From: OC GCP Questions
To: [redacted]
Subject: RE: GCP Question_EC chairman
Date: Tuesday, April 14, 2015 3:56 00 PM

Dear [redacted]

Thank you for your question, which Doreen assigned to me for a response. If I understand your question correctly, I think you are saying that the IEC Chairman, as an IEC member, was involved in the review of, and voted to approve a clinical study for which he/she also signed the clinical trial agreement. You stated that the IEC Chairman is neither the principal investigator nor subinvestigator on the specific study. I believe you are asking whether, by voting to approve the study AND signing the clinical trial agreement for that same study, the IEC Chairman should be considered to have a conflict of interest on an FDA-regulated study.

The FDA regulations regarding IRB membership can be found at 21 CFR 56.107 (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.107). In addition to describing the composition of the IRB membership, the regulations also state that no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The FDA regulations do not specifically define what constitutes an IRB member conflict of interest. When the regulations are silent, IRBs and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met. To assist in developing IRB written procedures, IRBs may consider the current guidance on this topic and address the issue of IRB member conflict of interest in their IRB written procedures.

FDA has guidance titled, "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" that applies to human subjects research conducted or supported by HHS or regulated by the FDA (see - http://www.hhs.gov/ohrp/policy/fguid.pdf). This guidance document provides some points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects and if so, what actions could be considered to protect those subjects.

The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf), addresses IRB member conflict of interest in section 3.2.1 and states that only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.

Also, FDA Information Sheet guidance – Frequently Asked Questions, section II, question 12 (available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm) provides guidance about selecting IRB members and states that when selecting IRB members, the potential for conflicts of interest should be considered. When members frequently have conflicts and must absent themselves from deliberation and abstain from voting, their contributions to the group review process may be diminished and could hinder the review procedure. Even greater disruptions may result if this person is chairperson of the IRB.

FDA also makes our inspection Compliance Program Guidance Manuals (CPGMs) available on our web site at http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm255614.htm. The CPGMs were developed to provide uniform guidance and specific instructions for FDA inspections of the various stakeholders involved in clinical studies (e.g., Clinical Investigators, Sponsors, IRBs). You can see in the CPGM for IRB inspections, there are various references to ensuring that no IRB member participates in the deliberation or voting of any study for which he/she has a conflict.

I recommend that you determine, in accordance with your IEC's written procedures, and in consultation with other appropriate members of your institution, whether the IEC Chairman has any conflict of interest given his/her role as IEC Chairman and the additional institutional duties for signing clinical trial agreements, keeping in mind that any IRB member who is determined to have a conflict of interest may not vote or count towards quorum on that project. FDA recommends that IRB members with a conflicting interest in a project recuse themselves by leaving the meeting room when the IRB conducts review of that project, except when requested by the IRB to be present to provide information. Any IRB member recusal should be noted in the minutes of the IRB meeting when recording votes on that IRB action.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again 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

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Friday, April 10, 2015 7:42 PM
To: OC GCP Questions
Subject: Re: GCP Question_EC chairman

Dear Doreen,
I would like to know if the EC chairman signed the contract while voted for study approval is fine.
Thank you very much.

[redacted]

On Apr 11, 2015 2:00 AM, "OC GCP Questions" <gcp.questions@fda.hhs.gov> wrote:

Good afternoon –

Could you please restate your question as I am not sure I understand your specific question?

Thank you!

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

From: [redacted]
Sent: Friday, April 10, 2015 2:57 AM
To: OC GCP Questions
Subject: GCP Question_EC chairman

> Dear Sir/Madam,
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> I'm writing to you to seek for your opinion for a question of EC chairman responsibility against GCP.
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> An EC chairman presented in an EC meeting to approve a clinical study and his name is listed in the EC membership list which provided to study team.
>
> The chairman also signed the contract/agreement for the same study. Because he is assigned/authorized (written documents provided from the institute) by the institute to act as an institution representative to sign clinical agreement/contract which included of study budget/financial/insurance etc. in which agreed by all parties.
>
> Please be noted that the chairman doesn't involved in conducting the study neither the principal investigator nor sub investigator.
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>
> With the circumstance, may I know your opinion if it is acceptable or will it be an FDA audit issue or called as a conflict of interest?
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>
>
> Look forward to hearing from you.
>
>
>
> Thank you very much,
>
>

[redacted]