From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, August 18, 2005 10:53 AM
To: [Redacted]
Subject: RE: Question: Subpart D regulations/Pharmacists on IRBs

Dear [Redacted], I found two emails in my box from you. It was not clear whether Carolyn responded to the Subpart D regulation question or not. If she didn't, let me clarify that the Subpart D regulations do apply to neonates involved in clinical investigations.

As to your question below concerning pharmacists serving on the IRB and possible conflicts of interest, the answer is more complex. Let me walk you through it:

Under FDA's IRB regulations, No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. (21 CFR 56.107(e)) In comment 60, in the preamble to the 1981 IRB regulations, the agency clarified that "FDA believes that the IRB or the institution should determine what constitutes a conflicting interest." (46 FR 8958 at 8966, January 27, 1981). Therefore it is really up to your IRB to decide what constitutes a conflicting interest by a pharmacist.

That being said, there are some individuals who, as part of an investigative team, assisting the investigator and who make a direct and significant contribution to the research data may be generally seen as having a conflict. Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the data are simply doing their job and would not be seen as conflicted. Similarly, if a pharmacist is only dispensing tablets and has no responsibility for preparing the test article(s) or evaluating or reporting data relative to the study activities, then the pharmacist can serve on the IRB without conflict and need not abstain from voting on that protocol. In fact, the regulations support the pharmacist's involvement in the IRB's membership through its requirement that the IRB possess the professional competence necessary to review the specific research activities (see 21 CFR 56.107). On the other hand, if the pharmacist will be compounding, labeling, monitoring and reporting test article compliance data, it would be appropriate to limit the pharmacist's involvement to providing information requested by the IRB and document that the pharmacist did not vote on the study in which there was a conflict. (See 21 CFR 56.107(e)). If one felt obligated to make each hospital pharmacist abstain from voting, it would seem that the same rationale could be applied to each nurse, resident, etc., who may pass by the research and be an IRB member; that wouldn't make any sense.

21 CFR 56.107(f) states "An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB." The use of consultants under this section frequently occurs when the expertise needed would otherwise be considered a conflict if the consultant were a member.

I hope that this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [Redacted]
Sent: Monday, August 01, 2005 4:37 PM
To: Carolyn.Hommel@OC.FDA.GOV
Subject: RE: Question: Subpart D regulations

Ms. Hommel: Thank you for the update. In addition to the question raised in my previous email, another question has recently arisen.

One of our clinical studies was audited yesterday by the sponsoring agency. The pharmacist that dispenses study drug for the trial also serves on our IRB. The study monitor said that this was a conflict and the pharmacist should be abstaining on this protocol during any votes related to the study. I would like FDA's interpretation, as our institution does not recognize that the role of a pharmacist would having any bearing on the conduct of the study nor would have any potential conflict of interest. Guidance on this would be much appreciated. Many thanks again.
[Redacted]

>>> "Hommel, Carolyn - OC" <Carolyn.Hommel@OC.FDA.GOV> 08/01/05 3:05 PM >>>
Dear Ms. [Redacted]:

Ms. Harrell forwarded your question to me; unfortunately, we are a small office (5 people total) and rather short staffed at the moment (2 of our staff are on leave; a third is on travel). The person who could answer your question directly is currently on leave, and for one of us two remaining folks to answer it will take a little research. So, please bear with us. We haven't forgotten you, but it may be another few days before you receive a definitive response.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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Rockville, MD 20857

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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, August 01, 2005 3:47 PM
To: pharrell@oc.fda.gov
Cc: [Redacted]
Subject: Fwd: Question: Subpart D regulations

Ms. Harrell: I sent this email to you on 7/25 and believe you were going to forward it to the appropriate department for review and response. I have not yet received any information on this subject. I would appreciate your guidance. Thank you.[Redacted]

>>> [Redacted] 07/25/05 3:25 PM >>>
To Whom It May Concern:

I would like to seek clarification regarding 21 CFR Part 50, Subpart D - Additional Protections for Research Involving Children specific to the following question:

Does Subpart D criteria and categories of research for approving children and adolescents also apply to neonates (newborns) receiving experimental drugs?

Your assistance is greatly appreciated.
[Redacted]