From: OC GCP Questions
To: [redacted]
Subject: RE: clinicaltrials.gov question
Date: Friday, September 07, 2018 3:14:53 PM
Attachments: [redacted]

Dear [redacted]:

Thank you for your inquiry. To further assist responsible parties in evaluating whether a study meets the definition of an applicable clinical trial, the NIH/National Library of Medicine has developed the attached checklist. Should you have additional questions regarding the applicability of the regulatory requirements, please contact the ClinicalTrials.gov staff at register@clinicaltrials.gov.

Sincerely,
Bridget Foltz

Bridget A. Foltz, M.S., MT(ASCP)
Health Scientist Policy Analyst

Office of the Commissioner (OC)
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration
bridget.foltz@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at bridget.foltz@fda.hhs.gov

From: [redacted]
Sent: Friday, September 07, 2018 10:02 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; [redacted]
Subject: clinicaltrials.gov question

To Whom it May Concern,

I am writing to confirm my understanding of the requirement for the registration of trials on clinicaltrials.gov. This question pertains to a retrospective trial testing tissue

samples on patients previously enrolled on specific treatment trials. If the trial in question will only include sending tissue samples to a lab for sequencing and those results will be assessed in connection with clinical outcomes reported on the treatment trials the patients were previously enrolled to -hence there is no intervention in the trial in question- I wanted to confirm the study does not need to be registered with the FDA. Of note the study will not be sent to the FDA as it definitely meets exemption criteria and there is no intervention.

Thank you

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]