From: OC GCP Questions
To: [redacted]
Subject: Re-consent or not
Date: Thursday, September 01, 2016 12:52:00 PM

Good afternoon –

It might be difficult to reconsent because the study population is large and the study has been completed since 2012. You might lose your study cohort. When submitting your application to FDA, you will need to discuss this situation with the review division and they can give you direction as to whether a waiver can be granted or whether they want you to try to reconsent.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

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: Thursday, September 01, 2016 12:13 PM
To: OC GCP Questions
Subject: Re-consent or not

Hi,

I have a consent question.

If a study was done in another country exclusively and the original consent stated that only that country's HA would review the subjects' records and then it was decided that that particular study should be included in a submission to the FDA, would FDA expect that all the subjects be re-consented with a new ICF to add "any HA" could review the subject records? Or would it be more likely that the FDA would grant a waiver if an alternative method to validate SD was agreed upon?

There are approximately 700 subjects and the study has been over since 2012.

Thanks.
[redacted]