From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Friday, August 06, 2004 12:56 PM
To: Daciek, Barbara J
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Barbara,
This question is probably better answered by OHRP, but after having talked with a contact over there, I think I can answer this. First of all, FDA regulations don't really specify what actions, if any, a CRO or sponsor must take to ensure that an IRB is in compliance. Therefore, this person could setup their own procedures and standards for how they accomplish this.

That said, I believe they could accept the institution's assurance number as an indirect indication that the IRB membership probably meets FDA requirements. The reason this is an indirect method is that strictly speaking institutions do not have to submit their IRB roster to get an assurance number. An assurance applies to the institution not their IRB, and an institution can use an IRB outside their institution. However, the IRB used by the institution must be registered with OHRP in order for the institution to get an assurance. Anyway, as part of the registration process the IRB must provide OHRP with a membership roster, which OHRP reviews for compliance. When the institution applies for an assurance OHRP verifies that the IRB is registered.

I hope this makes sense. You may wish to direct this correspondent to Jan Walden at OHRP (301)-402-5228 if they have further questions about OHRP assurances and registration.

Good Luck,
Stan

-----Original Message-----
From: Daciek, Barbara J
Sent: Monday, July 19, 2004 3:31 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

Hello,
Can you help me with this? I'll respond to the consumer.
Thanks
Barbara, Drug Information

-----Original Message-----
From: [Redacted]
Sent: Friday, July 16, 2004 3:14 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: I am involved with a regulatory affairs department at a CRO and need some clarificaation regarding compliance with the regulations regarding

assurance numbers and IRB rosters. Our default position is to collect a current IRB roster for each IRB overseeing studies administered by my firm. Some IRBs refuse to publish their IRB rosters and supply instead an assurance number. I am aware of the purpose of the number but my concern is whether we are compliant if we accept the assurance number without any further IRB information? Does a valid assurance number satisfy the documentation of IRB membership, diversity, investigator non-voting requirements, etc. Please advise.
Thanks for your assistance.