From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, July 24, 2003 8:24 AM
To: [Redacted]
Subject: RE: consent

Dear Ms. [Redacted],

Your question was forwarded to me for a response.

FDA regulations do not stipulate where the informed consent process must take place. As long as the potential study subjects have the opportunity to read and discuss the information about the study before they agree to participate and sign the form, FDA's informed consent requirements would be satisfied. That said, although the physician has privileges at both the hospital where potential study subjects are located prior to transfer (Hospital A) and the hospital where the radiology procedure will be done (Hospital B), it might be prudent for the physician to consult with the administration/IRB at Hospital A to ensure that he is not running afoul of that hospital's policy or procedures.

I hope this information is helpful

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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: Tuesday, July 15, 2003 1:02 PM
To: 'GCPQuestions@OC.FDA.gov'
Subject: consent

If a patient is transferred from one hospital to another for a radiology procedure not available at the first hospital, can he sign an informed consent form to participate in a clinical trial related to the radiology procedure prior to his transfer? In other words, can consent be obtained while in an institution not approved as a trial site?
Thank you for your assistance on this.

[Redacted]