From: OC GCP Questions
To: [redacted]
Subject: IRB review of plans to collect pregnancy outcome data in a clinical trial
Date: Monday, July 23, 2018 10:05:00 AM

Good morning –

We receive very few pregnant GCP questions. We suggest you contact the Division listed on the draft guidance that you mentioned in your email.

Division of Pediatric and Maternal Health (CDER) at (301) 796-2200 website Development Resources > Pediatric and Maternal Health Product Development

Or the Office of Pediatric Therapeutics. Please their website below.

Office of Special Medical Programs > Office of Pediatric Therapeutics

Please see the lower right hand corner to contact OPT directly.

Kind regards,

The OGCP Group

From: [redacted]
Sent: Thursday, July 19, 2018 10:02 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: IRB review of plans to collect pregnancy outcome data in a clinical trial

Good evening,

As you know, clinical trial protocols typically include plans to collect pregnancy outcome data in case a female subject (and sometimes a female partner of a male subject) becomes pregnant while on study drug or shortly after discontinuing study drug. In some cases, the study consent form provided to the IRB includes language to inform subjects of this possibility in case a subject becomes pregnant while on study. If such language is not included in the consent form, our IRB expects that, if a subject becomes pregnant on study, the study team would report the pregnancy to the IRB and submit a consent form for IRB review/approval at that time to obtain subject consent to collect pregnancy outcome data.

FDA Draft Guidance: Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials states the following:
"The FDA regulations do not contain a section similar to 45 CFR part 46, subpart B; however, the FDA recommends that these requirements be satisfied for FDA-regulated clinical research."

When research involves pregnant women, our IRB makes a determination that the requirements of 45 CFR part 46, subpart B are met, even if the research is not federally funded. Assuming pregnant women are excluded from the study and subjects are advised not to become pregnant while on study, does FDA expect the IRB to explicitly consider and document determinations under subpart B

just to cover the planned collection of pregnancy outcome data in case a female subject or female partner of a male subject gets pregnant while on study?

Thank you in advance.

[redacted]

[redacted]

[redacted]