**Research**

The federal government recently passed a national rule regarding the privacy of health information that impacts the Medical College of Wisconsin’s ability to use this information to carry out its research mission and conduct its day-to-day activities. This national rule is called the Privacy Regulation and is part of the Health Insurance Portability and Accountability Act (HIPAA).

The Privacy Regulation defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” The two most common methods for accessing protected health information (PHI) in research are:

- **Patient Authorization (Form)** - For most research involving human participants, the Principal Investigator must obtain the patient’s authorization to use PHI in research. At Froedtert and the Medical College this authorization language must be included in an approved Informed Consent for all new studies. For previously approved studies it may be a separate “Authorization to Use or Disclose Protected Health Information in Research” form.
- **Request for Protected Health Information in Research Without Patient Authorization (Form)** - Under certain circumstances, the Institutional Review Board (IRB) may grant a request to access PHI for research without a patient’s authorization. Examples include research involving retrospective data analysis or chart review, and identification or recruiting of research participants.

In addition, there are other methods of using PHI in research with differing requirements:

- **Research on Decedent’s Information** - If the research is conducted on a decedent’s PHI, it is possible to receive an expedited IRB review of the study.
- **Reviews Preparatory to Research** - It is possible to access PHI for preliminary research purposes such as hypothesis development or feasibility assessment.
- **De-Identified Data** - Health information that excludes all 18 patient identifiers before it is given to the research team is not considered protected health information. As a result, this type of information can be used/disclosed for research without IRB review.
- **Limited Data Set and Data Use Agreement** - Similar to “De-Identified Data” but dates and some geographic information can be used. This requires a data use agreement and IRB review.

If you wish to learn more about HIPAA and Research, and to access the forms described above, please visit the MCW HIPAA website at [http://infoscope.mcw.edu/display/router.asp?DocID=7961](http://infoscope.mcw.edu/display/router.asp?DocID=7961).