U-MIC TRANSCRIPT
Protected Health Information (PHI)

The Health Insurance Portability and Accountability Act (or HIPAA) Privacy Rule regulates the access, use, and disclosure of *protected health information* (or PHI) in human subjects research.

PHI is information

- created, used, or disclosed as part of an individual's health care;
- that others could use to identify that individual;
  and
- that is contained in the individual's
  - medical records;
  - billing records;
  - health plan records;
    or
  - other health care–related records.

In the University Health system, we collect the information contained in these records in the course of treatment, payment, and operations—or TPO.

Any *individually identifiable health information* that a *covered entity* possesses or transmits in any form is considered PHI. Covered entities include

- health care providers;
- health plans;
- employers;
  and
- health care clearinghouses, such as billing companies.

At the University of Michigan, certain schools and divisions are part of the Covered Entity, while others are not. U of M's Covered Entity consists of:

- the Health System, including hospitals and clinics;
- the Medical School;
- some aspects of the Dental School, the School of Nursing, Kinesiology, Public Health, the University of Michigan Transport Research Institute, and occasionally other units;
- and all faculty and staff within those schools and facilities.

Individually identifiable health information is information that relates to:

- an individual's past, present, or future physical or mental health;
- the health care an individual receives;
  or
- any past, present, or future health care payments;

and

that enables, or may enable, others to identify that individual.

In most cases, researchers must obtain a subject's authorization before accessing PHI. The Privacy Rule does, however, define certain circumstances under which a researcher may be allowed to access PHI without a subject's authorization.

For example, the researcher may request a waiver of HIPAA authorization. The Privacy Board or the IRB may grant a waiver only if

- the access, use, or disclosure of PHI involves no more than minimal risk to subjects' privacy;
- the study could not be conducted without a waiver;
  and
- the study could not be conducted without access to PHI.

A researcher may also be allowed access to PHI without a subject's authorization

- when using PHI solely in preparation for research;
- when accessing PHI about individuals who are now deceased;
  or
- when accessing a *limited data set*, in accordance with a data use agreement between the covered entity disclosing the PHI and the researcher accessing it; a limited data set does not contain certain types of identifiers.

In all other situations, researchers must obtain a subject's authorization before accessing PHI.

Contact the Privacy Board or the IRB for more information about PHI in research.

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