From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, February 01, 2006 9:34 AM
To: [Redacted]
Subject: RE: Request for information

Dear [Redacted]:

Your question about site management organizations (SMOs) was forwarded to me for a response.

The term, "site management organization," does not appear in FDA's regulations, so there are no direct regulatory requirements for them. However, SMOs would be regulated based on the functions they perform.

SMO is often used to designate otherwise unaffiliated, loosely organized groups of clinical investigators sharing common SOPs and patient databases, in which the principal investigator (1) is often geographically remote from the other clinical investigators and their sites, and, (2) has no direct authority over the other clinical investigators. FDA has also encountered situations in which "SMO" referred to entities that assumed contract responsibilities for a sponsor (i.e., taking on sponsor responsibilities under the regulations), or, in rare cases, SMOs have set up IRBs (which thereby fall under the IRB regulations). My point here is that SMOs are a heterogeneous lot --- and are regulated according to the groups they comprise and functions they undertake. So, for example, if an SMO performs any of the functions of a sponsor, then for those functions, the SMO would have to meet the regulatory requirements that apply to a sponsor. [Please note that a sponsor may transfer any or all of its obligations to a contract research organization (CRO) or SMO by means of a written contract (see Title 21 of the Code of Federal Regulations, Part 312. 52 (21 CFR 312.52)).]

Bear in mind that FDA may indeed conduct regulatory inspections of SMOs, and would inspect them according to the functions that they are performing.

You can find all of FDA's regulations for sponsors and clinical investigators (21 CFR 312) as well as FDA's other good clinical practice regulations by visiting FDA's Good Clinical Practice (GCP) website (http://www.fda.gov/oc/gcp).

I hope this is helpful.
Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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, January 31, 2006 7:03 AM
To: gcpquestions@oc.fda.gov
Subject: Request for information

Respected sir/Madam

Iam [Redacted] pursuing post graduation in [Redacted].
sir in regard to my curriculum Iam undergoing a dessertation work for six month.The topic I have chosen is on SITE MANAGEMENT IN CLINICAL TRIAL . sir i will be highly obliged if u can forwarrd me information on funcyioning of a SITE MANAGEMENT ORGANISATION ,the compliance they need to have and process involved in it.

I will be greatfull to you if can forward the getaiols to my mail.

Thanking you

Wiyh regards

[Redacted]