From: Toth-Allen, Jean
Sent: Wednesday, June 21, 2006 11:14 AM
To: '**[Redacted]**'
Subject: RE: Question about site name on regulatory documents

Dear Ms. **[Redacted]**,

Thank you for your inquiry regarding site identification on regulatory documents. Please excuse my delay in replying.

The Form FDA 1572, while a FDA regulatory form, is largely a tool to provide the study sponsor essential information about participating clinical investigators at a study site as well as any participating laboratories and other auxiliary medical institutions involved in the study - in addition to being a consistent vehicle to document clinical investigator agreement to comply with applicable regulations and the study investigational plan for pharmaceutical studies. It appears that the other documents referred to below are all related to the information supplied on the 1572. It is obviously essential that the sponsor know the correct mailing address for the investigational site for correspondence as well as delivery of the investigational product. However, I am not sure why the sponsor wants study documents to share one of four possible site names at your institution when they are developing regulatory contracts for studies to be conducted at any of the four sites. There are no regulatory requirements relevant to their request. This appears to be an aspect of the contract that you will need to negotiate directly with them. Sorry I cannot be more helpful.

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 Practices 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(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.

From: **[Redacted]**
Sent: Wednesday, June 07, 2006 3:26 PM
To: OC GCP Questions
Subject: Question about site name on regulatory documents
Importance: High

Is there any guidance on the proper site name that needs to be listed on the regulatory documents, 1572, etc? My organization has 4 sites, each with a different name, but all under the same tax-ID#. Site 1 is conducting a study with Dr. X who only works at site 1. We were required to use the same master study agreement that is in place for Site 2 and now the regulatory contacts at the Sponsor are requesting all regulatory documents be changed to use Site 2's name with site 1's address on all documents. This entails changing CVs for all investigators, consent change, 1572 form, etc.
We feel a note to file explaining the situation as Site 1 "doing business as" Site 2 would suffice.

Could you let me know if there is anything in writing that would help my case?

Thank you for your time.
[Redacted]