From: Toth-Allen, Jean
Sent: Tuesday, June 06, 2006 11:37 AM
To: [Redacted]
Subject: RE: Good Afternoon

Dear [Redacted]:

Thank you for your inquiry regarding pre-clinical studies using human tissue.

It is not clear if these pre-clinical studies concern tissues which will be incorporated into FDA-regulated products or feasibility studies during the development of in vitro diagnostic (IVD) devices.

For the case of tissues to be incorporated into FDA-regulated products, which are most likely regulated by the Center for Biologics Evaluation and Research (CBER) unless they are to be part of a combination product, pre-clinical studies may be either basic bench studies or safety studies. If the latter they are regulated under 21 CFR Part 58, Good Laboratory Practices. In either case, an IND would only be needed once the product was ready for study in humans.

If they are feasibility studies for IVD development, there is no specific regulation under which they fall, though they are considered FDA-regulated studies since the results are most likely pertinent to potential FDA marketing applications or submissions. (IVDs are regulated as devices and both CBER and the Center for Devices and Radiological Health (CDRH) regulate IVDs.)

Any study that is FDA-regulated and involves human subjects or their specimens requires that the regulations regarding human subject protection are followed. These regulations are 21 CFR Part 56, Institutional Review Boards, and Part 50, Protection of Human Subjects. Therefore, both IRB review and approval and informed consent are needed. (If an informed consent is required, all required elements listed in 21 CFR 50.25 must be included.) With regard to some select categories of specimens used in IVD studies, a guidance was recently published that invokes enforcement discretion to allow use of the specimens without informed consent, if all of the conditions for use stipulated in the guidance are fulfilled. This guidance is available at http://www.fda.gov/cdrh/oivd/guidance/1588.html. IRB approval of these studies is still required.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

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: [Redacted]
Sent: Tuesday, May 30, 2006 3:21 PM
To: OC GCP Questions
Subject: Good Afternoon

I have a couple of questions, I hope you can help me answer. I am new to the clinical trial and tissue side of FDA compliance.

It is unclear to me if products that are collected for pre-clinical use require an IND and if subjects who provide products for these pre-clinical studies should sign an informed consent that is approved by an IRB and if the informed consent should follow the required elements in 21 CFR 50.25.

Thank you in advance for your help.