

From: OC GCP Questions
Sent: Tuesday, February 25, 2014 10:21 AM
To: [REDACTED]
Subject: RE: LAR (Legal authorized representative) query

Dear [Redacted],

Your inquiry poses many interesting questions. However, your questions appear to be outside of the scope of FDA's authority. Your questions should be directed to counsel qualified in state or local laws applicable to your New Jersey jurisdiction.

In question 3, you mention FDA regulations concerning "Legally authorized representative" and "Guardian". In title 21, Code of Federal Regulations (CFR), § 50.3(l), "*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." In 21 CFR 50.3(l), the federal regulations defer to "applicable law". Therefore, who may serve as a legally authorized representative (LAR) is determined by the applicable State or local law.

In 21 CFR 50.3(s), "*Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. For purposes of subpart D of this part [21 CFR part 50], a guardian also means an individual who is authorized to consent on behalf of a child to participate in research." In 21 CFR 50.3(s), the federal regulations defer to "applicable State or local law". Please note, in 21 CFR 50.55(f), that permission by parents or guardians must be documented in accordance with and to the extent required by 21 CFR 50.27 – Documentation of informed consent. For the applicable federal regulations, please see <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>.

You might find helpful FDA's guidance document on frequently asked questions. Please see "Institutional Review Boards Frequently Asked Questions - Information Sheet", at www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm.

For your questions, however, it appears that applicable New Jersey state and local laws prevail.

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

Best regards,
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WO32/5129
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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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, February 24, 2014 1:16 PM

To: OC GCP Questions

Subject: LAR (Legal authorized representative) query

Importance: High

Hi,

1-In the cases that subject has appointed an advance directive for healthcare or a guardian which are the first and second line in order of priority does a legal document needs to be available, especially if a spouse, domestic partner or kids are alive which they are 3rd, 4th and 5th line of priority in descending order as to whom can be a LAR in the state of NJ?

(1) the health care representative of the subject pursuant to an advance directive for health care;

(2) the guardian of the subject who has the authority to make health care decisions for the subject;

(3) the spouse of the subject;

(4) the domestic partner, as defined in section 3 of P.L.2003, 27 c.246 (C.26:8A-3), of the subject;

(5) an adult son or daughter of the subject;

(6) a custodial parent of the subject;

(7) an adult brother or sister of the subject.

2- Should I still have any documentation in writing from the patient stating whom they want to be their LAR is the spouse will be making the decisions in a life

3- FDA regulations a "guardian" or LAR means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. Does it means that some legal document needs to be available in writing?

[Redacted]