MessageFrom: Toth-Allen, Jean
Sent: Thursday, December 29, 2005 9:57 AM
To: [purged]
Subject: RE: 1572 form

Dear Mr. [purged]:

Thank you for your inquiry regarding FDA Form 1572.

One of the main purposes of the 1572 is to provide the study sponsor with information about the clinical site and potential investigator(s), to enable the sponsor to determine whether the investigator(s) and site are qualified to participate in a given study. Since laboratory test results are often data pertinent to a study, the sponsor will want to know the name of the laboratory that will be conducting study-related testing. This information is provided under section 4 of the 1572. In addition, a listing of any sub-investigators (e.g., research fellow, residents, associates) is required in section 6. Individuals to be listed in section 6 are those who make a direct and significant contribution to the data - i.e., those who will play a key role in the collection and interpretation of data and/or in the conduct of the study itself. Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make direct and significant contribution to the data are generally not meant to be listed here. However, a general statement regarding the participation of site personnel in the ordinary duties of the site can be made here if deemed appropriate. It is doubtful that the Chief/Head of the local laboratory that would conduct testing for the study would even have any direct conduct with study specimens or the resulting data relevant to the study.

Hope this information is helpful.
Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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: [purged]

Sent: Wednesday, December 28, 2005 3:59 AM
To: gcpquestions@oc.fda.gov
Subject: 1572 form

Dear,

If during a clinical trial, the blood tests are analysed in the local laboratory at the hospital, do the principal investigator need to list the Cheif/ Head of the local lab on the 1572 form?

Thank you,
[purged]