From: OC GCP Questions
To: [redacted]
Subject: Site Level Audit Implications - Protocol Waiver
Date: Tuesday, December 18, 2018 10:30:40 AM
Attachments: [redacted]

Good morning –

Generally, FDA does not approve "protocol waivers". However, if the sponsor has communicated with FDA regarding this situation, please have the sponsor follow back with the FDA person they spoke with to inquire as to what type of written communication is expected regarding the decision made by FDA.

In addition, generally FDA expects that care is taken when a sponsor writes a study protocol (in consultation with experienced clinical investigators as necessary) that waivers are unnecessary. Any divergence from a protocol shared by all study sites risks collecting data that is not compatible from site to site and therefore not poolable for analysis. However, we do recognize that protocol waivers are sometimes requested by individual clinical investigators and sponsors make the decision that to allow a particular waiver would not adversely affect the results. In such cases, FDA expects to see that the clinical investigator requested the waiver prior to enrolling the subject in question and that there is documentation of the sponsor's agreement in the study file. FDA bioresearch monitoring (BIMO) post-inspectional letters have cautioned sponsors about allowing protocol waivers and even considered them protocol violations under some circumstances.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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.

From: [redacted]
Sent: Friday, December 14, 2018 3:28 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: Site Level Audit Implications - Protocol Waiver

To whom it may concern,

Due to site limitations, the Sponsor for a trial is granting us a Protocol Waiver for several lab specimens that cannot be processed within the required protocol timeframes. This waiver is being completed proactively, prior to the study being initiated at our site. The Sponsor mentions in the waiver form that they approve our site's participation with full knowledge of this limitation.

Would this type waiver pose any issues for our site, should we ever have an FDA audit for this trial? If so, is there any additional language that you may recommend be included in the waiver form? Thank you in advance for your assistance in this matter.

Sincerely,

[redacted]

[redacted]