November 6, 2014

The DUHS IRB has posted a new policy regarding male research subjects’ partners who become pregnant while the male subject is involved in a research study using an investigational drug. When a sponsor requests the use of or submits a pregnant partner consent form, please use the new template information sheet, rather than the sponsor-provided form. The new policy and template may be found via links below.

This template and policy give the pregnant partner information regarding why she is being asked to provide PHI (for herself and/or her infant), make it clear that providing this information is voluntary, and require the use of either DUHS’s Authorization to Release Protected Health Information? (medical release form) or the authorization/release form at the entity where the pregnant partner is a patient. Study specific language can be added/revised as appropriate, but key points to remember are that this is an information form, not a consent form. The pregnant partner is not a subject in the study. Permission/authorization occurs when the pregnant partner signs the medical release form.

Pregnant Partners of Research Subjects Policy

Pregnant Partner Information Form