From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, May 09, 2006 2:00 PM
To: '**[Redacted]**
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. **[Redacted]**:

Your question about completing the 1572 was forwarded to me for a response.

You asked, "For Box 1 and Box 6 of the FDA Form 1572, if an investigator put "Dr." instead of the degree of MD, is that sufficient information?"

The sponsor is required to obtain from each investigator a copy of the investigator's "...curriculum vitae [CV] or other statement of qualifications...showing the education, training, and experience that qualifies the investigator as an expert in the clinical investigation of the drug for the use under investigation." [See 21 CFR 312.53(c)(2).] The information contained in the CV or other statement of qualifications should allow the sponsor to determine if the investigator is indeed "...qualified by training and experience as [an] appropriate [expert] to investigate the drug." [21 CFR 312.53(a).] When the sponsor submits the protocol to FDA under an IND, the protocol must contain "...the name and address and a statement of the qualifications (curriculum vitae or other statement of qualifications) of each investigator, and the name of each subinvestigator...working under the supervision of the investigator...". [See 21 CFR 312.23(6)(iii)(b).]

Thus, it's fine if the investigator lists him/herself as "Dr.," provided the investigator has supplied the sponsor with sufficient information (CV or other statement of qualifications) to allow the sponsor to determine whether the investigator is, indeed, appropriately qualified to carry out the study.

Block #6 simply requires an investigator to list "...the names of the sub-investigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)." [See 21 CFR 312.53(c)(1)(viii).] While there is no explicit regulatory requirement to obtain/maintain copies of the CVs or statements of qualifications of subinvestigators, FDA's official guidance, the ICH E6, "Good Clinical Practice: Consolidated Guidance," recommends that copies of the CVs for both investigators and sub-investigators be maintained in the files of the investigator and the sponsor. [See Section 8.3.5.]

If a sponsor or contract research organization has any questions about the qualifications of a particular investigator or sub-investigator, it would certainly be in keeping with good clinical practice for the sponsor or CRO to ask the investigator for information about, or documentation of, that individual's
qualifications.

You will find links to FDA's regulations and the ICH E6 guidance on FDA's good clinical practice 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: CDER DRUG INFO
Sent: Saturday, April 29, 2006 11:55 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, April 25, 2006 7:06 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: **[Redacted]**

E-Mail: **[Redacted]**

Comments: For Box 1 and Box 6 of the FDA Form 1572, if an investigator put "Dr." instead of the degree of MD, is that sufficient information?

Please let me know ASAP.

Thank you,
[Redacted]