From: OC GCP Questions
To: [redacted]
Subject: protocol does not provide for LAR; subject has lost cognitive capacity with final study visit pending
Date: Tuesday, May 24, 2016 12:49:00 PM

Dear [redacted],

I'm not quite sure why the subject would need to be re-consented for a final visit, if the information to be collected in the final visit was already included in the original consent form/process, as specified by the protocol.

FDA's regulations in Parts 50 and 56 permit a subject's legally authorized representative to provide consent on behalf of the subject. However, in this case, you state that "the protocol requires that subjects have the ability to consent on their own behalf."

If the subject does need to be re-consented, e.g., for a change to the information to be collected in the final visit, it would be appropriate to first determine whether or not the subject still has the capacity to consent before discussing it further with both the study sponsor and IRB. This is potentially a protocol deviation, so it requires input from both the sponsor and IRB. If this is an FDA regulated study, the sponsor may need to discuss this with their FDA contact as well.

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

Best regards,

Sheila

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Office of Special Medical Programs, Food and Drug Administration

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, May 23, 2016 4:30 PM
To: OC GCP Questions
Subject: protocol does not provide for LAR; subject has lost cognitive capacity with final study visit pending

Good afternoon,

Our IRB has oversight for a [redacted] trial whose protocol requires that subjects have the ability to consent on their own behalf. During his participation, a research subject at one site experienced a medical event which has left him cognitively impaired to some extent and he may no longer be able to consent on his own behalf. The subject has discontinued investigational product, but is pending a

final study visit which includes a blood draw. If it is determined that the subject now lacks capacity to consent on his own behalf, would it be appropriate for the IRB to consider a subject-specific exception to the protocol to allow for appointment of an LAR to consent to this subject's participation in the final study visit?

Thank you for your guidance in this regard.

Sincerely,

[redacted]