

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

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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,

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**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

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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]  
[REDACTED]  
  
[REDACTED]  
[REDACTED]  
[REDACTED]