From: Hommel, Carolyn - OC
Sent: Tuesday, January 11, 2005 10:39 AM
To: [Redacted]
Subject: RE: IRB records

Hi, [Redacted],

I'm sorry for the delay in getting back to you.

As the answer to the question in the information sheets points out, there is no FDA regulatory requirement that sponsors or the public be provided access to IRB records nor a prohibition against doing so. Thus, the IRB and institution would need to develop their own standard operating procedures for releasing information or records about the IRB's membership and activities to the public and/or study sponsors, taking into account any state or local laws that may affect the release of such information.

With respect to your question as to whether the IRB can "keep its members anonymous," I'd have to say that there may be a drawback to doing so.

FDA's regulations on IRB membership [21 CFR 56.107(a)] state that the IRB is supposed to be "sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, ***to promote respect for its advice and counsel*** in safeguarding the rights and welfare of human subjects... " **[Emphasis added.]** Part of promoting respect for advice would include (in my opinion) knowing the general composition of the IRB and the qualifications of the members. Although IRBs may keep their members' identities confidential (in an effort to protect the members from being lobbied by sponsors to vote in a particular way), it may be interpreted as preventing IRB members from being held accountable for their decisions and have the unintended effect of undermining public "respect for [the IRB's] advice and counsel."

I hope this is helpful.

Carolyn

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-----Original Message-----

From: [Redacted]
Sent: Monday, January 03, 2005 4:10 PM
To: Hommel, Carolyn - OC
Subject: FW: IRB records

David's auto-response said to send it to you. Thanks for the help.

[Redacted]

-----Original Message-----

From: [Redacted]
Sent: Monday, January 03, 2005 4:08 PM
To: OC GCP Questions
Subject: IRB records

Hi, I am [Redacted]. I am confused about one of the answers on the IRB sheets.:

22. Are sponsors allowed access to IRB written procedures, minutes and membership rosters?

The FDA regulations do not require public or sponsor access to IRB records. However, FDA does not prohibit the sponsor from requesting IRB records. The IRB and the institution may establish a policy on whether minutes or a pertinent portion of the minutes are provided to sponsors. Because of variability, each IRB also needs to be aware of State and local laws regarding access to IRB records.

Does this mean that the IRB board doesn't have to release it but the public can foi a request and get it? I have a caller specifically asking if an IRB board can keep it's members anonymous from the client/sponsor of the trial. Any help is appreciated!

[Redacted]