From: OC GCP Questions
To: [redacted]
Subject: RE: Communication consulation plan prior to IND
Date: Tuesday, February 24, 2015 3:50:31 PM
Attachments:

Hi [redacted],

You are correct to be concerned. The IND regulations at 21 CFR 312.20(c) requires the sponsor to submit a separate IND for any clinical investigation involving an exception from informed consent under 21 CFR 50.24 and that such a clinical investigation is not permitted to proceed without prior written authorization from FDA. FDA would consider the conduct of community consultation as beginning the clinical investigation. Typically a review division is given a maximum of 30 days to make a decision about a new IND involving a 50.24 study, so I don't understand why the investigator has not heard from the review division. Perhaps the investigator-sponsor did not submit the protocol as a new IND and did not mark it as a study involving "Emergency Research Exception from Informed Consent Requirements" (see box 12 in the FDA Form 1571). Failing to do so could cause some delay if it is not quickly recognized by the review division that the study involves an exception from informed consent. I recommend the sponsor-investigator contact the review division responsible for the IND and recommend that the community consultation not be done until after the FDA issues a written authorization that the study may proceed.

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.

Thanks

Kevin

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From: [redacted]

Sent: Monday, February 23, 2015 5:12 PM
To: OC GCP Questions
Subject: Communication consulation plan prior to IND

Janet or others,

I have a PI with a multicenter randomized clinical trial of several approved drugs for status epilepticus. It would be IND exempt, except that it needs to be done under 21 CFR 50.24 wavier of informed consent. This is an academic medical center where I serve as IRB chair and is not [redacted].

The PI has submitted the protocol, consent, and community consultation plan to ask for the IRB's approval to proceed with the community outreach plan The issue is that the PI tells me that FDA has not yet issued an IND. This seems suspect to me because I know that FDA may make changes to the outreach plan, the protocol, or both as a condition of approving the IND, and it does not makes sense to commence on a community outreach plan for a protocol that may change, may require a different outreach plan, or may never get approved.

I am writing to find out if I am off base with requiring an IND before allowing the investigator to proceed with community consultation. Does FDA have any concerns about investigator proceeding with community consultation plans for 50.24 studies before FDA has issued an IND? Does FDA require the IND to be issued in advance of community consultation?

I would be happy to take a phone call.

Thanks,
[redacted]