From: OC GCP Questions
To: [redacted]
Subject: Clinical Trial - PI responsibility question
Date: Friday, February 20, 2015 12:18:41 PM

Good morning –

FDA regulations do not specifically address your question. I suggest you speak directly to the sponsor, instead of the CRO. If you cannot resolve the situation, you may choose to not be involved in that particular study.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, February 20, 2015 10:06 AM
To: OC GCP Questions
Subject: Clinical Trial - PI responsibility question

I have participated in clinical trials as the PI since 1988 (approx. 500 trials).

I am currently participating in an **obesity** trial where the CRO, acting on the behalf of the sponsor, has made an unusual request.

I have asked to remove from the electronic case report form the following items:

1. in the medical history section, any mention of **overweight or obesity**.

2. in the physical exam section, any mention of **obesity or overweight**.

I was told that since these were "vague and imprecise" terms, they should not be included in the case report form.

It was made clear at the beginning of the trial that this was how they wanted to handle the situation.

However, I have refused to remove this information from the case report form.

I have never been requested to remove this type of information especially since it seems to be pertinent to the trial.

Please advise on the appropriate way to handle this situation.

Thanks.

[redacted]