From: OC GCP Questions
To: [redacted]
Subject: Request for assistance re: IND reviews in parallel with IRB reviews
Date: Friday, June 17, 2016 2:02:00 PM

Dear [redacted],

Although FDA's regulations do not directly address this topic, 21 CFR 312.40, states, in part:

> Sec. 312.40 General requirements for use of an investigational new drug in a clinical investigation.
>
> (a) An investigational new drug may be used in a clinical investigation if the following conditions are met:
> (1) The sponsor of the investigation submits an IND for the drug to FDA; the IND is in effect under paragraph (b) of this section; and the sponsor complies with all applicable requirements in this part and parts 50 and 56 with respect to the conduct of the clinical investigations; and
> (2) Each participating investigator conducts his or her investigation in compliance with the requirements of this part and parts 50 and 56.
> (b) An IND goes into effect:
> (1) Thirty days after FDA receives the IND, unless FDA notifies the sponsor that the investigations described in the IND are subject to a clinical hold under 312.42; or
> (2) On earlier notification by FDA that the clinical investigations in the IND may begin. FDA will notify the sponsor in writing of the date it receives the IND.

As you can see, FDA's regulations do not require that IRB approval and submitting the initial IND to FDA (with the required 30 day review period) be done in any particular order; they are silent on this topic.

Although both IRB approval and having an effective IND are required before any subject recruitment begins, the study may be submitted to the IRB and FDA concurrently (or even seeking IRB approval first), as long as recruitment and enrollment does not begin before both effective IND and IRB approval are secured. A site that begins recruiting subjects would be considered to have begun the clinical investigation. To begin recruiting and/or advertising for subjects before the IND is in effect would not be in compliance with FDA's regulations. Another point to consider is that FDA may issue a clinical hold and require protocol changes before the study can begin. If that occurs, the IRB will have to review the revised protocol and approve that version, also.

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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From: [redacted]
Sent: Tuesday, June 14, 2016 2:31 PM
To: OC GCP Questions
Subject: Request for assistance re: IND reviews in parallel with IRB reviews

Dear Sir or Madam:

I am a regulatory researcher working on [redacted] to clarify clinical trial global regulatory requirements. I would greatly appreciate it if you could clarify whether an IRB protocol review may be conducted in parallel with the FDA's review of an IND application.

Thank you very much for any assistance you can provide.

Kind regards,
[redacted]

[redacted]