

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Study of an exempt device  
**Date:** Monday, March 09, 2015 4:12:46 PM

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Good afternoon –

It is best to ask the Center for Devices (CDRH). Please email them 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:** Monday, March 09, 2015 3:39 PM  
**To:** OC GCP Questions  
**Subject:** Study of an exempt device

Dear FDA,

When an investigator conducts research on a device that is determined to be exempt from 21 CFR 812 requirements for an IDE, is the investigator required to follow the abbreviated requirements under 21 CFR 812.2b?

Sincerely,

[REDACTED]