From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, September 29, 2005 3:36 PM
To: [Redacted]
Subject: RE: staffing for [Redacted] and clinical trials

Dear [Redacted]:

Thanks for clarifying what [Redacted] stands for. I wasn't familiar with the term.

The short answer to your question is that it would be up to the ethics committee [Redacted] to determine if there would be a conflict for one individual to serve in both positions. By raising the question, you would appear to have started in that direction.

To hold both positions is not a violation of any Food and Drug Administration (FDA) regulation, nor could I identify any ethical or other conflict that holding both positions would pose. (I suppose one could worry about employee misconduct, i.e., that the employee might have the ability to issue, on his/her own authority, [Redacted] approvals for oncology studies. However, assuming that (1) appropriate controls are established in the standard operating procedures (SOPs) for both the [Redacted] and the [Redacted] group, and (2) the employee is appropriately supervised to ensure that he/she abides by the respective SOPs of each, then such misconduct would not necessarily occur.)

One caveat: both positions potentially have a lot of responsibility attached to them and each (alone)could be very demanding for the person holding the position. While it may be a great experience for the person that you hire, it may also be very stressful for a single individual to have both jobs and to do each well.

To reiterate, however, it really is up to the [Redacted] to determine if there is a conflict (or the appearance of a conflict) for one person to hold both positions.

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)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
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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: [Redacted]
Sent: Tuesday, September 27, 2005 9:59 AM
To: OC GCP Questions
Subject: RE: staffing for [Redacted] and clinical trials

Hi Carolyn,
[Redacted] stands for our [Redacted] (independent research board) which reviews and approves clinical research protocols.
The administrative assistant would be preparing the documentation from [Redacted], preparing agendas, updating data bases, preparing letters to investigators and so on for the [Redacted].

This person would then also be working in the [Redacted] service doing such things a preparing submissions to [Redacted], filing and corresponding with study sponsors, filing in study case reports, minor case report form completion and so on.

My concern is that this shared role would be seen as a conflict of interest as the person would be working directly on the study and also in the office responsible for approving clinical research protocols.
So I would like feedback on how the FDA would view this shared role. If you have any further questions please let me know.
I look forward to hearing back from you.
[Redacted]

-----Original Message-----
From: Hommel, Carolyn - OC [mailto:Carolyn.Hommel@OC.FDA.GOV] **On Behalf Of** OC GCP Questions
Sent: Monday, September 26, 2005 4:34 PM
To: [Redacted]
Subject: RE: staffing for [Redacted] and clinical trials

Dear [Redacted]:

I'm not sure I understand your question. What is an "[Redacted]" administrative assistant? What does "[Redacted]" stand for? Please let me know, and I will try to obtain an answer to your question.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner

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-----Original Message-----
From: [Redacted]
Sent: Thursday, September 22, 2005 4:38 PM
To: gcpquestions@oc.fda.gov
Subject: staffing for [Redacted] and clinical trials

Hi,
We are considering replacing a part-time [Redacted] Data Manager (clerk) and a part-time [Redacted] administrative assistant with a Full-time Administrative Assistant that would be working 50% of the time in the [Redacted] office and 50% of the time in our [Redacted] service.
Is there a conflict of interest if the Administrative Assistant works in both areas at the same time?

I would appreciate it if you could give me your perspective on this dilemma.
Thanks,
[Redacted]

***
[Redacted]scanned this email for malicious content
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