From: OC GCP Questions
To: [redacted]
Subject: Question regarding informed consent and specimen usage
Date: Wednesday, May 25, 2016 1:28:00 PM

Good afternoon –

Please note that FDA does not require IRBs to stamp the consent form with approval and expiration dates. From the limited information in your email, it appears the subjects were properly consented and the specimens can be used. You may want to document the situation you describe in your email as a note-to-file in case there are questions should a FDA inspection occur at your site.

FDA does not have responsibility for the implementation of HIPAA. That is the responsibility of the Office of Civil Rights. 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 www.hhs.gov/ocr/privacy/, and OCR also has HIPAA Frequently Asked Questions that can be accessed at www.hhs.gov/ocr/privacy/hipaa/faq/index.html.

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

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, May 25, 2016 11:42 AM
To: OC GCP Questions
Subject: Question regarding informed consent and specimen usage

Hello, GCP experts –

I hope that you can help me with a question regarding informed consent and specimen usage.

We have an investigator-initiated study at our institution that can be summarized as follows:

- Head and neck cancer patients are consented.
- They gargle with a saline solution to collect any cells from the inside of their mouth. This saline sample is then analyzed in the investigator's lab.
- The patients undergo standard of care surgery to remove their head and neck tumor.
- If excess fresh tumor tissue is available, it is de-identified and routed back to the

investigator's lab to be passaged in mice as patient-derived tumor xenografts.

- Demographics (age, sex, tobacco use history) and info on the tumor (location, stage, grade, HPV status) are collected, but long-term follow-up (outcomes) are NOT collected.
- Surgery is the end of the patient's participation in the study.

The investigator consented the first four patients using a consent form that did not have the official watermark stamp-of-approval from our IRB. However, the content of the form was identical to the officially approved informed consent document with the watermark. Also, he consented the patients after the informed consent form was IRB approved.
He also failed to obtain a signed HIPAA form from these patients.

We contacted our local IRB to report this event and to seek guidance. They consider this to be a clerical error and feel that the patients were properly consented. The patient's safety and well-being were not affected by this at all. This investigator is very earnest (albeit somewhat new to clinical trials, especially running his own) and does not have any kind of track record of errors or misbehavior.
We recognize that there is nothing in the regs to address this specific situation, and we want to make sure that the specimens can still be used for research. The opinion here is a bit split on the issue, with the most conservative opining that the patients weren't "properly consented" and therefore that the specimens can't be used. Others feel that the patients are fully informed and that they can easily be reconsented (and HIPAA forms obtained) since this happened very recently.
Of course, we'd like to be compliant and we don't want to put the institution or the investigator at risk because a federal agency considers the fresh specimens to be "improperly obtained."

I'd appreciate any comment or guidance that you can offer. I'd be happy to provide more information over the phone if necessary.
Thank you in advance for your help!

Respectfully,

[redacted]