From: OC GCP Questions
To: [redacted]
Subject: question re: following pregnancy
Date: Monday, July 25, 2016 12:14:00 PM
Attachments: [redacted]

Good afternoon –

Sorry for the delay in responding to your question. My office did some searching and could not find any FDA guidance that is directly on-point for the question you asked. We also checked with the folks in Maternal Health and they confirmed there is no guidance on this point. Essentially there is no FDA guidance directly on point for the issue you are raising. Perhaps the institution you are dealing with truly does not have any local guidelines in which case the sponsor may need to guide them in what needs to be done. Our experience is that when there is a protocol driven plan to follow resulting pregnancies until completion, most sponsors have a standardized plan to capture the required information and do not rely on "local guidelines." If the push back is about including the plan to follow pregnancies until completion in the informed consent document then the response to the site would be that it should be in the ICD because the plan to follow pregnancies would be considered a "procedure to be followed" (21 CFR 50.25(a)(1)). It could also be argued that it is needed to in order to mitigate risk.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, July 21, 2016 11:24 AM
To: OC GCP Questions
Subject: question re: following pregnancy

Greetings.
I would like to know if there is any specific guidance issued by the FDA regarding following pregnancy through to outcome.

I know that 21 CFR 50.25 (a)(1) notes the inclusion in the eCRF of the items to be followed in the trial.
ICH guideline E8, Section 3.1.4.3 (a) addresses the need to follow pregnancy in study patients.
ICH Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting

E2D section 5.4.1 also refers to following pregnancy.

I have a regulatory coordinator at a site who is fighting me about including language that pregnancy will be followed *per local guidelines and data privacy*, stating that there are no local guidelines.

I appreciate your response.

[redacted]