From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, October 25, 2006 12:00 PM
To: [purged]
Subject: RE: Non-physician investigators

Dear [purged], To my knowledge, the regulations address your question only in very general terms. That is:

Sec. 312.50 General responsibilities of sponsors.
Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. Additional specific responsibilities of sponsors are described elsewhere in this part. ...

Subpart D--Responsibilities of Sponsors and Investigators Sec. 312.53 Selecting investigators and monitors.
(a) Selecting investigators. A sponsor shall select only investigators qualified by training and experience as appropriate experts to investigate the drug...

(c) Obtaining information from the investigator. Before permitting an investigator to begin participation in an investigation, the sponsor shall obtain the following:
(1) A signed investigator statement (Form FDA-1572) containing:...
(vi) A commitment by the investigator that he or she:...
(c) Will personally conduct or supervise the described investigation(s);...
(g) Will ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments...
(viii) A list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s).

I believe it would be the State law that would dictate what would qualify a person to prescribe tests in that State, i.e., whether a M.D. would be required. Further, I suppose that an IRB could decide that in order to reduce risks to subjects, only the M.D. could order specific tests described in a protocol--that would also seem consistent with the idea of "conducting or supervising the investigation."

I hope this is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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.

-----Original Message-----
From: [purged]
Sent: Thursday, October 19, 2006 4:59 PM
To: OC GCP Questions
Subject: Non-physician investigators

Good afternoon
Are there any FDA regulations that prohibit non-physician investigators
from requesting clinical services within an institution? For example,
could a PhD order a DEXA scan or should the protocol require an MD as
part of the study team to order this test?
Thank you.
[purged]