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From: Lee, Bonnie
Sent: Wednesday, April 21, 2004 3:26 PM
To: [Redacted]
Subject: Your IRB Questions

Dear [Redacted] ,

Your e-mail (below) was forwarded to me for response.

In regard to your first question, I would suggest that an IRB in part fulfills its responsibilities to determine that risks to subjects are minimized and reasonable by ensuring that the research institution has the facilities and staff to conduct the research. It is common, I believe, for academic IRBs to require the research project to be "signed off" by the Department head to ensure that departmental facilities can and will be used to support the research. I believe that most academic research offices also try to ensure that sufficient funding has been allotted to the research to support other institutional expenditures of resources (e.g., pharmacy, nursing, IRB review, etc.) Assuming that the IRB is located in an institution, it will have knowledge of all clinical studies ongoing at the institution (it would have approved those study) and thus, there would be no need for the IRB to ask separately for such a listing. I do not believe that the IRB is in the best position to independently assess the workload of research staff--the Department head or research office may be better able to do so. One reason why IRB decisions are reported to institutional officials is to allow those officials to determine whether the IRB's decisions are consistent with institutional commitments and standards. For example, one could imagine that certain religious institutions may be hesitant to allow research involving birth control to be conducted at the institution. It would be inconsistent with the institution's comments and standards. For other secular institutions, this may not be the case.

In regard to your second question, when an investigator signs an FDA-1572 form, the investigator provides assurance that the study will be reviewed by an IRB that complies with the requirements of 21 CFR Part 56. While an investigator can certainly ask for anything, there is nothing in the regulations that would compel an IRB to supply the assurance or certificate you suggest. It is possible to determine an IRB's compliance status, assuming it has been FDA inspected, by checking with FDA's Freedom of Information Act office to determine the results of the most recently completed (and closed) inspection. If the IRB had received a Warning Letter from FDA, it would be posted at: http://www.fda.gov/oc/gcp/clinenforce.html. One could also check with the Office for Human Research Protections, HHS, to determine whether the institution has an accepted federal wide assurance. See http://ohrp.osophs.dhhs.gov/irbasur.htm.

I hope this information is helpful to you.

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.

From: [Redacted]

I'd like to ask about two CFR provisions that involve the IRB:

21 CFR 56.107: ...the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice.

Question: Does the "ascertain the acceptability of proposed research in terms of institutional commitments" mean that the IRB should ask for, and evaluate, a listing of ongoing studies at the PI's institution so that the IRB can evaluate (1) whether the institution has enough staff for the study and (2) whether the staff's current or expected workload will allow the staff to adequately conduct the proposed research?

21 CFR 312.66: An investigator shall assure that an IRB that complies with the requirements set forth in part 56 will be responsible for the initial and continuing review and approval of the proposed clinical study.

Question: Does this requirement for an assurance of 'IRB compliance with the law' mean that an investigator might ask an IRB to present a 'certificate of operational compliance' conducted by a third-party expert - something akin to a financial audit in the business world?

Please don't hesitate to contact me should you need any additional information.

[Redacted]