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;
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.

*Posted: 7/11/2012*