From: OC GCP Questions
To: [redacted]
Subject: RE: compliance question
Date: Monday, January 05, 2015 1:00:00 PM

Dear [Redacted]-

Thank you for your question and your patience in our response. I appreciate you letting us know that we may have received the same question from your colleague and I wanted to check with my colleagues first before I responded to your question. It appears that our OGCP mailbox received a very similar question to yours earlier on the same day that you sent your question. I have copied below a redacted copy of the question and the response my colleague previously sent:

> **From:** OC GCP Questions
> **To: [redacted]**
> **Subject:** compliance / PHI question for clinical trial
> **Date:** Wednesday, December 24, 2014 11:38:26 AM
>
> Good morning --
>
> There is nothing that prevents a sponsor from collecting personal information about subjects in their studies. (Most, if not all, of which would be considered PHI under HIPAA). However, sponsors do not really need this information as their monitors and auditors can ensure that the data they receive coded for analysis does indeed come from specific study subjects who exist. Therefore, in most cases sponsors have refrained from collecting this type of information. However sponsors can ask and receive the requested information.
>
> Oversight of Clinical Investigations – A Risk Based Approach to Monitoring
> http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf
>
> The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) mentions in section 6.10 that the sponsor should ensure the protocol or other written agreement specifies who has access to source data/documents (you can access this guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf). I've copied below section 6.10 and other relevant sections of the ICH GCP E6 guidance for your consideration
>
> 6.10 Direct Access to Source Data/Documents
>
> The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s) by providing direct access to source data/documents.
>
> Direct access is defined as:
>
> 1.21 Direct Access: Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.
>
> It is expected that all parties involved with a study maintain the confidentiality of subject records and the extent that it is feasible is to be discussed as part of the informed consent process and be included in the informed consent document. The IRB is most often included in the informed consent document as one of the parties who may have access to the subject's records.
>
> You may wish 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.
>
> Happy Holidays to you too!
>
> 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.

From: [redacted]
Sent: Wednesday, December 24, 2014 11:21 AM
To: OC GCP Questions
Subject: compliance / PHI question for clinical trial

Good Morning,

I was asked by a sponsor to provide, prior to IRB approval, initials and ages of subjects, who experienced an adverse event related to an approved study drug. This information was intended for the feasibility of a new clinical trial. I was advised that this was permissable as per http://privacyruleandresearch.nih.gov/pr_08.asp#8e.

Now the sponsor is requiring an adverse event forms, prior to IRB approval, for these subjects which will include PHI [name, DOB, sex, height, weight, date of event] as per http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085589.htm.

The sponsor states that according to this FDA document we are allowed to release the PHI without IRB approval since the HIPAA privacy rule is not intended to disrupt safety reporting.

Is it permissible to release this information?

Thank you in advance for your time and guidance and Happy

[redacted]

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]
Sent: Wednesday, December 24, 2014 3:44 PM
To: OC GCP Questions
Subject: compliance question

Good Afternoon,
I am not sure if one of my colleagues asked a similar question already...

Our site was asked by a sponsor to provide, prior to IRB approval, the number of subjects who experienced an adverse event related to an approved study drug, intended for the feasibility of a new clinical trial.

Now the sponsor is requiring an adverse event form, also prior to IRB approval, which will include PHI (name, date of birth, date of event) as per http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085589.htm.

Is it permissible to release the adverse event form and information prior to IRB approval in this situation?

Happy Holidays,

[Redacted]