From: Klein, Richard M
Sent: Thursday, December 16, 2004 11:33 AM
To: [Redacted]
Subject: HIV Testing Inquiry Response

Dear Dr. [Redacted],

I am responding to your inquiry about whether someone found to test positive for HIV in the course of screening for a clinical trial should be informed of the finding. Good clinical practices dictate that before entering into a clinical trial, even in the screening phase, potential participants should be fully informed of the study procedures, including the tests which will be administered to determine eligibility for the study. HIV testing is certainly a noteworthy procedure, and prospective trial participants need to be informed that this is occurring, and of the results.

The situation is similar to blood donor screening, which requires that every effort be made to inform donors when evidence of communicable disease is detected.

Depending on the type of testing being performed in the trial participant screening - for example, whether Western Blot Confirmatory testing is done - it might be appropriate to inform potential participants that preliminary testing has yielded a positive result, and the person should be referred to a qualified medical facility for definitive testing.

I hope this information is helpful, and responds to your original question. Please feel free to contact me if you have additional questions related to this inquiry.

Richard Klein
HIV/AIDS Program Director
Office of Special Health Issues
Food and Drug Administration

From: [Redacted]
Sent: Sunday, November 28, 2004 7:17 AM
To: gcpquestions@oc.fda.gov
Subject: question

Respected Sir,

During screening procedure to assess the fitness of volunteer for bioequivalence study, if we found someone HIV positive, should we disclose it to person?

What should be ideal procedure to handle such cases?

thanking you,

[Redacted]