From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, March 15, 2006 8:32 AM
To: '**[Redacted]**
Subject: RE: FDA Form 1572 and IRB

Dear Ms. **[Redacted]**,

Under 21 CFR 312.53(c), the Statement of Investigator Form FDA-1572, must be completed and signed by the investigator who will be serving as the clinical investigator for a sponsor. This regulation requires that this form be maintained by the sponsor. There is no regulatory requirement that this form be given to the IRB. Of course, an IRB can always ask that a copy of this form be provided as part of the materials that it will review when making decisions about research activities. If an IRB elects to require this form as part of the research proposal, it would be appropriate to include this requirement in a written SOP.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
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

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, March 14, 2006 3:35 PM
To: OC GCP Questions
Subject: FDA Form 1572 and IRB

Good afternoon:

Does the FDA recommend that IRBs receive a copy of the FDA Form 1572?

[Redacted]