MessageFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, December 09, 2004 1:44 PM
To: [purged]
Cc: Lepay, David
Subject: RE: Can you help?

Dear Dr. [purged]:

Your e-mail to Dr. David Lepay was referred to me for a response. You asked:

"1. Are there circumstances in which research use of an approved prescription drug might appropriately be judged to be minimal risk? The case I'm concerned about is an IRB that judged a comparison of 2 triple therapies for HIV to be minimal risk, apparently using the rationale that they were FDA approved drugs."

In general, FDA's Review Divisions are responsible for determining whether a study requires an IND or is exempt from FDA's IND requirements [See 21 CFR 312.2]; the Review Divisions routinely issue letters for this purpose. I would suggest that any IRB that is reviewing a study involving a combination therapy should ask the clinical investigator to provide confirmation from FDA as to whether an IND is needed or the study is exempt (and thus could be considered a minimal risk study).

Please note that studies that are exempt from the IND requirements still need to comply with the requirements for IRB review and informed consent set forth in 21 CFR 56 and 50 (respectively).

I have referred your second question to the Center for Devices and Radiological Health for a direct response.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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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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----Original Message-----
From: [purged]
Sent: Tuesday, November 30, 2004 11:48 AM
To: DLepay@oc.fda.gov
Subject: Can you help?

Dear David,
I was wondering if you'd be willing to give me an opinion on a couple of issues that have arisen from one of our reviews:
1. Are there circumstances in which research use of an approved prescription drug might appropriately be judged to be minimal risk? The case I'm concerned about is an IRB that judged a comparison of 2 triple therapies for HIV to be minimal risk, apparently using the rationale that they were FDA approved drugs.
2. The same IRB judged a trial of an SR device to be minimal risk. Do you know of circumstances in which this might be appropriate?
Thanks!
[purged]