From: OC GCP Questions
To: [redacted]
Subject: Release of Clinical Trial Records for Life Insurance
Date: Monday, July 31, 2017 8:22:00 AM
Attachments: [redacted]

Good morning –

I spoke to a colleague here in OGCP and we have not addressed this question previously. I think your last paragraph is accurate. Also you may want to check with the site's reviewing IRB for guidance. I am pretty sure that the subject would need to sign a medical release form for information for the life insurance. I am not sure what this form would say in detail.

Lastly, this situation might fall under the HIPPA Privacy Rule. I can refer you to the Office of Civil Rights (OCR) since HIPAA is enforced by OCR, not FDA. You can find information about HIPAA-related issues, including de-identification and PHI, on their website at www.hhs.gov/ocr/privacy/. You should also be able to find contact information available there should you not find the answers to your specific questions on the website.

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

From: [redacted]
Sent: Thursday, July 27, 2017 3:03 PM
To: OC GCP Questions
Subject: Release of Clinical Trial Records for Life Insurance

Dear GCP Questions,
I have recently had a new scenario and in researching have been unable to confirm this one. If a study subject for a clinical trial is applying for life insurance and needs all of their medical records. Would it be possible to release her records from the trial? We have only seen the medical records released, but then if the research records are part of the medical record (so they have an EMR with all research and clinic records), the insurance company would have visibility?

I am not sure that the ICF would limit the sharing of patient's data by the patient themselves, but

depending on the confidentiality language the ICF should probably be reviewed for this. I would think it would be left up to Sponsor of the clinical trial then if regulations do not cover this. Perhaps there is an element of redacting of some data that could be allowed if there were concerns (such as protocol identifiers or anything that could point a reviewer to know what the study was).

I looked over the Barnett GCP Q&A as well regarding subject request and sharing of trial date, but I think the question needs to be directed to the site as to whether the site maintains both the clinic medical records, as well as, the study source record. One would expect the medical record should reflect the subjects medical history and SOC treatments and may mention the subject being in a trial. The subject has every right to have access to/copies of the clinic record.

Any other references that I could research on this topic?

[redacted]

Kind Regards,

[redacted]