From: OC GCP Questions
To: [redacted]
Cc: [redacted] Less, Joanne
Subject: RE: master personnel lists
Date: Tuesday, June 24, 2014 2:53:00 PM

Dear ŵWŜŘl·ŎǘŜŘ6-

Thank you for your question and thanks to you and ŵWŜŘl·ŎǘŜŘ6 for talking with me and Pat McNeilly. We appreciate that your leadership wants to streamline and provide flexibility while being attentive to the IRB's responsibilities for reviewing investigator and study personnel qualifications. As you know, the regulations don't specifically address your scenario. When the regulations are silent, IRBs and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

As you mentioned, you are aware of and have considered FDA's guidance for IRBs, Clinical Investigators, and Sponsors titled, "IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed" (found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf).

We had an opportunity to briefly discuss the information you provided to OGCP about the proposed process to streamline communicating to the IRB the study personnel who will be working on any given study utilizing the services of the Clinical Trials Office (CTO). Based on the information provided, it appears that the process is permissible. Although we cannot determine whether or not the proposed process is in compliance with the regulations (as that can only be assessed on an inspection), we can give you some points-to-consider in setting up such a centralized process with your CTO.

Our understanding of the proposed process involves the following:

> The CTO prepares a master list of the ~15 to 20 personnel (i.e., nurse coordinators, study coordinators and support staff) that are affiliated with the CTO and for whom a ŵWŜŘl·ŎǘŜŘ6 investigator has engaged the services of the CTO. The master list of study personnel includes all those who **<u>may</u>** work on any such study (you mentioned that the CTO may support multiple studies; approximately 150 protocols/year). The IRB application for review of any such study will reference this master list of study personnel because any one of those study staff has been determined to be qualified and **<u>may</u>** work on any of these studies. In order to be included on the master list, study personnel are vetted by the CTO for required credentials, qualifications, and training **<u>and</u>** the IRB also reviews the study staff information and approves such individuals. Once approved by the IRB, the study personnel will be included on the master list. Your IRB has decided to manage this process under a single standalone protocol which includes an initial and continuing review process, and also has a process for review of modifications.
>
> Should there be a change in study personnel on the master list (e.g., a study coordinator leaves, and a new nurse coordinator is hired), the CTO will coordinate the submission of the change in study personnel to the IRB in a single submission. Any new study personnel will be added to the master list after being vetted by the CTO and their information will be reviewed and approved by the IRB prior to the investigator and CTO allowing that individual to participate in study-related activities. Along with the master list of study personnel, there will be a master list of all of the studies affected by the change in personnel included in the IRB submission. If the IRB approves the change in study personnel, the IRB will issue a single approval letter to the CTO on behalf of all the investigators and studies affected by the change, and the CTO will distribute a copy of the IRB approval letter to all affected investigators for their study records. This modification process will be managed under the single standalone protocol through the modification process.

I've listed here some points-to-consider that came up in our discussion of your question. This list is not meant to be all-inclusive:

- Based on the unique circumstances of this centralized process, we recommend that both the CTO and the IRB have SOPs specific to addressing how this process will function, including clear delineation of roles and responsibilities. All involved parties should be trained on such SOPs and understand their roles and responsibilities.

- Because the IRB must assess the adequacy of the research site, it is critical that the IRB review information about the study staff and confirm whether the site is appropriately staffed.

- The regulations at 21 CFR 56.109(e) require the IRB to notify <u>investigators</u> and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval. It is critical that if the proposed process utilizes the CTO as the responsible party who will receive the IRB approval for changes to the master

list of study personnel on behalf of the affected investigators and the CTO is responsible for passing the written IRB approval on to the investigator, that this process is followed and that it is spelled out in the SOP. In accordance with applicable regulations, IRBs and investigators will be held responsible for ensuring complete study records upon inspection.

- It is critical that all investigators working with the CTO fully understand their role and the role of the CTO when working together on any given study. Both parties should be trained on the processes to be utilized.

- It is critical that the investigator not be "left out of the loop" on any of the processes being coordinated by the CTO on their behalf for any given study, and that investigators are fully aware of their responsibilities on any study they are working on with the CTO.

- Investigators should be comfortable with all CTO study staff assigned to work on any one of their studies and should have a mechanism to provide feedback about support staff to the CTO should they have a complaint, a concern, or encounter a problem with any of the staff.

- If a study protocol dictates study-specific qualifications required of study staff, the CTO and IRB must ensure that the master list of study personnel includes someone with such study-specific qualifications.

- The question came up about how ~15 to 20 study staff included on the master personnel list who **may** work on any of the CTO studies (which can number ~150 studies) are going to be able to be knowledgeable about so many studies at any given time since they will be qualified to work on **all** such studies. This should be considered when developing this process and the accompanying SOPs.

I hope this information is useful. 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: Thursday, June 12, 2014 10:43 AM
To: Less, Joanne
Cc: [Redacted] OC GCP Questions
Subject: master personnel lists

Dear Dr. Less,

Our IRB received a request to allow a clinical trials office (CTO) service center to create a master list of research nurse coordinators which would be referenced on the protocols of investigators using the CTO, as a single entry on the IRB study personnel list. The proposal includes coordination between the CTO and IRB office to maintain and document credentials, qualifications, federal, human subject and institutional training requirements. The list would be limited to research nurses, coordinators or support staff (not investigators).

The CTO provides research nurse services to multiple investigators and may work with over 150 protocols per year. If they have a change in personnel, they must contact all of those investigators and request that the PI submit a protocol modification to update the personnel list for each of his/her studies that the CTO assists with. Utilizing a master list would streamline by eliminating the need to update each protocol. If the practice is permissible, our IRB would require that the CTO have a process or SOP to attest that the collective qualifications are not compromised by staff turnover (e.g., ensure replacement staff have equivalent qualifications, utilize a master task delegation log, etc.).

Since we would expect that the majority of the protocols involved would be FDA-regulated, we wanted to first determine if this

practice would be permissible.

- If so, would coordination at the administrative level be adequate (between the CTO and IRB office personnel)?
- Or, should it be managed as an single IRB protocol which would engage the IRB as well as the CTO and IRB office, in initial, modification, and continuing review? In this scenario, the IRB Chair could review the study personnel change (ensure appropriate qualifications) on the Master CTO Personnel Protocol (which in turn would apply to all 150 protocols the unit provides services to).

Our leadership wants to support streamlining and flexibility efforts; however, we are very attentive to the IRB's responsibilities in reviewing investigator and study personnel qualifications. We would not want to compromise that duty in any way or engage in a practice that would be questioned by FDA.

We look forward to hearing from you and appreciate any guidance and advice you can provide.

Best Regards,

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