From: OC GCP Questions
To: [redacted]
Subject: Requesting Interim Reports from the FDA for Clinical Research
Date: Thursday, March 19, 2015 1:20:57 PM

Good afternoon –

I think you need to contact someone in the Center for Biologics (CBER). Please see their contact information below.

Questions about biologics (other than gcp questions)
301-827-2000
OCOD@fda.hhs.gov (consumer oriented)
Industry.Biologics@fda.gov (manufacturers's assistance)
Questions about whether a product is subject to IND regulations: call 301-827-2000

Kind regards,

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

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 19, 2015 11:32 AM
To: OC GCP Questions
Subject: RE: Requesting Interim Reports from the FDA for Clinical Research

Dear Ms. Kezer,

Thanks so much for getting back to me. I think there was confusion as we were being directed by an employee of a different company who is completing clinical research. Technically, our company is patient-funded research and has different requirements per the ώŴŜŘĬ·ŎűŜŘß, which is our IRB.

If additional questions arise I will certainly take you up on the offer to speak with a specified center, thank you!

Kind regards,

[redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: March 10 15 8:10 AM
To: [redacted]
Subject: Requesting Interim Reports from the FDA for Clinical Research

Good morning [redacted]–

Marsha only works part time for us now so your email was forwarded to our GCP mailbox. Can you give me a little bit more information as to what you mean as "FDA interim reports"? Interim reports of what? Are they being required by FDA? I checked with my colleagues in my office and we are not familiar with FDA interim reports. Also can tell me if the research that you are conducting involves a drug, biologic, or device? I might have to send you to one of the Centers for an answer.

Thank you so much.

Doreen

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

From: [redacted]
Sent: Monday, March 09, 2015 12:44 PM
To: Melvin, Marsha *
Subject: Requesting Interim Reports from the FDA for Clinical Research

To Whom It May Concern:

I was informed that any clinical research studies should be requesting and reviewing "FDA interim reports". Do you have any information regarding this, or a recommendation as to whom to contact to learn more about this?

Thank you for your time,

[redacted]