From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, August 31, 2005 1:39 PM
To: [purged]
Subject: RE: FDA form 1572

Dear Dr. [purged],

All studies conducted under an IND, including those conducted within and outside of the United States (USA), must comply with the IND regulations in 21 CFR Part 312. Under 21 CFR 312.53, a sponsor must obtain a signed "Statement of Investigator", Form FDA-1572, before permitting an investigator to begin participation in an investigation. Based on your e-mail message below, you are doing the right thing by requiring that each investigator sign a 1572 before the investigator participates in an investigation.

I hope this is helpful information to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD
20857

Telephone: 301-827-3340
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-----Original Message-----
From: [purged]
Sent: Wednesday, August 24, 2005 9:43 AM
To: [purged]
Subject: FDA form 1572
Importance: High

----- Forwarded by [purged] on 24/08/2005 15:43 -----

[purged] To: [purged]
cc:
24/08/2005 15:22 Subject: FDA form 1572

Dear Ms [purged],

I refer to our brief discussion over the phone some minutes ago.

Do we, as a sponsor of a clinical trial running under an US-IND, have to collect FDA 1572 forms also for investigational sites outside of the US? We do this routinely, but just wanted to have it confirmed.

Thank you very much for a brief reply!

Sincerely,

[purged]