From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Take Video for Patient and Send Out of the Clinic
Date: Wednesday, September 05, 2018 11:09:00 AM
Attachments: [redacted]

Good morning –

From a FDA perspective only, FDA regulations do not specifically address videotaping of subjects. If you, or some other entity wants to require videotaping, then you must carefully think through how you will implement such a requirement, how you will ensure the CIs understand the requirement, that the IRB/IEC reviews the requirement, and most importantly, that subjects understand the requirement and agree to and document their agreement to being videotaped.

Again, FDA regulations do not explicitly address the issue of taking pictures or videotapes of subjects. However, one criteria for IRB review and approval of research is to determine, where appropriate, that adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data. See 21 CFR 56.111(a)(7). The informed consent regulations require a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. See 21 CFR 50.25(a)(5). Thus, I believe you would also need IRB review and approval of the plan to videotape the subjects, as well as the permission of each subject who is consented for the study, with a fair explanation of why the videotape was being made, what was going to happen with the videotape, who would have access to it, and the extent to which confidentiality would be maintained.

As such, a description of the videotaping should be included in the protocol and the consent form.

I cannot comment on the PHI question. Videotaping might fall under HIPPA in the US. In the US there is HIPPA (privacy) requirement for medical records. 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. 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.

You might be interested in FDA's guidance document on Protecting the Rights, Safety, and Welfare of Study Subjects. Link below.

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Wednesday, September 05, 2018 4:21 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Take Video for Patient and Send Out of the Clinic

Hello Officer,

Is it permitted that in a clinical trial, the sponsor asks the site investigator to take a short video for patient, and send it to study PI (at another investigational site) to verify the patient's performance status (only to confirm whether the patient is eligible for the trial)?

- Should this video be considered PHI?
- Is it permitted if the video was processed with no identifiable contents, e.g., with mosaic on the patient's face?

Please instruct.

Kind Regards,

[redacted]