From: OC GCP Questions
To: [redacted]
Cc: Kalb, Soma;
Subject: RE: Question about Clinical Investigations
Date: Wednesday, April 29, 2015 4:21:00 PM

Dear [redacted] -

Thank you for your question and your continued patience in our response. As I previously shared with you, OGCP consulted the appropriate staff in CDRH for a response. We were also informed that CDRH received a similar request for a determination on this proposed study so we have coordinated our responses.

We noted the protocol (page 6) says, "*The aim of the present study is to perform an exploratory analysis of device data to determine if there are changes in breathing or other therapy parameters that could predict deterioration of cardiac condition prior to re-hospitalization*". Therefore, it appears that data from the various PAP devices, which collected multiple parameters about the patients' breathing and treatment, will be evaluated in conjunction with information on heart failure related admissions and outpatient visits from the patients' medical records to determine whether the device data can be predictive of the need for re-hospitalization of cardiac patients.

We also note that the protocol (page 7) indicates that the database OSU creates will be de-identified and coded by OSU and then sent to the manufacturer, Philips Respironics for further analysis by them for changes in PAP therapy data prior to a readmission for heart failure.

Whether or not the manufacturer intends to submit data from this study to the FDA now, or at a later time, it is within FDA's regulatory authority to inspect/review data that is collected regarding questions of safety and effectiveness. Thus the study meets the definition of a clinical investigation outlined in 21 CFR 50.3(c) as the results are "…intended to be submitted later to, *or held for inspection by* FDA…."

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again 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 the Commissioner, Food and Drug Administration

From [redacted]
Sent: Monday, April 20, 2015 5:23 PM
To: Donnelly, Janet; OC GCP Questions
Subject: Question about Clinical Investigations

Dear Janet-

I hope you are well! Sorry to bother you (again), but…

When my office had a previous question about INDs you kindly helped us to confirm that we had directed the question to the appropriate division. The current question does not involve an IND or IDE; it is about whether a proposed study is defined as a "clinical investigation" and therefore, subject to FDA requirements (specifically, those requiring that informed consent be obtained). I have also copied the official GCP mailbox in this case, after first checking to see whether I could find a similar question in the redacted GCP emails. If this is not the right place to ask the above question, would you mind forwarding it to that right

person/place?

A quick explanation: We have been asked to review a study evaluating the relationship between sleep apnea and heart disease. The study proposes analysis of retrospective data, collected originally from individuals with heart failure treated with a CPAP or BiPAP device manufactured by Philips Respironics. It appears to us (based on the attached protocol) that the study was co-designed with the sponsor; and data will be either analyzed by (one version of the protocol) and/or shared with Philips (the protocol was modified once we asked for clarification of the manufacturer's involvement). The investigator has stated that if he finds a relationship between the recorded data and clinical outcomes, "this will be very useful to Philips Respironics on many levels." Hence, my question about whether the data may be "intended to be later submitted to or held for inspection by FDA," and therefore, the study should be defined as a clinical investigation. (We would ordinarily not investigate further if this were designed only as an "in house" investigator-initiated study.) As you might guess, the investigator was hoping to conduct this study under a waiver of informed consent, which the IRB could consider if it were to determine that the study need not comply with FDA regulations.

The investigator is very anxious to submit the study and believes that we are unnecessarily (and inappropriately) delaying him by considering that he may need to comply with FDA regulations. Any advice that you could provide would be much appreciated!

Thanks,

[redacted]