From: OC GCP Questions
To: [redacted]
Subject: RE: List of members attending EC meetings
Date: Friday, February 27, 2015 12:02:00 PM

Dear [redacted] -

Thank you for your question. Neither the FDA IND regulations for sponsor recordkeeping and retention found at 21 CFR 312.57, nor the IDE regulations for sponsor records found at 21 CFR 812.140(b) specifically require a sponsor to have a list of IRB/IEC members in their records. When the regulations are silent, sponsors, CROs, IRBs, institutions, and investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met. However, when the regulations are not specific, guidance may be helpful.

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. Section 8.2.8 recommends that documentation of IRB/IEC composition be filed in the investigator/institution files, and sponsor files (where required). As stated in section 8.2.8, the purpose of having such information on file is to document that the IRB/IEC is constituted in agreement with GCP.

I also wanted to share that FDA is aware that some sponsors and investigators located outside of the United States (US) may have concerns about sharing the names of IEC members. In 2008 FDA amended its regulations on the acceptance of foreign clinical studies not conducted under an IND ("non-IND foreign clinical studies") as support for an IND or an NDA, ANDA, or a BLA (collectively known as "marketing applications" or "applications for marketing approval"). The final rule requires that such studies be conducted in accordance with GCP, including review and approval by an IEC and informed consent from subjects. The GCP requirements in the final rule encompass both ethical and data integrity standards for clinical studies. This final rule, which took effect on October 27, 2008, is found at 21 CFR 312.120 and is intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies as well as the quality and integrity of the resulting data.

FDA has Guidance for Industry and FDA Staff titled, "*FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions*" (which can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294729.pdf). This guidance document is intended to clarify for sponsors and applicants how they can demonstrate compliance with the requirements of 21 CFR 312.120. It provides recommendations for the submission of information, whether in an IND or application for marketing approval for a drug or biological drug product, to demonstrate that a non-IND foreign clinical study was conducted in accordance with GCP.

As mentioned in the guidance, there may be governing laws relating to privacy concerns in some countries that may prevent disclosure of IEC information, including names of IEC members. The FAQ guidance (see page 10, and text copied below for reference) provides some guidance on this:

> *b. What information must the sponsor or applicant provide to FDA and what information must the sponsor or applicant maintain with respect to the names and qualifications of all IEC members?*
>
> Answer: The sponsor or applicant is required by 21 CFR 312.120(b)(6) to provide only the name and address of the IEC that reviewed the study and a statement that the IEC meets the definition of an IEC in 21 CFR 312.3(b). However, as provided in 21 CFR 312.120(b)(6), the sponsor or applicant must maintain records supporting the statement, including the names and qualifications (e.g., occupation, training, and experience) of all IEC members, and must make these records available for Agency review upon request. If that is not possible because of governing law relating to privacy concerns, FDA recommends that sponsors and applicants clearly document the attempts made to obtain IEC member names along with an explanation as to why the IEC member names cannot be obtained or disclosed. Such information can then be submitted to FDA in a waiver request, as described below in Section III.C.

While there is no specific FDA regulatory requirement for sponsors to keep a copy of the IRB/IEC list of members in their respective files for FDA-regulated studies conducted under an IND or IDE, the guidance recommends keeping the list, and some sponsors may have their own expectations or SOPs for this documentation to be included in the files. I suggest that you discuss expectations about keeping an IRB/IEC list in the sponsor records with the appropriate sponsor representative(s).

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, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

---

From: [redacted]
Sent: Wednesday, February 25, 2015 10:19 AM
To: OC GCP Questions
Subject: List of members attending EC meetings

Hi,

Is it mandatory for a sponsor to have list of EC members who attended the EC meeting approving their protocol/protocol amendments to confirm that majority of the members of the IRB were present, including at least one member whose primary concerns are in nonscientific areas?

Some ECs do not provide this list , though they provide the membership list and a confirmation that EC operates as per ICH GCP.

[redacted]