From: Lepay, David
Sent: Wednesday, February 18, 2004 5:23 PM
To: **[Redacted]**
Cc: **[Redacted]**
Subject: RE: **[Redacted]** Hospital Membership Update with FDA

Dear Ms. **[Redacted]** :
There is no FDA reporting requirement related to the roster (or changes to the roster) for IRB membership or chairmanship. Membership information (including updates) must be documented and maintained by the IRB as part of required IRB records (see 21 CFR Part 56.115(a)(5) --- accessible from our GCP website www.fda.gov/oc/gcp through the link to "Clinical Trial Regulations"). But, again, this is not information that requires reporting to FDA.

You should, however, also check with the DHHS Office for Human Research Protections, assuming your institution has an assurance with OHRP. FDA does not use an assurance process (and therefore certain OHRP regulatory requirements may apply under the assurance that have no direct parallel at FDA).

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs,
OSHC, Office of the Commissioner, US 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: Wednesday, February 18, 2004 3:35 PM
To: Lepay, David
Cc: **[Redacted]**
Subject: RE: **[Redacted]** Hospital Membership Update with FDA

David :

Is there someone in your office that can answer Ms. [Redacted] 's question about IRB updates.

Thanks
[Redacted]

-----Original Message-----
From: **[Redacted]**
Sent: Wednesday, February 18, 2004 9:31 AM
To: **[Redacted]**
Subject: RE: **[Redacted]** Hospital Membership Update with FDA

[Redacted] ,

Thank you for your response. But I could not find the answer on t he website that is why I sent the e-mail is there someone else I can contact that would know the answer?

Thank you,

[Redacted]

This is not my area of expertise. You may find your answer in the following link
http://www.fda.gov/oc/ohrt/irbs/default.htm
-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, February 17, 2004 1:20 PM
To: disclosure@oc.fda.gov
Subject: **[Redacted]** Hospital Membership Update with FDA

Good afternoon,

I am trying to update my files and I was wondering if I need to report change in membership / chairmanship of my IRB to the FDA? Could you please advise me on this and if so. What form do I need to fill out and where do I send it?

Thank you for your time.

Sincerely,

[Redacted]