From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, March 24, 2005 2:01 PM
To: [Redacted]
Subject: FW: IRB Questions
Dear [Redacted],

The criteria for IRB approval of research are contained in FDA's regulations at 21 CFR 56.111 and the documentation requirements are contained at 21 CFR 56.115. The IRB is correct that there is no explicit requirement in FDA's regulations to review the investigator's qualification or the investigator's brochure. It is actually a responsibility of the sponsor to "...select only investigators qualified by training and experience as appropriate experts to investigate the drug." See 21 CFR 312.53. While an IRB may review the qualification of the investigator in a general way (e.g., to ensure the investigator is a cardiologist if the research involved cardiology) to ensure that risks to subjects are minimized, a more detailed assessment is really left to the sponsor. The IRB may provide insight into the qualification of the investigator through that individual's reputation at the institution--and that insight may certainly assist the IRB in its review determination. Similarly, while the IRB may need some information that may be contained in the investigator's brochure, there is no FDA regulatory requirement that the IRB receive and review the investigator's brochure. The "Self-Evaluation Checklist for IRBs" indicates through asterisks those items that are addressed in regulations, but it does not necessarily indicate what the regulations state.

Guidance, including the ICH GCP guidance, represents FDA's current thinking on a topic and should be viewed as recommendations. It 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 can be used if that approach satisfies the requirements of the applicable statutes and regulations.

I believe that the 'NIH number" is actually a Federal Wide Assurance number. For further information about the assurance process, implemented by the Office for Protection from Research Subjects, HHS, I encourage you to review the information on this topic on their web site at: http://www.hhs.gov/ohrp/assurances/assurances_index.html. While the existence of an assurance number may not "confirm compliance" with the regulations, it does document that the institution has assured HHS that it will comply with the common rule and the HHS human subject protection regulations (45 CFR 46); and those regulations are comparable to FDA human subject protection regulations at 21 CFR parts 50 and 56. Generally, we believe that the assurance number provides some comfort level vis a vis the IRB's compliance, recognizing that onsite inspections cannot be done across the board.

I hope that this information is helpful to you.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.
-----Original Message-----
From: [Redacted]
Sent: Monday, March 14, 2005 9:30 AM
To: druginfo@cder.fda.gov
Subject: IRB Questions

Dear Sir/ Madam,

I recently conducted some audits in the US and this has led to a debate which I hope you may be able to assist with.

Regarding IRB approval documentation;

I noted that the IRB approval did not explicitly document that they had reviewed the Investigator's qualifications (CV) or the Investigator's brochure (IB) (as is required by ICH GCP). The auditee responded that it is not a CFR requirement that these documents are reviewed by the IRB and that 'the FDA considers ICH GCP to be a guideline and compliance with this is not required.'
I have located a 'Self-evaluation Checklist for IRBs' on the CDER website which indicates that IRBs should be reviewing the above documents.

I noted that there was no statement by the IRB to confirm that they operate in compliance with CFR regulations. The auditee responded that the IRB had an assurance number from the National Institutes of Health (NIH) and this is sufficient to confirm compliance.

In summary, my questions are:
* Should IRBs be reviewing CVs and IBs (and documenting this review)?
* Does the FDA consider ICH GCP a 'guideline' with which compliance is not required?
* Does the presence of an NIH number confirm compliance with CFR regulations (and ICH GCP)?

Thank you for your assistance.

Kind regards,

[Redacted]

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