From: OC GCP Questions
To: [redacted]
Subject: GCP advice - informed consent
Date: Friday, May 15, 2020 10:33:23 AM
Attachments: [redacted]

Good morning –

Thank you for your inquiry.

The following is an excerpt from the regulations identifying the general requirements for informed consent.

§ 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. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

As you can see, the regulations require that there be an exchange of information but not the format for the exchange. In guidance, FDA has previously acknowledged a practice similar to what you described. Please see FDA's Information Sheet Guidance "Institutional Review Boards Frequently Asked Questions" (available at www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm) that includes the following:

34. Is getting the subject to sign a consent document all that is required by the regulations?

No. The consent document is a written summary of the information that should be provided to the subject. Many clinical investigators use the consent document as a guide for the verbal explanation of the study. The subject's signature provides documentation of agreement to participate in a study, but is only one part of the consent process. The entire informed consent process involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject to consider all options, responding to the subject's questions, ensuring that the subject has comprehended this information, obtaining the subject's voluntary agreement to participate and, continuing to provide information as the subject or situation requires. To be effective, the process should provide ample opportunity for the investigator and the subject to exchange information and ask questions.

Please see two guidance documents that might be helpful to you.

Use of electronic Informed Consent - https://www.fda.gov/media/116850/download
Informed Consent Information Sheet - https://www.fda.gov/media/116850/download
A Guide to Informed Consent - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent

To answer your question, yes a PI can delegate the task of signing the informed consent. Please note, even though the task has been delegated, the PI/CI is ultimately responsible for overseeing the study. The sponsor should be in agreement with the delegation of tasks by the CI.

FDA's regulations do not require the signature of the clinical investigator on the consent form (assuming that consent is obtained by someone else). It's really up to the IRB, however, to determine the acceptability of the process to be used for obtaining informed consent, as long as that process is consistent with the regulations. Having said that, if the IRB's procedure is to require the investigator to sign the form (for example, if there is a space on the consent form for him to do so), then we assume the IRB requires that signature and we may note that as a violation of the regulations if the signature is missing. As I've said, however, there is no specific requirement in our regulations for the investigator to sign the form, so the IRB can always modify the process, particularly if requiring the clinical investigator's signature on the form is too burdensome.

Please see FDA guidance Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects https://www.fda.gov/media/77765/download

Kind regards,

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From: [redacted]
Sent: Friday, May 15, 2020 8:52 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: GCP advice - informed consent

Dear All

Can I ask your advice on GCP

My question concerns the signing of informed consent

According to the GCP, the informed consent may be signed by the Investigator or a person delegated by him/her. This means that the informed consent can, for example, be signed by a study nurse if the researcher has delegated it?
Can only the medical doctor sign informed consent?

Thank you for help.

[redacted]