From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, September 19, 2006 9:01 AM
To: [Redacted]
Subject: RE: Question

Dear [Redacted]:

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. 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)).

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).

There is also a set of slides on SMOs, presented by one of my colleagues, Stan Woollen, prior to his retirement from FDA, posted on the website. Once at the site, please click on "Educational Materials". The presentation on SMOs is about halfway down the list.

I hope this is helpful.

Sincerely,

Carolyn Hommel
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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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-----Original Message-----
From: [Redacted]
Sent: Monday, September 18, 2006 4:13 PM
To: OC GCP Questions
Subject: Question

What is the agency current thinking about SMOs? How to select and manage SMOs?

[Redacted]