**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Videotape and Images
**Date:** Thursday, September 12, 2019 11:42:01 AM
**Attachments:** [redacted]

---

Good morning -

Thank you for your email. According to 21 CFR 312.23(a)(6)(ii) that requires in those phases "detailed protocols describing all aspects of the study." As such, a description of the videotaping should be included in the protocol and the consent form. FDA regulations do not explicitly address the issue of taking pictures or videotapes of subjects and or procedures. 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 and procedure, 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. You might also have to be aware of state and local laws as well as HIPPA regulations when considering videotaping. FDA regulations do not address storage of the video. This should be addressed in your internal processes. You will also need to consult your institutional officials as well as the reviewing IRB.

Since you mention it is a device study, you want to contact the Center for Devices (CDER) at DICE@fda.hhs.gov

For you second question, I sent your email to ORA. They perform FDA inspections. See the answer below.

Kind regards,

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




ORA Answer # 2 -

If the images collected are protocol required source data and are used to evaluate or assess safety or efficacy, then the images should be available for FDA to review during an inspection.

The site should be provided access to the images at some point during or immediately after the trial to ensure ALCOA-C.

Even if the site is required to be blind to the image, the sponsor (or central reader) should assure FDA can be provided access to the image in some way, during the inspection.

Let us know if you have any other questions.

Diane C. Van Leeuwen, CSO
Bioresearch Monitoring Program Expert

Office of Bioresearch Monitoring Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration
phone (949) 608-2978
mobile (202) 657-9174
diane.vanleeuwen@fda.hhs.gov

---

**From:** [redacted]
**Sent:** Thursday, September 12, 2019 3:00 AM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** Videotape and Images

Dear FDA Representative,

I have two unrelated questions regarding videotapes and images that I would appreciate your opinion on.

1. If a protocol for a device study indicates that the Investigator or sponsor will videotape the study procedure/surgery (also included in the ICF), is it required for the site to maintain the video or is it acceptable for only the sponsor to *maintain/store* the videotape?

2. If images are required for a study whereby the image taken at the site is directly uploaded to a central reader and the site does not have the capability of reading the image, is there any requirement for the site to be able to show the image to an FDA Investigator during an investigator inspection?

Thank you,

[redacted]