From: Beers Block, Patricia
Sent: Tuesday, November 07, 2006 8:44 AM
To: **[Redacted]**
Subject: RE: 1572

Dear Ms. **[Redacted]**,

Your message was forwarded to our office for a direct reply. Block #3 of Form FDA 1572 requires the name and addresses of locations where the clinical investigation will be conducted. The CV for an investigator referenced in Block #2 of this form is intended to document the education, training and experience that qualifies the investigator as an expert in the clinical investigation of the drug for the use under investigation. The regulations don't go into the level of detail of your question. Certainly the CV can contain information about current studies (which might include locations where studies are currently being conducted). I'm not certain if this adequately answers your question. Please let me know if you need further clarification.

Regarding your question about upcoming changes in clinical trials, I think you might want to be aware of the agency's new critical path initiative recently announced in FDA press release P06-86 (see http://www.fda.gov/bbs/topics/NEWS/2006/NEW01396.html for an electronic version of this press release). Briefly, FDA announced a series of new policy and regulatory developments to strengthen the Agency's oversight and protection of patients in clinical trials and the integrity of resulting data in an effort to modernize the agency's approach to bioresearch monitoring as part of the Critical Path Initiative. The Human Subject Protection and Bioresearch Monitoring (HSP /BIMO) Initiative will facilitate the modernization of the regulation of clinical trials and bioresearch monitoring, specifically the protection of human subjects and the integrity of data in clinical trials, and encompasses devices, foods, human drugs, biological drug products and veterinary medicine.

The new effort is part of an HHS-wide initiative to employ recent advances in basic science, including genomics and molecular analysis, in order to bring about more effective development and review of therapies, and to enable increasingly targeted and individualized care management for patients.

"As clinical trials continue to evolve, in particular becoming increasingly large, decentralized and global, the FDA's approach to bioresearch monitoring and human subject protection must also evolve and modernize," said Janet Woodcock, FDA Deputy Commissioner for Operations at this year's Drug Information Association annual meeting. "BIMO will help FDA modernize biomedical research monitoring making the most efficient use of its resources to help ensure the safe conduct of clinical trials, including taking appropriate opportunities to leverage existing oversight done by private entities to accomplish the Agency's risk minimization goals."

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/ FDA
5600 Fishers Lane, Rm. 14B17

Rockville, MD 20857

Tel: 301-827-6473

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: Wednesday, November 01, 2006 4:04 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: When completeing Form FDA 1572, does the Principal Investigator's Curriculum vitea have to affiliate to all addresses listed in Section 3?

I heard there are changes coming for Clinical Trials, can you give me any insight into what they maybe?

Thank you,

Kindest Regards
[Redacted]