From: OC GCP Questions
To: [redacted].
Subject: ICF
Date: Wednesday, November 30, 2016 7:48:00 AM
Attachments: [redacted]

Good morning –

"Caregiver consent" process, including a signed consent form, is not necessary for a caregiver to oversee medication and provide input in the study, unless the caregiver is providing consent as the subject's legally authorized representative (LAR) when the subject's ability to do so is impaired.

Additionally, we do not believe that the caregivers would be considered human subjects under 21 CFR 50.3(g), 21 CFR 56.102(e) or 21 CFR 812.3(p). Therefore, informed consent for their ancillary role in the clinical trial and data collection process would not be required under FDA regulations. That said it would be advisable for caregivers to be provided with instructions on what they would need to do for the subjects participating in the study.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Office of Good Clinical Practice
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U.S. FOOD & DRUG ADMINISTRATION

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: Tuesday, November 29, 2016 12:55 PM
To: OC GCP Questions; gcp.questions@fda.gov
Subject: ICF

We have a trail at our site that the sponsor requires a CAREGIVER to oversee medication compliance and provide some input on the scales (CNS trial). The caregiver are paid for their participation by the sponsor. My question is the IRB does NOT require a caregiver's ICF. What is your opinion on this process?