AdvocateAuroraHealth

Memo

Date: April 2022

From: AAH Research Subject Protection Program/ AAH IRB

Re: ***Purpose of the last page of the AAH IRB consent document***

Research Subject Protection Program

In accordance with federal regulations and AAH RSPP/IRB policies and procedures, the Principal Investigator of the research study must conduct the consent interview unless he or she delegates his or her responsibility for conducting the informed consent interview to another individual who is both knowledgeable about the research study and under the investigator's direct supervision.

If the research study is conducted in the state of Wisconsin and involves a medical treatment or intervention in which consent is normally obtained in the clinical setting, and the medical records will be maintained at an AAH facility, Wisconsin state law requires documentation that a physician [who is the principal investigator or a sub-investigator in the study] has informed the patient [subject] about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. It is the AAH RSPP/ IRB's position such discussion should take place prior to the initiation of any research related activity, and any attempt to delegate this responsibility to another individual (e.g., a non-physician study coordinator) would constitute a breach of the physician's duty to provide informed consent under state law. However, it is ultimately the Principal Investigator's decision.

The last page of the consent document is used to verify and document for AAH's medical record the specific individual who had explained to and discussed with the subject, or the subject's Legally Authorized Representative, Legal Guardian, Health Care Agent, or Parent, as appropriate, the following items related to the above procedure(s) before the initiation of the research-related intervention:

- The nature of the research
- Potential risks and benefits
- The alternate treatments available to the subject and the benefits and risks of each

This page of the consent is located after the subject's signature page, and is not initialed by the subject. As long as the documentation shows that the consent discussion took place before any research-related intervention was initiated, this page does not need to be signed on the same day that the subject signed the consent document.