From: OC GCP Questions
To: [redacted]
Subject: RE: Please advise and confirm
Date: Wednesday, March 29, 2017 10:33:00 AM
Attachments: [redacted]

Dear [redacted],

If you have determined that you trial is an applicable clinical trial, you should register your trial as you appear to be doing. It may be advisable to familiarize yourself and possibly others at your institution with the requirements of the new HHS regulations related to ClinicalTrials.gov. The regulations are codified at 42 CFR part 11 and a copy may be found at https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission . You may also wish to review the preamble to the regulations which contains a great deal of information and may assist you in the event you have questions.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Patrick J. McNeilly, Ph.D.
Senior Health Policy Analyst

Office of Good Clincial Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Tuesday, March 28, 2017 5:15 PM

To: OC GCP Questions
Subject: RE: Please advise and confirm

Dear Dr. McNeilly,

Thank you for your swift response and clarification. Based on the checklist, I have determined that we will need to register the study on www.clinicaltrials.gov. According to the information provided on the website, the requirement is to register an applicable study within 21 days of the first subject enrollment. However, we inadvertently missed this deadline as our site was not aware of this guideline. Our first enrolled subject was on 14-FEB-2017, thus 9 business days have passed since the 21 day window closed. I anticipate registration of our study in the next 1-2 days; however, please clarify what steps are required from our site due to our inadvertent error.

I look forward to your response and thank you tremendously for your time and guidance.

[redacted]

Regards,

[redacted]

[redacted] OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Monday, March 27, 2017 12:38 PM
To: [redacted]
Subject: RE: Please advise and confirm

Good afternoon,

The National Institutes of Health has developed a checklist to assist in determining whether a trial is an applicable clinical trial. The checklist and accompanying elaborations document can be found on the ClinicalTrials.gov website at http://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf .

Please note that the regulations at 42 CFR 11.10 state the following: "Control or Controlled with respect to a clinical trial, that data collected on human subjects in the clinical trial will be compared to concurrently collected data or to non-concurrently collected data (*e.g.,* historical controls, including a human subject's own baseline data), as reflected in the pre-specified primary or secondary outcome measures. For purposes of this part, all clinical trials with one or more arms and

pre-specified outcome measure(s) are controlled." (emphasis added).

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Patrick J. McNeilly, Ph.D.
Senior Health Policy Analyst

Office of Good Clincial Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Monday, March 27, 2017 12:30 PM
To: OC GCP Questions
Subject: Please advise and confirm

To whom it may concern,

We are conducting a clinical trial that involves two FDA approved products (a FDA approved device and a FDA approved drug). The study does not involve a control group as all subjects receive the same treatment. Since there is not a comparison group, please confirm that this study does not need to be registered on www.clinicaltrials.gov.

Thank you for your time.

Regards,

[redacted]