From: OC GCP Questions
To: [redacted]
Subject: Clinical Investigation Site Registration/Identification
Date: Wednesday, November 15, 2017 12:55:00 PM
Attachments: [redacted]

Good afternoon –

I spoke to an OGCP colleague and we don't think you need to register. However, it might be a good idea to let the FDA regulatory project manager of the IND know that you are adding a site if you are functioning as the sponsor as the CRO.

Kind regards,

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

From: [redacted]
Sent: Wednesday, November 15, 2017 9:49 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Clinical Investigation Site Registration/Identification

Hello,

If a new clinical investigation site is being established under a CRO, is it necessary to register/self-identify the site (aside from BA/BE study self-identification requirements)? Of course the site will be listed on FDA Form 1572 with the investigator before the trial is to begin.

Thank you,

[redacted]