From: OC GCP Questions
To: [redacted]
Subject: RE: 21 CFR 50.25(c)
Date: Thursday, August 13, 2015 3:05:00 PM

Good afternoon,

Please be aware that the determination of whether a trial is an applicable clinical trial (ACT) must be made by the responsible party associated with that trial and familiar with all aspects of the clinical trial. FDA cannot make that determination for any party. Trials which do not meet the definition of an ACT have no statutory obligation to register or submit results to ClinicalTrials.gov.

Should the IRB disagree with the responsible party's determination of whether a trial meets the definition of an ACT and the need to include the statement at 21 CFR 50.25(c), the IRB may wish to consider handling the situation in a similar manner to that described for determining whether an IND or IDE is needed. FDA's guidance document IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed suggests that the IRB request supporting information from the sponsor regarding the basis for its determination. If the issue cannot be resolved, that IRB can follow its procedures for resolving controverted issues.

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

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

From: [redacted]
Sent: Tuesday, August 11, 2015 7:44 PM
To: OC GCP Questions
Subject: 21 CFR 50.25(c)

Hello,

I have several questions relating to 21 CFR 50.25(c).

Our IRB is being presented with a device study in which the objective is to evaluate the uncorrected binocular distance, intermediate and near visual acuities, and assess patient's

spectacle independence and satisfaction in individuals undergoing bilateral cataract extraction that have received two different arms of [redacted] of the same diffractive-multifocal model.

All study subjects will receive the same [redacted] in their dominant eye. Of these study subjects, half will receive one [redacted] in their non-dominant eye and the other half will receive a different multifocal 1-piece IOL in their non-dominant eye. All 3 [redacted] being used in this study are currently marketed and being used according their approved labeling.

The intent is to determine which arms can “outperform” the “conventional” approach of implanting a [redacted] with the same addition in both eyes regarding binocular uncorrected visual acuities for distance, intermediate and near, providing superior patient outcomes and satisfaction.

Based on our review of the definition of "applicable clinical trial" from reading the “ELABORATION OF DEFINITIONS OF RESPONSIBLE PARTY AND APPLICABLE CLINICAL TRIAL,” document dated March 9, 2009, which is linked from the clinicaltrials.gov website, it would appear that the study being proposed meets the definition of an applicable device clinical trial. We feel that 1) it is prospective clinical study of health outcomes, (2) it compares an intervention with a device against a control in human subjects (the study has 2 arms each with different interventions (but would this qualify as a control?)); and (3) the studied device is subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (FDC Act).

However, the study sponsor is asserting that registration of this study on clinicaltrials.gov is not required, as they do not believe it meets the definition an "applicable clinical trial." Based on their assertion, the required statement as described in 21 CFR 50.25(c) has not been included in the sponsor’s draft informed consent document and they are objecting to the IRB adding the statement.

Based on this information, would you agree that this device trial would indeed meet the definition of an "applicable clinical trial,” thus requiring registration on clinicaltrials.gov?

It is my understanding that the investigator and/or sponsor are responsible for determining whether a trial is an applicable clinical trial. However, if the IRB disagrees with this determination, is it within our purview to require they register?

Thank you in advance for your input.

[redacted]