From: Toth-Allen, Jean
Sent: Tuesday, October 31, 2006 1:55 PM
To: [Redacted]
Subject: RE: Need info

Dear [Redacted],

Thank you for your inquiry regarding the transport of biopsy specimens from [Redacted] to your laboratory.

FDA regulates medical products (drugs, biologics, devices) throughout their life cycle (investigational phase, marketing approval, general availability) as well as foods and cosmetics. If the samples in question are essential to a study that will be submitted to FDA to support a marketing application or submission, we would expect documentation of their origin, their whereabouts throughout the study, and their final disposition. We are not, however, involved with the procurement and/or transport of any medical products or biological samples even if they are involved in FDA-regulated studies.

However, there are likely state and local laws that govern purchase and transport of specimens, both within the United States and internationally. You may want to check with your university and/or research colleagues as to their experiences in this regard, as well as with your university's research office. You should also pose this question of your local and/or state health departments.

Sorry I cannot be more helpful. 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, gcp.questions@.fda.hhs.gov, in lieu of responding to my personal e-mail address.
Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practice 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: Monday, October 30, 2006 4:46 PM
To: OC GCP Questions
Subject: Need info

Hi, I would like to ask if it is possible and which is the best way to get from [Redacted] biopsy specimen from patients under going [Redacted]. Specimens will come in [Redacted]. This is a research proyect.
I'll appreciate any advice from you

[Redacted]