From: OC GCP Questions
To: [redacted]
Subject: RE: ICF question on surrogates
Date: Monday, July 18, 2016 2:20:43 PM

Hi [redacted],

Thank you for your question. As you note in your question, FDA regulations define a legally authorized representative (LAR) as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research" [21 CFR 50.3(l)]. The key point to consider when determining who may serve as an LAR is that the individual (or judicial or other body) must be authorized under applicable law to consent on behalf of the prospective subject. In the United States, the legal authority for who may serve as an LAR is determined by state and local law. If you are uncertain about state and local laws governing who can serve as an LAR, FDA recommends consulting with your legal counsel. Although most, if not all states, have laws that govern who may serve as an LAR for medical decisions in a clinical care context, very few states specifically define who may serve as an LAR for research purposes. Where applicable law exists to determine who is authorized to serve as an LAR to consent to an individual's participation in research, consent must be obtained from an LAR in accordance with this law. In the absence of an applicable law determining who is authorized to serve as an LAR to consent to an individual's participation in research, FDA recommends following state and local law as to who can serve as an LAR to consent for an individual's clinical care. FDA regulations do not define the phrase "health surrogate" you use in your question but I assume you mean someone who can serve as an LAR to consent for and individual's clinical care. Assuming this is correct, then the hierarchy you outline seems reasonable; however, I recommend conferring with legal counsel to assure that your guidance is consistent with local and state law.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Thank you,

Kevin

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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: Friday, July 15, 2016 10:53 AM
To: OC GCP Questions
Cc: [redacted]
Subject: ICF question on surrogates

Hi,

I am writing to obtain some guidance on the FDA regulations as they pertain to allowing a surrogate to consent for a patient either at study initiation or for a re-consent secondary to diminished capacity. To elaborate I am defining diminished capacity as being either a patient who has impaired decision making abilities secondary to their disease (i.e. brain tumor, brain mets etc) or a patient with cognitive disabilities. I am not speaking about emergency trials or situations. Please know I am speaking from the point of view of a sponsor, where the consenting and patient management would be occurring at the participating hospital.

I am aware that the FDA in title 21, CFR 50.3(l), says, “legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.” I am also aware that because the regulations say "applicable law," the the local state law defines who can be a legal representative, but I wondered about health surrogates, defined as a non-legal appointed person to make health decisions for the patient.

Does the FDA differentiate a legal representative vs. a health surrogate in any way or if local IRB guidelines and local and state laws are being followed, is it acceptable? Per the FDA or GCP does there seem to be an issue in allowing a site (remember I am speaking as a sponsor) to be allowed to use a health surrogate if they are abiding by local and state law and IRB policies?

I view the hierarchy for consenting as follows; #1) the preference is of course to be able to consent the actual patient, #2) if they are unable to consent the patient secondary to diminished capacity (be it secondary to brain mets or cognitive disabilities), then the legal authorized representative can consent, #3) if the patient does not have a legal authorized representative then a health surrogate may be used. Of note, with any instance the appropriate IRB approvals and documentation are needed. Does this seem appropriate and in line with guidance?

If someone can email me back that would be great!

thanks
[redacted]

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