From: OC GCP Questions
To: [redacted]
Subject: RE: research protocols and Catholic Ethical and Religious Directives
Date: Friday, September 05, 2014 9:06:48 AM
Attachments:

Dear [redacted],

Given the details you provided, your IRB's advice to the sponsor to amend the protocol in the usual manner and submitting a protocol amendment to the FDA is appropriate. If the sponsor has any concerns with your advice they may contact the review division responsible for their IND for additional guidance, if needed.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Kevin

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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, August 29, 2014 9:21 AM
To: CDER DRUG INFO
Subject: research protocols and Catholic Ethical and Religious Directives

Dear FDA,

My office reviews research at [redacted], a health system comprised of more than [redacted] hospitals. Within the city of [redacted] and its immediate environs there are [redacted] hospitals, one of which is a Catholic hospital- [redacted]. In order for clinical research to be conducted at [redacted], study documents are reviewed for adherence to the Catholic Ethical and Religious directives (ERDs). Part of the review for is the presence of birth control/contraception language, which is not acceptable per the ERDs. If the protocol and/or ICF includes birth control language, the study cannot be conducted at [redacted] or any of its affiliated offices.

There have been IND trials with birth control language that have been denied at [redacted] (but allowed

to proceed at other [redacted]. Following denial, some sponsors have offered to provide separate [redacted]-only protocols (with revised birth control language), or "Local Protocol Notes to File/Addenda." These documents were to be created for use at [redacted] (to fulfil the ERD requirements), while all other research sites would continue to use the original protocol.

[redacted] has not approved these proposals. We have instructed the sponsors that if they choose to revise/remove birth control language they must amend the protocol in the usual manner and submit that amendment to the FDA for approval, as it affects the safety of subjects.

I'm contacting FDA because this is primarily an issue with IND trials, most of which (appropriately) include birth control language. I'd like information and guidance regarding these proposals for separate protocols/addenda. The first time it was proposed I thought this was completely inappropriate and could not be approved. Now that there have been three different sponsors offering us separate documents, I am wondering if there is some regulation that allows this.

Feel free to call me to discuss.
Many thanks,
[redacted]

[redacted]