From: OC GCP Questions
To: [redacted]
Subject: RE: Question of Clinical Document Submissions
Date: Wednesday, November 14, 2018 8:16:00 AM
Attachments: [redacted]

Dear [redacted],

Investigator Brochures and protocols are generally submitted together, included with the rest of the IND content. Please see 21 CFR 312.23 for the IND content and format, which can be found at https://www.ecfr.gov/cgi-bin/text-idx?SID=a298e784900a4cf5a730ca2cd23fbd9f&mc=true&node=pt21.5.312&rgn=div5#se21.5.312_123.

I recommend that you contact your FDA review team to discuss any alterations to the standard submission information. If you have not had prior discussions with the Agency about this product, you can contact druginfo@fda.hhs.gov for additional help regarding IND submissions.

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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, November 13, 2018 11:26 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question of Clinical Document Submissions

I'm writing to inquire if an Investigator's Brochure must be submitted to the Agency before the sponsor approved clinical study protocol? For example, if the clinical study protocol has been reviewed and approved by the sponsor, but the IB is still in revision can the clinical protocol be submitted first? Specifically, if the clinical study will not be initiated for several months later and the IB would be submitted a few weeks after the clinical protocol, but before the study starts?