From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, June 06, 2002 4:36 PM
To: [purged]
Subject: RE:

Dear Dr. [purged],

Your IRB is correct. FDA regulations define as human subject as "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control." See 21 CFR 56.102(e). FDA's informed consent regulations state that "...no investigator may involve a human being as a subject in research...unless the investigator has obtained the legally effective informed consent of the subjects of the subject's legal authorized representative." 21 CFR 50.20. Informed consent must be documented by a signed consent form unless the IRB waives the requirement for such a signed form. See 21 CFR 50.27. The IRB can only do that if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. 21 CFR 56.109(c)(1). The IRB did not make such a finding in your case; thus, the subject had to provide her written informed consent before the study procedure was initiated.

I hope this information is helpful to you and that it will provide you with the information you need to conduct research in accordance with FDA regulations in the future.

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Office for Good Clinical Practice
Office of Science Coordination & Communication, HF-34
Food and Drug Administration
5600 Fishers Lane, Parklawn, Room 9C24
Rockville, MD 20857
Telephone: 301-827-3259
Fax: 301-827-1169
E-Mail: BLee@oc.fda.gov

-----Original Message-----
From: [purged]
Sent: Monday, June 03, 2002 5:10 PM
To: gcquestions@oc.fda.gov
Subject:

Hello,

I have been the chief investigator in an IRB approved study involving breast imaging using a recently developed high sensitivity, small field of view gamma camera. Breast imaging is performed in two patient populations; one group is comprised of patients who are being evaluated for breast cancer (i.e. breast mass seen), the other group is comprised of women with a questionable palpable or mammographic finding who are further evaluated using Tc-Sestamibi and the new camera. Sestamibi (miraluma) is FDA approved for further evaluation of the second group of patients, as is the camera.

My question is, in the second group, where the drug, its indicated use, and the procedure are FDA approved, is a written informed consent form legally was performed allowable if verbal consent was obtained prior to the initiation of the procedure? The study could have been performed as a standard procedure outside the study, but I planned to use the data in the study from the start. After obtaining verbal consent, the patient became anxious thinking about her upcoming surgery (within hours) and was crying. Her son, also a radiologist, said that he would have her sing the consent the following day.

The IRB disallowed the patient stating that the FDA demands that written informed consent be given prior to study initiation. It is my understanding that this only applies to investigational drugs/devices and/or "off-label-uses" of approved drugs. If you need additional information from me please e-mail or call 814-877-6184.

Thank you,
[purged]