question about good clinical practiceFrom: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, February 06, 2006 12:23 PM
To: [purged]
Subject: RE: question about good clinical practice

Dear [purged],

In response to your question (below), we do not think that there is an ethical responsibility to provide treatment to the individuals; however, there is an ethical responsibility to inform them that they have the infection and provide initial counseling. We're assuming that the discovery of HIV infection is part of the screening process, but the HIV treatment is not part of the study. That is, this isn't an HIV treatment study, but the screening for it includes an HIV test. Similar to what is done with blood screening for donors, when someone comes up positive, the bank doesn't take the donation, and they inform the person they are seropositive. We believe in that situation there is counseling provided, and probably referral for medical care if the person wants to pursue treatment at that time.

We are not aware of any guidance that would put the onus on the people who discovered the infection to provide treatment. If there were, that would be a major responsibility and raise questions such as: Would they provide treatment for the first week, or a lifetime? Treating the illness itself is the responsibility of the (potential) subjects unless the study itself is designed to study treatment for HIV.

I hope this information is helpful to you. I was looking for, but couldn't find, an old PHS policy statement (probably from the early to mid-'80's) that addressed the issue of the obligation to disclose the results of HIV tests and offer counseling. You might want to do some google searching to see if you can come up with it. My recollection was that it offered some useful advice. (Although it may be dated if it's as old as I think it is.)

Sincerely,

Bonnie
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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: [purged]
Sent: Friday, February 03, 2006 1:12 PM
To: gcpquestions@oc.fda.gov
Subject: question about good clinical practice

we are designing a study and would like to know the answer to the following question:
If a participant in an FDA-appproved clinical trial is identified with HIV infection as part of the trial procedures, is there an ethical or other responsibility to treat the person's HIV infection?
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