

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Request for medical device clinical trial guidance document  
**Date:** Friday, November 13, 2015 7:00:35 AM

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Good morning –

The 1572 form is used for IND studies. An investigator agreement is needed for FDA-regulated device research. If you have specific questions regarding medical devices, you can contact the Center for Devices (CDRH) directly at [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)

Kind regards,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst  
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.

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**From:** [REDACTED]  
**Sent:** Thursday, November 12, 2015 8:08 PM  
**To:** OC GCP Questions  
**Subject:** RE: Request for medical device clinical trial guidance document

Good Evening.

I could not find the information on form 1572; whether it is required for the medical device clinical research or not. I greatly appreciate your help!

Thank you

[REDACTED]