September 26, 2017

IRB Announcement – Shinal Case and Human Research

Thomas Jefferson University's Response to the Shinal Case as It Pertains to Human Research

On June 20, 2017, the Pennsylvania Supreme Court ruled in the case, *Shinal v. Toms*, which has ramifications for obtaining a patient's informed consent for research participation. In *Shinal*, the treating physician's physician assistant obtained the patient's signed written consent form for treatment for brain surgery. Unfortunately, during surgery, Mrs. Shinal suffered permanent injury from complications and sued the physician, alleging his failure to explain the risks of and alternatives to her surgery. The Court ruled that obtaining informed consent was not delegable and required direct physician interaction with the patient. The Court stated*: "**Informed consent requires direct communication between physician and patient, and contemplates a back-and-forth, face-to-face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent. The duty to obtain the patient's informed consent belongs solely to the physician."***

OHR and Jefferson's Legal Counsel have reviewed the implications of this case as it relates to obtaining consent in the research setting. We are in the process of full evaluation of our policies and informed consent template, but ***at the current time, the Shinal case does not change our approach to obtaining consent as outlined in our policies***.

The *Shinal* case concerned medical treatment and not research. The policies for securing patient consent for medical treatment at Thomas Jefferson University Hospitals (TJUH) are consistent with Pennsylvania's MCARE Act (see below) and other applicable laws. See, TJUH Policy No. 117.03 Informed Consent that states in part: "The responsible attending or consulting physician, or his/her physician designee, shall provide the patient or patient surrogate with a full explanation of the procedure and/or treatment to be performed, the foreseeable consequences, the benefits, the potential short and long term risks, complications, alternative courses of treatment, likelihood of achieving treatment goals and possible results of non-treatment".

The research consenting process for Jefferson is outlined in OHR policy IC 701. The principal investigator is responsible for ensuring that the consent process meets regulatory standards. An investigator (PI or a Co-I) must be available to review directly with research subjects certain key information and address any questions they may have. Other elements of the consenting process can be delegated to key personnel, but an investigator's signature on the research consent attests that an investigator was able to directly address risks with the subject or legally authorized representative and to answer questions. An investigator is not required to be present during the entire consenting process, as there may be elements of consent better addressed (compensation procedures, screening schedule) by key personnel. These requirements outlined in our policy have not changed in response to the *Shinal* ruling.

Our interpretation has largely followed that of other hospital systems within Pennsylvania. An excellent commentary outlining issues in more detail is available. We will update the Jefferson research community of any changes, but in the mean time we would welcome any questions you or sponsors have about our approach to research consent.

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The Medical Care Availability and Reduction of Error (MCARE) Act of 2002 states:
(a) Duty of physicians. Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:
1. Performing surgery, including the related administration of anesthesia
2. Administering radiation or chemotherapy
3. Administering a blood transfusion
4. Inserting a surgical device or appliance
5. Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner