**From:** OC GCP Questions
**To:** [redacted]
**Subject:** RE: Question re -Forms for IND
**Date:** Monday, November 26, 2018 1:42:00 PM
**Attachments:** [redacted]

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Dear [redacted],
There are several forms required for an IND (Investigational New Drug) application. This link takes you to a general information page; there are links on the left side of the page for regulations, guidances, policies, and forms.
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm

You may want to contact both the drug manufacturer and FDA's Small Business and Industry Assistance (SBIA) staff regarding a "pre-IND meeting" prior to beginning your study. More information on this topic can be found at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069906.htm . SBIA can be reached at (866) 405-5367 (toll free), (301) 796-6707, or by email at CDERSBIA@fda.hhs.gov

Best regards,

Sheila

**Sheila Brown, RN, MS**
*Policy Analyst*

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**Office of Good Clinical Practice (OGCP)**
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*This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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.*

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**From:** [redacted]
**Sent:** Monday, November 26, 2018 12:52 PM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** Question re -Forms for IND

Dear FDA,

What forms are needed for a research study that wants to study a new use for an FDA approved drug?

Thanks,

[redacted]

[redacted]

[redacted]