From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, September 17, 2004 10:23 AM
To: [Redacted]
Cc: CDER DRUGINFO
Subject: RE: IRB and ICF Requirements
Dear [Redacted] ,

Controls in a clinical investigation are considered study subjects under FDA regulations, so IRB review and informed consent are required in the scenario you describe. There are no exemptions for anonymous samples. Furthermore, company employees may be considered a vulnerable population; IRB review is especially important in this instance to assure that employees are not subject to coercion or undue influence.

I hope this information is helpful.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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: CDER DRUGINFO
Sent: Saturday, September 11, 2004 1:49 AM
To: OC GCP Questions
Subject: FW: IRB and ICF Requirements

-----Original Message-----
From: [Redacted]
Sent: Friday, September 10, 2004 11:52 AM
To: druginfo@cder.fda.gov
Subject: IRB and ICF Requirements
To Whom It May Concern,

I would like to inquire about IRB approval and Informed Consent requirements regarding blood samples obtained from company employees.

We would like to obtain blood samples (blood draws will be performed by a hospital laboratory) from employees to be used as controls while performing assays ([Redacted]) that are a part of a clinical trial protocol. Employees are not administered drug and the samples are anonymous so no one can identify the employee that the sample came from. Samples would be obtained from employees rather than a sample bank due to the handling requirements of the samples.

Your response is greatly appreciated.

Respectfully,

[Redacted]