**From:** OC GCP Questions
**To:** [redacted]
**Subject:** HIPAA question
**Date:** Monday, March 02, 2015 10:41:15 AM

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Good morning –

Below is a previous answer from FDA's Office of Medical Policy regarding subject withdraw and adverse event reporting.

*A sponsor should continue to collect data on a subject experiencing an ongoing adverse event (and record the data in the CRF) if the information that would be obtained is pertinent to the investigation (e.g., could contribute useful information about the safety profile of a drug). Factors to consider include whether the event is serious and the extent to which the event is already characterized. If the event is serious, the investigator should generally continue to follow the patient, and should always follow if the event is also unexpected. For nonserious events there may be less reason to continue to follow, particularly for events already listed in the Investigator Brochure.*

*Generally, the protocol should provide for follow-up of some types of adverse events until they are resolved (or clinically stable if not expected to resolve). The investigator should seek clarification from the sponsor if necessary. If the sponsor has specific concerns, they should discuss them with the review division.*

*The follow-up period provided for in the protocol is generally considered adequate to capture adverse events that may be related to the test article. However, if an investigator believes an event occurring after the patient has completed the trial may be related to the test article, the investigator should inform the sponsor. The sponsor should evaluate as it would any other event reported by the investigator.*

You might find this guidance useful. Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf

Unfortunately, I cannot advise you regarding matters concerning the Health Insurance Portability and Accountability Act (HIPAA) as HIPAA and its related statutes are under the jurisdiction of the Office for Civil Rights (OCR) and not FDA. However, you may want to consult the Health Insurance Portability and Accountability Act (HIPPA) For questions regarding issues pertaining to HIPAA, you may contact OCR directly at OCRPrivacy@hhs.gov . Here also is a link to OCR's general website for HIPAA http://www.hhs.gov/ocr/privacy/ , and OCR also has HIPAA Frequently Asked Questions that can be accessed at 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.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

and does not bind or otherwise obligate or commit the agency to the views expressed.

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**From:** [redacted]
**Sent:** Friday, February 27, 2015 1:26 PM
**To:** OC GCP Questions
**Subject:** HIPAA question

Dear Sir or Madam,

I am an IRB panel member and I am reviewing a consent for an industry sponsored study with the below paragraph in the consent. This appears to be a gross violation of the HIPAA regulations, though I understand that this appears to be about safety, however, I am very uncomfortable with this. Would it be possible for you to give me some advice? Thank you so much for your attention in this matter.

If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Kind regards,

[redacted]