From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, May 05, 2004 12:00 PM
To: [Redacted]
Cc: Chhabra, Renu
Subject: RE: Archived tissue samples and informed consent

Dear [Redacted],

It is really the responsibility of the IRB to determine its policies relative to the research you have described and the questions you have asked about informed consent. Clearly, one cannot obtain informed consent from individuals who have died. However, an IRB is in a position to decide whether the research could pose risks to others (e.g., family of the deceased subject), whether identifying information from the specimen should be removed or whether specific safeguards are needed to ensure confidentiality of information that could identify the subject (or family), etc. Under 21 CFR Part 50, I believe you are required to obtain informed consent from surviving patients in order to conduct research on their archived samples, unless consent was obtain for that research at the time the specimen was taken. Because you have indicated that consent was not obtained for this research, as it was not anticipated at that time, it would need to be obtained now. I hope this information is helpful to you.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy, GCPP, 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: Monday, May 03, 2004 5:29 PM
To: druginfo@cder.fda.gov
Subject: Q: Archived tissue samples and informed consent

Dear Sir/Madam,

I am writing with questions regarding patient informed consent for genomic and non-genomic testing in a closed clinical research trial.

Briefly in an investigator-initiated trial for lung cancer, tumor tissue samples were collected from patients for diagnosis. At the time the study was conducted and the patients were consented, no testing of the tumor tissue samples was planned in the protocol and so was not discussed in the patient informed consent. Currently, following completion of the study, the investigator wishes to conduct genomic and non-genomic testing on the tumor samples. Most of the patients on the trial have expired.

We have the following questions:
Can genomic and/or non-genomic testing be done on archived samples collected from patients who are now deceased?

For surviving patients, would separate informed consent forms need to be obtained for genomic and non-genomic testing on the archived samples?

Would the genomic and non-genomic testing of the archived samples from expired patients need to be approved by our IRB?

Thank you.

[Redacted]