From: OC GCP Questions
To: [redacted]
Subject: FDA -- Sequence of steps for obtaining an IND
Date: Friday, March 16, 2018 12:16:00 PM
Attachments: [redacted]

Good afternoon –

Please see the weblink below that discusses INDs.

Investigational New Drug (IND) Application

You will also need to contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov and or by phone (855) 543-3784, or (301) 796-3400.

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: Thursday, March 15, 2018 6:59 PM
To: OC GCP Questions <OCGCP.Questions@fda.hhs.gov>
Subject: FDA -- Sequence of steps for obtaining an IND

Hi All:
Is there a good resource available that specifies the sequence of steps for launching a clinical trial and obtaining an IND? For example, I've heard conflicting accounts on where a protocol should be submitted first. Most accounts indicate that the steps should be DSMB (revise based on feedback) → IRB (revised based on feedback) → FDB (revise based on feedback.). The most recent account indicated that the FDA should be first. I'd appreciate any direction/guidance.

Thanks.

Sincerely,

[redacted]