From: Lepay, David
Sent: Sunday, January 25, 2004 10:24 PM
To: [Redacted]
Subject: RE: FDA obligation

Dear Dr. [Redacted]:

FDA inspections are directed to areas under FDA jurisdiction. This would generally include clinical investigations of FDA regulated products (drugs, biologics, vaccines, medical devices, medical foods, etc.) --- both commercial studies as well as investigator-initiated studies involving FDA regulated products.

FDA inspects study sponsors, clinical investigators, and institutions/IRB's --- but would not expect an institution/IRB to have or obtain records that are required to be maintained by a study sponsor or clinical investigator. The focus of FDA IRB inspections is to ensure compliance with FDA IRB regulations (under Part 56 of Title 21 Code of Federal Regulations --- which can be accessed from our GCP website, www.fda.gov/oc/gcp, through the link to "Regulations"). What we look at in inspections is outlined in the Compliance Program (SOP for our inspectors) that addresses IRB inspections. This too can be accessed through our GCP website through the link to "Bioresearch Monitoring Program" and hence to the Compliance Program for IRB's.

Finally, you may want to review 21 CFR Parts 312 and 812 (accessible from the Regulations link above) to better understand the scope (and definitions) relating to FDA oversight.

Again, an FDA IRB inspections would focus on matters within FDA jurisdiction: i.e., first establishing that the IRB is involved (and appropriately involved) in reviewing studies under FDA jurisdiction, and then in ensuring that FDA regulations (under 21 CFR Part 56) are being followed by the IRB for review of such FDA-regulated studies. An FDA inspector may incidentally inquire about other (e.g., non-FDA regulated) studies under review by an FDA-regulated IRB, but this is more to ensure that FDA-regulated studies are being appropriately recognized and also to ensure that the IRB is adequately resourced to handle its total workload.

I hope this information helps to answer your query.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs,
OSHC, Office of the Commissioner, US FDA

> -----Original Message-----
> **From:** [Redacted]
> **Sent:** Wednesday, January 14, 2004 10:28 AM
> **To:** dlepay@oc.fda.gov
> **Subject:** FDA obligation
>
> Dear Dr. Lepay:
>
> [Redacted] asked me to contact you regarding the following questions.
>
> As IRB chair at the [Redacted] --we have a reporting responsibility to OHRP and are a non-covered entity by HIPAA criteria. At a joint meeting with [Redacted]

(hospital) IRB representatives yesterday afternoon, we were informed that the FDA can audit any or all of our studies, including requiring us to obtain patient records which are not in our possession for FDA review. We were advised to add the [Redacted] IRB to the confidentiality section of [Redacted]'s Informed Consent Document. We were surprised at this and have been unable to verify it in the code of federal regulations CFR Title 21 FDA. Would you know what our obligation might be to the FDA? Or what document we might look to for verification or clarification?

Thank you in advance for your response.

[Redacted]