From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, August 21, 2002 10:29 AM
To: [purged]
Subject: RE: Informed Consent

Dear [purged], It is difficult to answer your question in the abstract without many more details, however, we genrally recommend that informed consent be obtained. FDA's informed consent regulations are in 21 CFR Part 50. These regulations apply to any clinical investigation that involves a test article and one or more humans xubjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to requirements for prior submission to the FDA under these sections of the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. I hope this is helpful to you.

Bonnie M. Lee

-----Original Message-----
From: [purged]
Sent: Tuesday, August 13, 2002 9:23 AM
To: gcpquestions@oc.fda.gov
Subject: Informed Consent

To FDA GCP Staff,

My question is this: Do informed consents for human blood or tissue samples collected from living or deceased patients for the purposes of diagnostic research only fall under the same regulations as do clinical drug studies? In this situation, the donor will not be receiving any drug, herb, or special instruction of any kind. They are only donating specifically diseased tissue or blood. What regulation, if any does the informed consent for non-transplant tissue donated for research fall under?

Thank you in advance for your response to my little question. I look forward to hearing back from you.

[purged]