From: Lepay, David on behalf of OC GCP Questions
Sent: Monday, October 20, 2003 2:14 PM
To: [Redacted]
Subject: RE: Informed Consent/Patient Protection

Dear Ms. [Redacted]:

Our Good Clinical Practice website (www.fda.gov/oc/gcp) links to FDA's GCP regulations and guidances, including proposed regulations and draft guidances as well as "In the News" items. I am not otherwise clear (from the information provided) which specific regulation you may be seeking. Our Informed Consent regulations are generally contained within 21 CFR Part 50; our Institutional Review Board regulations are found in 21 CFR Part 56. Both sets of regulations can be accessed from the website (above) through the link to "Regulations" and hence to specific Parts.

I hope this information addresses your query.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs
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 20, 2003 12:33 PM
To: gcpquestions@oc.fda.gov
Subject: Informed Consent/Patient Protection

Hello,
I am trying to locate a copy of the FDA regulation (not HHS) governing Informed Consent/Patient Protection in effect on May 1, 2002 and October 1, 2003. Do you have a website reference that I can search for this information? Can you provide the reference (CFR) to the aforementioned regulation?
Thank you for your time.
Sincerely,
[Redacted]