From: OC GCP Questions
To: [redacted]
Subject: RE: Site Management Organization (SMO) for Clinical Research
Date: Thursday, July 16, 2015 9:29:00 AM

Dear [redacted] -

Thank you for your emailed question, and for your voice mail message. FDA does not define an SMO in any of its regulations. FDA regulations also do not address licensure for the conduct of clinical trials. You may want to consult your legal counsel about any local and state licensure requirements. Your state licensing board may also be of assistance to you.

Simply for your information, FDA regulations speak to the responsibilities of sponsors, clinical investigators, and institutional review boards (IRBs), as well as contract research organizations (CROs) for investigational pharmaceutical studies. Title 21, Code of Federal Regulations - 21 CFR Part 312 covers pharmaceutical studies (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312) and Part 812 covers medical device studies (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812). IRB requirements are found in 21 CFR Part 56 (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56). Informed consent is addressed in 21 CFR Part 50 (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50).

I'm sorry I could not be more helpful.

If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From [redacted]
Sent: Monday, July 13, 2015 11:50 AM
To: OC GCP Questions
Subject: Site Management Organization (SMO) for Clinical Research

Hello-

I have a general license research question and am hoping you can help me. What licenses are required for a Site Management Organization (SMO) for Clinical Research? Thank you in advance for your help.

Regards,
[redacted]