From: OC GCP Questions
To: [redacted]
Cc: [redacted]
Subject: RE: Query on providing IRB member List to Sponsor
Date: Friday, October 20, 2017 2:06:11 PM
Attachments: [redacted]

Dear [redacted] -

Thank you for your questions. I understand that you contacted OHRP with these same questions and received a response on behalf of OHRP. I will respond to your questions as they pertain to the FDA regulations.

As you indicated, the FDA regulations at 21 CFR 56.115(a)(5) require that an institution, or where appropriate an IRB, prepare and maintain adequate documentation of IRB activities, which includes a list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant. This list, often referred to as the IRB roster, is part of the IRB records that must be maintained at the IRB per the regulations at 21 CFR 56.115.

The FDA IND regulations at 21 CFR 312 subpart D discuss the responsibilities of sponsors and investigators for drug and biologic studies (see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4). The FDA IDE regulations at 21 CFR 812 subparts C and E address responsibilities of sponsors and investigators for device studies (see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1&subpartNode=21:8.0.1.1.9.3 and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1&subpartNode=21:8.0.1.1.9.5). However, these regulations do not specifically address your questions about providing a list of the IRB members/IRB roster to a sponsor.

When the regulations are silent, IRBs, institutions, sponsors, investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

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 essential documents for the conduct of a clinical trial in section 8 of the guidance. Specifically, section 8.2.8 states the IRB/IEC composition should be maintained at the investigator/institution, and also the sponsor, where required, to document that the IRB/IEC is constituted in agreement with GCP.

I've copied your questions below, and provided some thoughts on each:

A

i) Is this with the compliance of USFDA if IRB provide the list of IRB members/attendees, 'with or without' *voting* to the sponsors with names and their designation at institute, details of their experience and training of research ethical principles?

RESPONSE: Providing a copy of the IRB roster to the sponsor is not required by the FDA regulations, however, the ICH GCP E6 guidance noted above, recommends that the IRB/IEC composition be filed with the investigator/institution, and also the sponsor, where required. I am familiar with the IRB providing a copy of the IRB roster to the sponsor when requested, but I am not familiar with the IRB providing a copy of the voting record to the sponsor. However, since the regulations don't address this issue, this is a decision your institution/IRB should discuss. You should discuss your questions with the appropriate individuals at your institution/IRB to decide what information the institution/IRB will provide to the sponsor.

ii) Will it be considered a violation to provide such a list to the sponsor; or is it a violation in any international policy/authority.

RESPONSE: As stated above, providing a copy of the IRB roster to the sponsor is not required by the FDA regulations. The ICH GCP E6 guidance, which is recognized as official FDA guidance, represents the agency's current thinking on GCP and does not create or confer any

rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statues, regulations, or both. Guidance should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. I am not able to comment on any international policy/authority.

B

iii) Can IRB restrict to provide sponsor ONLY the 'statement of IRB Composition as per ICH-GCP and it's compliant with regulatory policies, quoted above?

RESPONSE: As stated above, providing a copy of the IRB roster to the sponsor is not required by the FDA regulations, but the ICH GCP E6 guidance recommends/addresses this question in section 8.2.8. Again, your institution/IRB should discuss your questions and decide what the institution/IRB will provide to the sponsor.

iv) Should IRB provide complete list of IRB members/Attendees ANONYMOUSLY, with medical and non-medical synonym (physician/non-physician/non-scientific), and status at IRB membership (affiliated member/guest/non-member)?

RESPONSE: As stated above, the FDA regulations at 21 CFR 56.115(a)(5) requires that an institution, or where appropriate an IRB, prepare and maintain adequate documentation of IRB activities, which includes a list of IRB members. These regulations include the type of information that is required on the roster for the IRB's records. Again, your institution should discuss your questions and decide what the institution/IRB will provide to the sponsor.

C

v) Should this list be only maintained at Investigator Site File, to be checked at inspection or monitoring by the sponsor's Compliance Monitor (Clinical Research Associate)? And Not provided to the sponsor at all in any of above forms?

RESPONSE: As stated above, the ICH GCP E6 guidance addresses the essential documents for the conduct of a clinical trial in section 8 of the guidance. Specifically, section 8.2.8 states the IRB/IEC composition should be maintained at the investigator/institution, and also at the sponsor, where required, to document that the IRB/IEC is constituted in agreement with GCP.

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
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Thursday, October 19, 2017 1:26 AM
To: OC GCP Questions
Cc: [redacted]
Subject: Query on providing IRB member List to Sponsor

Dear Sir/Madame,

This correspondence is from the desk of [redacted]

Name of Institution operating IRB: [redacted]

This email is being sent to you to understand the policy on 'providing the IRB member's list to the sponsor' on request, with the decision letter of their proposal reviewed in Full Board Meeting.

Sponsors here asks the list of IRB members who attended the meeting in which sponsor's research proposal had been reviewed so as to ensure the composition of IRB and requirements of members qualifications and credentials.

As per **US FDA**, under 21 CFR Part 56 (Institutional Review Board); subpart 56.115, and; **OHRP** 45 CFR Part 46, Section 46.115; IRB records need to be maintained for the purpose of ensuring the compliance of IRB with national, ICH-GCP, US FDA or other relevant regional or international authority.

Please provide us your expert guidance on below queries.

A

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Hope to get your comprehensive response and guidance, helping us to design our ethical operations.