From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, April 21, 2003 10:03 AM
To: [Redacted]
Subject: RE: Question Regarding Enforcement

Dear Ms. [Redacted],

I received your request for information about specific cases in which FDA has taken enforcement action against clinical investigators and institutional review boards (IRBs) for failure to obtain appropriate informed consent from human subjects in a clinical drug trial.

I have included a slide that depicts the most common deficiencies found during clinical investigator inspections conducted by FDA's Center for Drug Evaluation and Research during Fiscal Year 2001.

As you can see, there were problems with the informed consent document in 17% of all inspections conducted. This category covers a whole range of problems, from failure to identify a contact person should study subjects have problems during the study, to failure to include a complete list of all known risks associated with the test article. This category does not include instances in which consent was not obtained at all--that, fortunately is pretty uncommon in studies conducted in the U.S.

However, it has occurred in some instances, and I have identified for you, a couple of links to correspondence and the decision of the presiding officer pertaining to specific individuals who failed to obtain informed consent from subjects in their studies.

http://www.fda.gov/foi/nooh/law.pdf

http://www.fda.gov/foi/clinicaldis/halikaspo.pdf

http://www.fda.gov/foi/clinicaldis/halikascd.pdf

I am also providing you with the general links to FDA's FOI reading room website for Warning Letters [http://www.fda.gov/foi/warning.htmand] and for Notices of Disqualification Proceedings and Opportunity to Explain (NIDPOEs) [http://www.fda.gov/foi/nidpoe/default.html]. You would have to search these letters individually to determine which letters include citations for failure to obtain informed consent from the study subjects.

Another link that may be useful to you is http://www.fda.gov/foi/clinicaldis/default.htm. This page contains links to the reports of presiding officers and decisions of the Commissioner in various past disqualification cases. Again, you would need to search these individually to determine if failure to obtain consent was material to the case.

I hope this information is helpful to you.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program

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Office of the Commissioner
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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, April 14, 2003 3:06 PM
To: gcpquestions@oc.fda.gov
Subject: Question Regarding Enforcement

Hello,

I am a law student at [Redacted] and I am doing research regarding lack of informed consent for human subjects in clinical trials.

I am interested in specific cases of FDA action (particularly disqualification and restrictions) against IRB's and/or clinical investigators for failure to obtain appropriate informed consent from human subjects in clinical drug trials. Is there anyway that you can send me some information about specific instances in which the FDA stepped in to enforce the informed consent provisions? Does the FDA tend to issue restrictions or disqualifications for this type of non-compliance, or is it usually a lesser enforcement?

Thank you very much.

[Redacted]