From: OC GCP Questions
To: [redacted]
Subject: Requirements for birth control
Date: Friday, October 19, 2018 2:32:49 PM
Attachments: [redacted]

Good afternoon –

There is a FDA *draft* guidance that was issued in April 2018. "Pregnant Women Scientific and Ethical Considerations for Inclusion in Clinical Trials" https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM603873.pdf. I am not sure if your question is addressed in this guidance.

However, it is probably best to consult the contacts on the guidance. Please see below.

For questions regarding this draft document, contact the Division of Pediatric and Maternal Health (CDER) at (301) 796-2200 or the Office of Communication, Outreach, and Development (CBER) at 800-835-4709 or 240-402-8010.

Division of Pediatric and Maternal Health --About the Center for Drug Evaluation and Research > Division of Pediatric and Maternal Health

Office of Women's Health - Office of Women's Health

Consumer Updates > Pregnancy: A Time for Special Caution

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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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: Friday, October 19, 2018 1:44 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Requirements for birth control

Good afternoon,

If a study does not specify that birth control is required however the protocol states the subject should not be actively pursuing fertility is there any guidance in ICH GCP about this?

Kind Regards,