A Review of Regulations, Wisconsin Law, and Best Practice

★Excerpt from the May 2016
Clinical Trials Communication Committee (CTCC) Newsletter★

By: Rachel Delaney, Corporate Counsel Research

Properly obtained informed consent is a key element of any research study or clinical trial. Here is a summary of best practice approaches and legally required approaches to obtaining informed consent:

1. What is the physician’s duty in obtaining informed consent?
Wisconsin law requires physicians to perform the discussion of risks, benefits, and alternatives to obtain informed consent for clinical interventions (Wis. Stat. 448.30). Therefore, when a trial or study requires a clinical intervention, the physician must conduct the risks, benefits and alternatives discussion with the study subject for that intervention. If the trial or study does not require a clinical intervention, the risks, benefits, alternatives discussion may be done by a person qualified to do the discussion who is not a physician.

The Common Rule goes farther than discussion of risk, benefits, and alternatives for proper informed consent to be obtained. However, the Common Rule does not require that the additional elements of informed consent outside of the risks, benefits and alternatives discussion be done by a physician. Those additional elements may be delegated to a person with the right training and qualifications.

2. Can physicians delegate the risks, benefits, alternatives discussion to non-physician practitioners?
In Wisconsin, the risks, benefits, alternatives discussion must be done by a physician when there is a clinical intervention that will be ordered or performed by the physician. The physician cannot delegate this duty to a non-physician practitioner. However, a non-physician practitioner may conduct the risks, benefits, alternatives discussion with the patient for general consent to participate in the study, so long as the physician obtains separate consent for the specific clinical intervention that the physician is ordering or performing.

3. What is the appropriate timing of obtaining informed consent for research studies?
Informed consent must be obtained prior to screening the research study subject. Wisconsin law requires hospitals to obtain prior informed consent for the patient’s participation in any form of research (DHS 124.05(3)(i)). Screening a patient is a form of research because it is a procedure required by the study protocol. FDA subregulatory guidance indicates that while an investigator may discuss the availability of and possibility of studies with a prospective patient without first obtaining consent, informed consent must be obtained prior to initiation of any clinical screening or procedures, including procedures performed to determine eligibility for participation in the study. Work that is done as preparatory to research may still be done prior to obtaining informed consent, as permitted by HIPAA.

The informed consent duty in Wisconsin has been elevated to a higher standard due to recent court interpretations of medical malpractice actions where negligent consent is claimed as a separate cause of action (See, Jandre v. Physician’s Insurance Co. of Wisconsin). Documenting that informed consent was properly obtained is the best defense to show that consent was properly obtained by a qualified individual prior to initiation of any research procedures.