

**From:** [OC GCP Questions](#)  
**To:** [REDACTED] [GCP Questions](#)  
**Cc:** [REDACTED] [George, Sherry; Hawkins, Anthony; Kalb, Soma](#)  
**Subject:** RE: certificate of confidentiality  
**Date:** Thursday, May 28, 2015 10:32:00 AM

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Dear [REDACTED],

The contacts for COCs vary by Center, and the application is slightly different for INDs (drugs/biologics) and IDEs (devices). The contacts can give you the submission information needed for the type of study you want to conduct.

CDER (drug studies): Ms. Sherry George, [sherry.george@fda.hhs.gov](mailto:sherry.george@fda.hhs.gov) or John Ng, [john.ng@fda.hhs.gov](mailto:john.ng@fda.hhs.gov)

CBER (biologics/some device studies): Mr. Anthony Hawkins, [anthony.hawkins@fda.hhs.gov](mailto:anthony.hawkins@fda.hhs.gov) or Ms. Pat Holobaugh, [pat.holobaugh@fda.hhs.gov](mailto:pat.holobaugh@fda.hhs.gov)

CDRH (device studies): Dr. Soma Kalb, [soma.kalb@fda.hhs.gov](mailto:soma.kalb@fda.hhs.gov)

The primary contacts are cc'd on this email for your convenience.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov).

Sheila

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**From:** [REDACTED]  
**Sent:** Tuesday, May 26, 2015 3:35 PM  
**To:** OC GCP Questions  
**Cc:** [REDACTED]  
**Subject:** certificate of confidentiality

Can you direct me how to apply for a certificate of confidentiality for a clinical trial?

Thank you,

[REDACTED]