From: OC GCP Questions
To: [redacted]
Subject: RE: deception in description of randomization procedure
Date: Thursday, September 01, 2016 1:03:00 PM

Dear [redacted] -

Thank you for your question. You are correct that the FDA regulations for informed consent do not permit alteration of the consent elements. From the brief description of this issue, it sounds as if, by design, the sponsor does not want to fully describe the randomization scheme until completion of the study, and plans to disclose what each subject received after conclusion of the study. What you describe suggests that the proposed language for the ICF regarding randomization for Phase 2 that you shared is not accurate and you are trying to determine how to best address this issue in the ICF.

Some IRBs include a description of the randomization scheme in the ICF. Other approaches may be acceptable and, rather than provide inaccurate information in the ICF, the IRB may choose to consider an alternative approach for this study given its design. The IRB may decide to describe the products involved in the study, and it may be appropriate to generally indicate that subjects will receive both products at some point during the study. Keep in mind that I don't have the details of the study, or any information about how the ICF explains what the purpose of the study is, but I offer the following points for consideration:

- The ICF may need to describe that both lens A and lens B will be used in the study, that both products are FDA-approved (as long as this is an accurate statement, which I am not able to confirm given the limited information provided), that subjects will receive both products during the course of the study, and that subjects will be told which product they received in Phase 1 and Phase 2 after their participation in the study is completed (or as described in the IRB-approved protocol).

- The IRB may consider, if applicable, including a general statement in the ICF that tells prospective subjects that at some point in the study all subjects will get lens A and lens B. It should be clear to prospective subjects that they will have exposure to both lens A and lens B during the course of the study.

- The ICF may need to clearly describe why the information about assignment in Phase 1 and Phase 2 will be withheld until completion of the study (e.g., so that it does not bias or influence the subject's experience).

- The IRB will want to ensure that the information provided about the purpose of the study outlined in the ICF is in line with whatever is said in the section describing study procedures and which products subjects will receive (which in this case is both products).

There may be other alternative mechanisms the IRB considers in how to best describe what will transpire during the study without biasing prospective subjects. The ICF should be clear to inform prospective subjects that they will be exposed to both products during the course of the study. I suggest you discuss your question with the IRB and appropriate institutional officials as there may be other mechanisms to consider based on the details of the study.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

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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: Tuesday, August 30, 2016 3:43 PM
To: OC GCP Questions

Subject: deception in description of randomization procedure

Good afternoon,

This question pertains to a study of 2 FDA-approved contact lenses. The study will have 2 phases; all subjects wear lens A in phase 1, and all subjects transition to lens B in phase 2. The study is designed to measure user comfort when transitioning between the 2 lenses.

Our question arises because the proposed consent form specifically describes a randomization scheme whereby subjects will be randomized to either lens A or lens B in phase 2; in fact, all subjects will receive lens B in phase 2. The investigative team plans to debrief subjects at the conclusion of the study to tell them that the randomization scheme described in the consent form was not observed (by design) and that all subjects received lens B in phase 2.

Recognizing that FDA regulations for informed consent do not allow alteration of the consent elements:

1. Can you confirm that it would be inappropriate to inaccurately describe the phase 2 randomization schedule in the consent form?
2. Can you confirm that it would be appropriate for consent language to state "you will receive either lens A or lens B in phase 2," without making a description of the randomization scheme for phase 2?

Thank you for your consideration of this inquiry.

[redacted]