From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: Research Chart
Date: Tuesday, September 25, 2018 12:32:00 PM
Attachments: [redacted]

Dear [redacted],

FDA's regulations and guidance are silent on the topic of providing a copy of a subject's entire research record to the subject. From your email, it appears that you are willing to share the results of lab results and other tests performed.

The Office of Civil Rights regulates HIPAA. They have some questions/answers on their website, one of which pertains to this topic. It is copied here for your convenience:

> **Q: Does the Privacy Rule give subjects a right to access their research records during the course of a clinical trial?**
>
> **A:** The Privacy Rule does afford subjects and patients a right to inspect and obtain a copy of their PHI held by covered entities in what is termed a "designated record set." A designated record set includes any record that is maintained by the covered entity or its business associate that is a medical, billing, enrollment, or payment record or other record that is used to make decisions about the subject of the information. It may be, in some cases, that research data would not be considered part of the designated record set if, for example, the research data is not used to make decisions about the individual and not part of the medical record. In that case, the individual would not have a right to access the data, but this should be examined on a case-by-case basis with institutional officials. In the case of research that includes treatment, including clinical trials, the Privacy Rule permits a covered entity to suspend the individuals' access rights until the end of the research study, provided the individual agreed to the suspension when consenting to participate in the research and was informed that right of access would be re-instated upon completion of the research. The Privacy Rule permits the covered entity to insert in the Authorization form a statement by which the subject agrees to the suspension of right to access during the clinical trial and that informs the individual that the right to access will be reinstated upon completion of the research.
>
> Covered entities are required to have policies and procedures for responding to access requests, and researchers that are workforce members of a covered entity may wish to coordinate any response to a subject's request with the medical records department, privacy officer, or legal counsel to ensure compliance with both the Privacy Rule and institutional policies.

It can be found under the topic "Clinical Research and the HIPAA Privacy Rule" at https://privacyruleandresearch.nih.gov/clin_research.asp . OCR can be reached at OCRPrivacy@hhs.gov, if you have any questions about their regulations and policies.

I recommend that you also confer with your legal staff, IRB, and sponsor(s) regarding the drafting of an SOP on this topic.

I hope this information is helpful to you. If you need further assistance, please feel free to

contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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Policy Analyst

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U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Monday, September 24, 2018 3:18 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Research Chart

We have recently had a patient call and request his research chart be sent to him. I have always been told we cannot do this as his chart was specific to a protocol in which we sign a Confidentiality agreement with the sponsor. We were happy to send lab results and other test performed. Would you be able to give our site some guidance and point us toward a guideline so that we may create an SOP for future reference.

Thank you,

[redacted]

[redacted]