From: OC GCP Questions
To: [redacted]
Subject: clincial trial question <gcp.questions@fda.hhs.gov>;
Date: Monday, July 07, 2014 9:52:25 AM

Good morning –

It appears from your email that the IRB believes your study needs IRB oversight. I cannot comment further on this. As you know an IRB's primary role is to protect the health, safety, and welfare of research subjects. It might be best to continue meeting with the IRB to go over issues that you see as road blocks to you starting your study.

You might find this guidance document helpful.
Guidances > Institutional Review Boards Frequently Asked Questions - Information Sheet

Kind regards,

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

From: [redacted]
Sent: Sunday, July 06, 2014 4:01 PM
To: OC GCP Questions
Subject: Re: clincial trial question <gcp.questions@fda.hhs.gov>;

Miss Kezer (and all!)

Thanks so much for your reply to my question which is helpful.

Based on your response, am I correct in believing that it is not an FDA requirement that any particular version of a HIPAA form must be used for a prospective medical study? I understand that you can not respond for OCR requirements and will ask them as well!

I have a follow up question that remains from my first e-mail, which I have inserted below:

If the IRB in this case won't change their position I will have to terminate the study (I'm not comfortable having patients sign such a broad form for such a specific study.) Do I have any other options to continue the

study without ongoing IRB support?

I am somewhat confused about the need for ongoing IRB support of the study I referenced below. The reality is that I am performing this as a self assessment of techniques that may help decrease complications or pain associated with surgery and I just want to make sure that I understand any regulatory requirements for this type of work.

The IRB in this case was engaged as I had applied for grant funding to help defer the cost of the study. I would hate to be accused of performing illegal human research---especially when I'm merely trying to find a way to decrease problems associated with a surgery I already perform! Can you help direct me to a source to understand the regulatory requirements of the FDA for prospective studies?

Any advice you can give me or direct me towards would be helpful!

Thanks!
[redacted]

From: OC GCP Questions <gcp.questions@fda.hhs.gov>
To: [redacted]
Sent: Saturday, July 5, 2014 10:04 AM
Subject: clincial trial question <gcp.questions@fda.hhs.gv>;

Good morning –

The IRB that you are working with may have a standard operating procedure that states that all subjects need to sign a HIPPA form. As you know this form is used in standard medical practices and treatment.

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. For questions regarding issues pertaining to HIPAA, you may wish to contact OCR directly at OCRPrivacy@hhs.gov. I suggest you send your question to OCR to get their response. 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

From: [redacted]
Sent: Wednesday, July 02, 2014 5:21 PM
To: OC GCP Questions
Subject: clincial trial question <gcp.questions@fda.hhs.gov>;

Hi! I love the website and found lots of good information, but am stuck with a certain question on which I would like an opinion.

I am an Ear, Nose and Throat doctor and have designed and instituted a simple clinical study regarding tonsillectomy, post operative pain, and complications. Patients undergoing surgery are given an over the counter available drink (can purchase at the grocery store) that will help with hydration. The study will then determine if the group given the drink does better than the control group.

I have worked with our local hospital IRB who has approved the study design. However, I have been instructed that every patient will have to sign a HIPPA form that authorizes review of their entire medical record (including psychiatric history and HIV status) by any entity that needs to review the data for any clinical purpose regarding the study as well as states that this data may leave the control of the institution and the investigator.

I've asked if we can avoid using this document (by anonymizing the data or not linking the data collection to a patient chart) and have been told that it is an FDA requirement. Both patients and myself find the broad language unacceptable for the purposes of this study.

I can't find anything on the FDA site to support the IRB's statement. Can you help lead me to the correct information?

If the IRB in this case won't change their position I will have to terminate the study (I'm not comfortable having patients sign such a broad form for such a specific study.) Do I have any other options to continue the study without ongoing IRB support?

Thanks for any guidance and support!

[redacted]