From: OC GCP Questions
Sent: Friday, May 15, 2015 11:44 AM
To: [redacted]
Subject: RE: IND waiting period

Hi [redacted],

The regulations 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." FDA's interpretation is that obtaining informed consent and screening subjects for a specific study that is subject to an IND is considered "beginning the clinical investigation" and such activities cannot be performed until an IND is in effect (30 days after FDA receives the IND, or earlier if the sponsor is so notified by FDA). Obtaining informed consent and screening subjects for an IND study prior to the IND being in effect is not in compliance with the FDA regulations.

Some Phase 1 units may develop a general screening protocol and accompanying screening informed consent form that are not specific to a particular study and not subject to an IND, but that provide for general screening procedures to be performed and such information to be retained by the site for future purposes (i.e. contacting potential subjects for a future study occurring at the site). Additional information can be found in FDA's Information Sheets at the following web link: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm .

I hope this information is useful.

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and 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.

[redacted]

From: [redacted]
Sent: Thursday, March 26, 2015 7:32 AM
To: [redacted]
Subject: IND waiting period

Per our conversation [redacted] – our policy is not to screen subjects during the 30 day IND FDA review period but we have had some sponsors agree with us and others not agree. Your input is greatly appreciated. Here is the question:

May a Phase 1 site begin screening procedures such as signing Informed Consent, obtaining safety labs, physical exams, etc., with IRB approval, during the 30 day IND FDA review period and begin dosing AFTER the 30 day FDA review period based on regulations below?

The regulations 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."
312.3 (b) specifically defines “clinical investigation” to mean “any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.”
312.21 (a) defines a Phase 1 trial as including “the initial introduction of an investigational new drug into humans.”

Thank you.
[redacted]