**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Informed Consent
**Date:** Tuesday, February 25, 2020 11:29:34 AM
**Attachments:** [redacted]

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Good morning –

Thank you for your email. FDA allows the PI to delegate the task of consenting, including to research coordinators, as long as that does not conflict with local IRB policy. Please see additional information below.

The FDA informed consent regulations at 21 CFR 50.20 address the general requirements for informed consent (see www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.20 ) and state in part:

Sec. 50.20 General requirements for informed consent.

Except as provided in 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

The regulations at 21 CFR 50.27 address documentation of informed consent (see www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.27 ) and state in part:

Sec. 50.27 Documentation of informed consent.

(a) Except as provided in 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.

So the FDA regulations require that the subject, or the subject's legally authorized representative (LAR) sign the informed consent form. FDA's regulations at 21 CFR 50 do not require an investigator signature on the consent form, although this may be a requirement of the IRB, the institution, or state/local laws. Questions about state/local law would be outside of FDA's purview and we are not able to provide legal advice. I suggest you discuss the requirements for the informed consent form and the process with your IRB and other appropriate institutional officials.

There are some FDA guidance documents that address the informed consent form and the process that may be of interest to you. The ICH GCP E6(R2)Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance – see https://www.fda.gov/media/93884/download) suggests in section 4.8.8 that:

4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be

signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.

FDA also has guidance titled, "Institutional Review Boards Frequently Asked Questions - Information Sheet" that can be found at Institutional Review Boards Frequently Asked Questions | FDA. Question #39 addresses the question about who should be present when the informed consent interview is conducted:

39. Who should be present when the informed consent interview is conducted?

FDA does not require a third person to witness the consent interview unless the subject or representative is not given the opportunity to read the consent document before it is signed, see 21 CFR 50.27(b). The person who conducts the consent interview should be knowledgeable about the study and able to answer questions. FDA does not specify who this individual should be. Some sponsors and some IRBs require the clinical investigator to personally conduct the consent interview. However, if someone other than the clinical investigator conducts the interview and obtains consent, this responsibility should be formally delegated by the clinical investigator and the person so delegated should have received appropriate training to perform this activity.

There is also a guidance document titled, "A Guide to Informed Consent - Information Sheet" that can be found at A Guide to Informed Consent | FDA There is text under the section labeled "The Consent Process" that states in part:

The clinical investigator is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. FDA does not require the investigator to personally conduct the consent interview. The investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.

For your second question, please see FDA's guidance on the 1572 form. https://www.fda.gov/media/78830/download Please see questions 32 and 33. If research staff are obtaining informed consent, she/he should be listed on the 1572 form.

I hope this information is helpful. Please contact us again at gcp.questions@hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

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.

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**From:** [redacted]
**Sent:** Monday, February 24, 2020 3:26 PM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Cc:** [redacted]
**Subject:** Informed Consent

Hello,

Our site is exploring the possibility of having clinical research coordinators obtaining informed consent for interventional research studies. I did review the FDA 2014 training slides and saw that FDA does not require the investigator to personally conduct the consent interview. At this time only the PI and sub-I obtain consent; The investigators do both the consent interview and sign the form. May you please provide guidance to the following questions below:

- Can clinical research coordinators sign the consent form as person obtaining consent?
- Is it required that research staff obtaining consent need to be listed on the 1572?

Thank you,
[redacted]