Jefferson - Office of Human Research (OHR)

OHR Announcement

Subject: Changes to Investigator Signature Options in Consent Form - November 11, 2021

A change to state law and the Jefferson Hospital Policy has resulted in the need to change the consent requirements for research. These requirements have been part of the research consent process for several years, and even though it is changing, it is now simpler and less restrictive. These requirements apply to all Jefferson studies regardless of location.

If a study involves MCARE procedures (see list in OHR Policy IC 701), a physician investigator or "qualified practitioner" must review the purpose, procedures, risks, benefits, and alternatives to participation with the study participant. The other elements of consent may be provided by properly trained and qualified key personnel.

For this purpose, the term "qualified practitioner" means a co-investigator or key personnel who is one of the following: Physician Assistant, Certified Registered Nurse Practitioner, Midwife, Certified Registered Nurse Anesthetist, another physician or a physician participating in a medical residency or fellowship training program who has knowledge of the patient's condition and the procedure to be conducted on the patient and shall be acting under the supervision of, at the direction of, or in collaboration or cooperation with, the physician.

There are now 2 investigator signature line options in the consent form. For each option, the investigator is certifying that the appropriate individual(s) reviewed the consent information with the study participant. For studies involving MCARE procedures, the investigator must be a physician. Please note that in both cases the investigator signs the consent form. The difference is in what the investigator is certifying.

OPTION 1: Include for studies involving MCARE procedures.

By signing below, you the **physician investigator**, certify that you and/or a qualified practitioner who is also a co-investigator or key personnel, reviewed the purpose, procedures, risks, benefits, and alternatives to participation with the study participant. The other elements of consent may be provided by properly trained and qualified key personnel.

OPTION 2: Include for all other studies.

By signing below, you the **investigator**, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

For ongoing studies, you may keep the investigator signature line in the consent form as is. The options above will be used for new studies.