From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, March 11, 2005 4:05 PM
To: [Redacted]
Subject: FW: Hospital Responsibility in Research
Dear [Redacted],

FDA regulations address the responsibilities of sponsors, investigators, monitors, Institutional Review Boards (IRBs) and others, but contain little information about the responsibilities of institutions. I do know that lawyers I know have talked about how institutions tend to be held responsible for what goes on within the four walls of the institution; and as a philosopher, I can only take their word for that. The problem that FDA would have in assigning institutional responsibility is that a lot of FDA-regulated research is not carried out in traditional institutions; rather, it may be carried out in private practitioner offices. That being said, FDA's IRB regulations do address some responsibilities of the IRB in relation to its institution. The complete regulations are available on our website at: http://www.fda.gov/oc/gcp/regulations.html
* Each IRB needs to follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of: any unanticipated problems involving risks to subjects or others; any instance of serious or continuing noncompliance with FDA regulations or the requirements or determinations of the IRB; or any suspension or termination of IRB approval. (21 CFR 56.108(b))
* An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. (21 CFR 56.109(e))
* FDA may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects. (21 CFR 56.110(d))
* Research covered by FDA's regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. (21 CFR 56.112)
* Any suspension or termination of [IRB] approval shall include a statement of of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the FDA. (21 CFR 56.113)
* In complying with FDA's regulations, institutions...may use joint review, ...or similar arrangements to avoid duplication of effort.
* An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities. (21 CFR 56.115(a))
* FDA may refuse to consider a clinical investigation if the institution or the IRB that reviewed the investigation refuses to allow an inspection. (21 CFR 115 (c))
* Subpart E of 21 CFR Part 56 discusses lesser administrative action for noncompliance that FDA can take as well as grounds for disqualification of the IRB or institution. Of particular note is that statement in 21 CFR 56.120(c) that "The parent institution is presumed to be responsible for the operation of an IRB, and the Food and Drug Administration will ordinarily direct any administrative action under this subpart against the institution..." (see the regulation for its full text).

Clearly, institutions have an important role in establishing an environment for the ethical conduct of research. In recent years, there has been a lot of discussion about human subject protection programs and how each party (or entity) has an important role in ensuring that research is carried out with the best interests of the subjects in mind. There are some independent accreditation programs that have been established that list online criteria to assess the quality of the institution in addition to other aspects of the institution's human subject protection program. While IRB review may take place outside your institution, that is only one aspect of human subject protection. Investigators who have direct interaction with patients are on the frontline for protecting subjects and the institutions in which they work are there to ensure that protection takes place.

The Department of Health and Human Services Office for Human Research Protections has additional information on their website that may be helpful. Please see: http://www.hhs.gov/ohrp/ and their quality assurance site at: http://www.hhs.gov/ohrp/qi/

I hope that this information is helpful to you. Have a pleasant weekend.
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: CDER DRUGINFO
Sent: Wednesday, March 09, 2005 9:14 AM
To: OC GCP Questions
Subject: FW: Hospital Responsiblity in Research

-----Original Message-----
From: [Redacted]
Sent: Wednesday, March 09, 2005 7:44 AM
To: druginfo@cder.fda.gov
Subject: Hospital Responsiblity in Research
At [Redacted], a discussion has begun on EXACTLY what is the specific responsibilities of the hospital regarding research within the hospital.

There is a city-wide IRB that approves studies for several hospitals as well as [Redacted] (of which I am a member of that IRB).

I have not been able to find any written document on CDER's website or any other government website that explicitly states the hospital has any obligation to monitor any aspect of the research.

Of course, I understand the role fo the IRB as well as the investigator, and that is not the question.

Please focus the answer specifically to the hospital's role or obligations in research conducted on its premises, and where I can find the written guidelines and/or policy governing hospitals in research.

Thank you,
[Redacted]