From: OC GCP Questions
To: [redacted]
Subject: Recruitment and Screening of Subjects during the 30 day IND waiting period
Date: Friday, February 02, 2018 9:02:00 AM
Attachments: [redacted]

Dear [redacted] --

Thank you for your question and please accept my apologies for the delay in responding. Your query was forwarded to the Office of Good Clinical Practice (OGCP) for a response and some internal vetting was required.

As you know, the regulations for drugs and biologics at 21 CFR 312.20(b) state:

"A sponsor shall not begin a clinical investigation subject to 312.2(a) until the investigation is subject to an IND which is in effect in accordance with 312.40."

CDRH's regulations for devices under 812.110 more specifically state:

"An investigator may determine whether potential subjects would be interested in participating in an investigation, but shall not request the written informed consent of any subject to participate, and shall not allow any subject to participate before obtaining IRB and FDA approval."

Taken together, these regulations indicate that subjects may not be consented or screened, as consent would be required before study-specific screening activities may begin. However, some initial activities related to determining a potential subject's interest in the yet active study may occur. Such activities should be limited to recruitment efforts to inform potential subjects, or a community that a study may soon begin on a given condition. However, screening subjects to determine eligibility would not be acceptable until the protocol is approved by an IRB and, for drug and biologic studies, the IND is in effect.

In summary, investigators may perform limited activities to determine whether potential subjects would be interested in participating in a study, but must not request the written informed consent of any subject to participate, and must not allow any subject to participate before obtaining both IRB approval and, for drug and biologic studies, an IND is in effect.

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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, December 19, 2017 10:04 AM
To: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Cc: [redacted]
Subject: Recruitment and Screening of Subjects during the 30 day IND waiting period

Hello colleagues at FDA:

I am writing to request information regarding the position of FDA on the recruitment and screening of subjects during the 30 day waiting period relating to the issuance of an IND. Subjects would have been consented during this period.

Previously, the [redacted] did not permit the recruitment and screening of subjects during this period of time. Based upon reports from sponsors that other IRBs were permitting this recruitment and screening activity, we re-contacted AAHRPP and received the response below that this activity is viewed as acceptable now. If you read from the e-mail at the bottom of this e-mail it will help provide the full story.

Can you please let me know whether FDA agrees with [redacted] that so long as subjects have been consented, and no research interventions are conducted, subjects may be recruited and screened during this 30 day period.

Thank you very much.

[redacted]

[redacted]