

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Single Patient INDs and HIPAA authorization for research  
**Date:** Wednesday, March 30, 2016 7:11:22 AM

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Good morning –

Under FDA regulations, HIPAA is not part of the essential elements of informed consent (21 CFR 50.25).

FDA does not have responsibility for the implementation of HIPAA. HIPAA is the responsibility of the Office of Civil Rights. You may wish to consult the Health Insurance Portability and Accountability Act (HIPAA) For questions regarding issues pertaining to HIPAA, you may contact OCR directly at [OCRPrivacy@hhs.gov](mailto:OCRPrivacy@hhs.gov) . Here also is a link to OCR's general website for HIPAA [www.hhs.gov/ocr/privacy/](http://www.hhs.gov/ocr/privacy/), and OCR also has HIPAA Frequently Asked Questions that can be accessed at [www.hhs.gov/ocr/privacy/hipaa/faq/index.html](http://www.hhs.gov/ocr/privacy/hipaa/faq/index.html). You may also wish to discuss your question with other in-house legal staff, including any Privacy Officer, within your sponsor organization and/or institution.

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:** Tuesday, March 29, 2016 12:47 PM  
**To:** OC GCP Questions  
**Subject:** Single Patient INDs and HIPAA authorization for research

Dear FDA,

When a physician obtains a single patient IND in order to provide a patient with an investigational agent and is managing this drug and treatment under an IND, should the HIPAA authorization include the research language or should the physician rely on the standard hospital notice of privacy?

Sincerely,

[REDACTED]