From: Toth-Allen, Jean
Sent: Friday, May 26, 2006 8:06 AM
To: [purged]
Subject: RE: question about GCP regulation

Dear [purged],

Thank you for your inquiry.

With regard to the term "third party," the regulation uses this term to denote someone other than a member of the IRB or the study investigational team - i.e., someone who would be knowledgeable of clinical trials but is not associated with either the conduct of the specific study or the IRB's review of it. The regulation is giving the IRB, or someone designated by them, the authority to witness any part of the investigational study they deem necessary, including the informed consent process.

FDA regulates the parties that participate in the conduct of clinical trials - sponsors/monitors, clinical investigators, and reviewing IRBs. We do not directly deal with "institutions." To conduct a clinical trial, the parties involved need to meet the regulatory requirements pertinent to them. The responsibilities of sponsors/monitors and clinical investigators in pharmaceutical studies can be found in 21 CFR Part 312, Investigational New Drugs; for device studies, these can be found in 21 CFR Part 812, Investigational Device Exemptions. The responsibility of IRBs can be found at 21 CFR part 56, Institutional Review Boards, with specific references also found in Parts 312 and 812. All FDA regulations can most easily be accessed through http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm. There are also numerous guidance documents available, one of the most generally useful for IRBs and investigators is the FDA Information Sheets available at http://www.fda.gov/oc/ohrt/irbs/default.htm.

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, gcpquestions@oc.fda.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(d) 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: [purged]
Sent: Monday, May 22, 2006 2:54 AM
To: OC GCP Questions
Subject: question about GCP regulation

Dear MisoMe:
I have two questions about GCP.Firstly,What's the meaning of "IRB shall have authority to observe of have a third party observe the consent process and the research"in CFR 21 part 56 ?what is the "the third party"? Secondly, What kind of institution can assume clinical trial,and is there any criterion about institution?
Please write to me back as soon as possible!
Yours,[purged]