

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Compassionate Device Use  
**Date:** Monday, October 05, 2015 5:45:21 AM

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Good morning –

It is best to send your email directly to the Center for Devices (CDRH) at [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov). This Center oversees compassionate device use.

Kind regards,

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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:** Friday, October 02, 2015 3:05 PM  
**To:** OC GCP Questions  
**Subject:** FW: Compassionate Device Use

Good afternoon,

My question is regarding Expanded/Compassionate Use of a Device. I research this topic and there seems information regarding IRB concurrence. However, it does not provide details what that entails. The FDA Guidance on Expanded Access (attached) requires IRB approval. What is the current guidance on expanded access regarding IRB approval?

Thank you,

[REDACTED]