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The Health Insurance Portability and Accountability Act (or HIPAA) Privacy Rule is designed to protect the privacy of protected health information (or PHI) that healthcare providers keep about their patients. HIPAA also regulates the access, use, and disclosure of PHI in research.

PHI is information

- created, used, or disclosed as part of a person's health care;
- that others could use to identify that person;
- and
- that is contained in records relating to treatment, payment, and operations (or TPO); these include
  - medical records;
  - billing records;
  - health plan records;
  - or
  - other health care–related records.

The IRB or Privacy Board is responsible for reviewing research involving PHI. Studies involving U of M Health System patient data should undergo review by IRBMED, to ensure that they comply both with human subjects research regulations and with the HIPAA Privacy Rule.

Usually, a researcher must obtain a subject's written authorization before using or disclosing that subject's PHI. A signed HIPAA Authorization allows the researcher to use or disclose the subject's PHI in a particular study. Keep in mind that HIPAA Authorization included in a clinical consent document *does not* cover research-related activities.

Under certain circumstances, a researcher may use and disclose PHI in research without a subject's authorization. For example, the researcher may use or disclose PHI without HIPAA Authorization in a limited data set, according to the terms of a Data Use Agreement. A limited data set does not include information that directly identifies the subject or others. Additionally, a researcher does not need subjects' HIPAA Authorization

- to review PHI for projects that are preparatory to research
- or*
- to use or disclose a deceased person's PHI

In certain cases, an IRB may grant a waiver of HIPAA Authorization. A HIPAA waiver may apply to the full duration of a study or only to part of it, such as the recruitment period, and may apply to all subjects or only to some. An IRB may grant a waiver of HIPAA Authorization if the study at hand meets all of the following criteria.

- First, the use or disclosure of PHI present no more than minimal risk to subjects' privacy. This requires adequate plans to protect health information identifiers from improper use and disclosure and to destroy identifiers as soon as possible, as well as the researcher's written assurance that PHI will not be reused or shared with others.
- Second, the research could not practicably be conducted without the waiver.

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- Third, the research could not practicably be conducted without access to and use of the PHI.

For projects involving access to or use of PHI, a researcher requesting a full waiver of informed consent should also request a waiver of HIPAA Authorization for the entire project. If the consent waiver will apply only to recruitment, with documented consent to follow, the researcher should request a waiver of HIPAA Authorization for the recruitment portion.

The IRB or Privacy Board should discuss requests for full or partial waivers of HIPAA authorization and should document their decision in the meeting minutes.

An IRB or Privacy Board member performing an Expedited review should document in the reviewer checklist whether the study meets the criteria for a waiver of HIPAA Authorization.

*Posted: 7/24/2013*