From: OC GCP Questions
To: [redacted]
Subject: Question Regarding Section 6 of 1572 - who must be listed
Date: Friday, September 06, 2019 12:09:54 PM
Attachments: [redacted]

Good afternoon –

I send you email to the Center for Drugs (CDER). Please see their answer below. They assist my office with 1572 questions.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

This is a more complicated situation I feel like since it is partly interpretation of the pathology collector's responsibilities. It took me a while to look through this. I did find some information that may be helpful for them however, in the Guidance for Industry : Structure and Content of Clinical Study Reports., section 6 (page 5) it states,

There should be provided in Appendix 16.1.4 a list of the investigators with their affiliations, their role in the study, and their qualifications (curriculum vitae or equivalent). A similar list for other persons whose participation **materially affected the conduct of the study** should also be provided in Appendix 16.1.4. **In the case of large trials with many investigators, the above information may be abbreviated to consist of general statements of qualifications for persons carrying out particular roles in the study with only the name, degree, and institutional affiliation and roles of each investigator or other participant.** The listing should include: A. Investigators. B. Any other person carrying out observations of primary or other major efficacy variables, such as a nurse, physician's assistant, clinical psychologist, clinical pharmacist, or house staff physician. It is not necessary to include in this list a person with only an occasional role, e.g., an on-call physician who dealt with a possible adverse effect or a temporary substitute for any of the above. C. The author(s) of the report, including the responsible biostatistician(s).

It would be ideal if the sponsor went back to the Division/regulatory project manager (RPM) with the inquiry but since this is one of the sites, that gets more complicated. I think the main issue is determining whether these investigators materially affected the conduct of the study. I also wonder if OMP CDEROMP@fda.hhs.gov would be helpful in helping further define what 'materially affected the conduct of the study' and if that would be relevant in this case. I couldn't find much information to further define this.

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From: [redacted]
Sent: Sunday, September 01, 2019 5:37 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question Regarding Section 6 of 1572 - who must be listed

Hi

I am hoping you can help with advice regarding a request from a CRO to a site to list personnel on the 1572. The request seems to be an unnecessary burden of additional paperwork for the site that does not add to the robustness of the trial conduct.

The trial requires collection of nasopharyngeal swabs. These are taken by trained laboratory pathology collectors who do this routinely as part of their job. They have CVs that state they are trained for this role. There are no trial-specific differences in taking the swabs compared to standard of care.

The CRO has requested the pathology collectors be added to the 1572 and that they complete all of the associated paperwork including financial disclosure, addition to the site delegation log, GCP training etc. This is based on the CRO interpretation of FDA 1572 FAQs 31. and 33. The CRO's rationale is that the pathology collector is a sub-investigator doing protocol required tests that have a significant contribution to the data. Presence of clinical respiratory symptoms at certain timepoints (with or without the presence of laboratory-confirmed pathogens) is the primary endpoint. The site disagrees with this interpretation as the pathology collector is simply taking a swab as part of their standard role that they are trained to do regardless of whether the patient is in a study or not. They have no impact on the patient care, medical decisions or trial data outcomes.

The site in question has a high level of quality and compliance. The site wishes to be compliant with standards but is increasingly burdened by additional requests for paperwork that do not seem to support the aims of GCP or regulatory requirements. I would appreciate if you could advise whether or not FDA considers that the pathology collectors need to be listed on section 6 of the 1572.

For your information, I am a QA Consultant and the site has approached me for advice. While I have provided my input, it would be helpful to have the opinion of the FDA on the interpretation of the responses in the FAQs. It would also help me to provide accurate advice as to FDA requirements given that this is a common situation.

Many thanks

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