**VUMC IRB Guidance Regarding Pregnant Partner Forms:**

When the collection of pregnancy outcome data is limited to safety surveillance, neither the pregnant partner nor the infant is considered a human participant under FDA regulations.

According to 45 CFR 46, the partner/infant would be considered a human participant if the protected health information (PHI) collected about them were to be used or disclosed for research purposes. Under 21 CFR 50 the partner or infant would not meet the definition of a human participant, nor would the collection of this data be considered a clinical investigation as defined by 21 CFR 50.

In accordance with the aforementioned regulations, when a pregnancy occurs in the partner of a research participant, this is considered a safety event, and the VUMC IRB does not consider the partner to be a research participant (i.e. collection of this information does not meet the definition of “Research” under 45 CFR 46). Therefore, the VUMC will not review and stamp pregnant partner consent forms as research consent documents. The collection of this PHI, though, does requires HIPAA authorization from the pregnant partner. This authorization document will not be stamped by the IRB, per the reasons stated above, but it can and should be used in instances where a pregnant partner needs to provide authorization for release of their protected health information.

Alternatively, if a pregnant partner will have research procedures performed on them, they will be included in study enrollment numbers, and the data being collected from them is for research purposes, then they are considered research participants. If the pregnant partner is a research participant, then the VUMC IRB will review and approve the Pregnant Partner consent form as a research informed consent document. This consent document will need to have all of the required elements of informed consent in accordance with the federal regulations, and include all locally required institutional language pertaining to informed consent documents.