sensitive topics, and some individuals may wish to personally decide when such information is shared, and with whom. Recruiting individuals via mail using information provided by their relatives is risky for the Biobank.⁵ People who receive Biobank information in the mail may feel that their privacy was violated, particularly if they were previously unaware of the project. The very presence of the recruitment information in their home could also force the recipient to disclose personal information that the recipient wishes to keep private (if, for instance, a roommate sees the recruitment information). This feeling could negatively influence the individual's impression of the Biobank in general, and the clinic as a whole.

Mitochondrial disease is a severe life-limiting genetic condition, for which there is no cure and few treatments. Since it is a relatively rare disease, research proceeds slowly. The availability of samples from family members increases the power of genetic research and could expedite studies that will hopefully improve health outcomes.

The protected information the Biobank collects about potential participants from their family members is quite narrow. We know that each person has a first-degree relative with mitochondrial disease, and beyond that, we only request names, birth dates, and basic contact information. Sometimes we receive additional personal information, which is kept in a secure database and only disclosed to the person who is the subject of the information until enrollment.

The Mitochondrial Disease Biobank exists to provide research samples linked to medical information. HIPAA protects information shared with the Biobank, but allows disclosure of personal data to the person the data is about. Since the personal information being discussed here is limited in scope, and the potential benefits of research biobanking are great, it is ethically permissible to use protected information provided by family members to contact potential Biobank participants.