From: OC GCP Questions
To: [redacted]
Subject: RE: Person Obtaining Consent Inquiry
Date: Wednesday, December 07, 2016 3:41:00 PM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question. The FDA informed consent regulations at 21 CFR 50.20 address the general requirements for informed consent (see http://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 http://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 Good Clinical Practice: Consolidated Guidance*, (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) 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 http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm. 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

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm. 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.

In July 2014 FDA put out a draft guidance titled, "*Informed Consent Information Sheet – Guidance for IRBs, Clinical Investigators, and Sponsors*" found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf that, when finalized, will supersede the guidance titled, "*A Guide to Informed Consent*" mentioned above. Although draft, **page 25 includes a section on the delegation of the consent interview** that should be helpful to you.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
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Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

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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: Monday, December 05, 2016 3:44 PM
To: OC GCP Questions
Subject: Person Obtaining Consent Inquiry

I have a question regarding who may sign the ICF for therapeutic oncology research studies in [redacted]

I'm working under the following assumptions/information:

- My research has determined that [redacted] law does not directly address human research (except for research involving fetuses). [redacted] law does require physician consent for chemotherapy treatment.
- Clinical trials are distinguished from treatment (http://www.fda.gov/ForPatients/ClinicalTrials/ClinicalvsMedical/default.htm); this is why participants are known as participants and not patients, because they are not undergoing treatment, but rather taking part in research.
- FDA does not require the consenter to sign a research ICF at all...only the participant (or LAR) must sign (Attach 1); OHRP is in accord (Attach 2). Thus, with no state law on point, technically we don't need any signature line at all, except for the patient's.
- 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 (Attach 3).
- The physician will always be involved in the consent process, and that will be documented in the Clinic Notes, to introduce the study and explain the mechanism of action, potential risks, and any alternatives.

If all these points are true and accurate, and please correct me if not, then is it permissible for non-physicians (including PAs, NPs, and Clinical Research Nurses/Coordinators) to sign the consent for therapeutic oncology studies, provided this is delegated appropriately, the individuals are trained on the consent process generally, and study-specific training is documented?

[redacted]