From: OC GCP Questions
To: [redacted]
Subject: RE: Email for Questions to the FDA
Date: Tuesday, October 28, 2014 1:32:00 PM

Dear [Redacted]-

Thank you for your question and so nice to hear from you! Information about the OGCP public mailbox can be found on our web site at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134476.htm. You can send GCP questions to the mailbox at gcp.questions@fda.hhs.gov. You may also find it helpful to know that we post redacted copies of our public queries along with OGCP's reply on the web at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm and many folks find this information helpful to be able to see other questions that have come in and how OGCP responded. The queries and responses are grouped by category and are available from the year 2002 through 2013 (the year 2014 queries and responses will get posted in early 2015).

With regard to your question about an investigator initiated study, the FDA regulations define a sponsor-investigator rather than the term "Investigator Initiated Studies (e.g. IIT)" as you mentioned. The definition of sponsor-investigator at 21 CFR 312.3(b) says:

> *Sponsor-Investigator means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.*

As the definition in 312.3 above specifies, an investigator who serves as both sponsor and investigator must follow the applicable regulations for **BOTH** the sponsor and the investigator.

I have provided a link to FDA's guidance titled, "*Guidance for Clinical Investigators, Sponsors, and IRBs Investigational New Drug Applications (INDS) – Determining Whether Human Research Studies Can Be Conducted Without an IND*" – see http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm229175.pdf. Because your question can actually be quite complex, I recommend you take a look at this guidance to assist you and the sponsor-investigator in determining whether the proposed research study involving human subjects must be conducted under an IND. As suggested in the guidance, I also recommend that you seek advice from FDA on the applicability of the IND regulations if needed. Section VIII of the guidance document provides information on the process for addressing inquiries concerning the application of the IND requirements.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. As I mentioned above, you may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]
Sent: Monday, October 27, 2014 7:34 PM
To: Donnelly, Janet
Subject: Email for Questions to the FDA

Hi Janet,

I hope this email finds you well. You had mentioned to me once [Redacted] that there is an email at the FDA where one can send questions regarding clinical trial conduct. Can you share this with me please as I could not find it on the FDA website.

On another note, I had a quick question or more like a confirmation of my understanding regarding a clinical research study. Isn't it true that a PI performing a study that is being used for publication only should follow the FDA regs regarding Investigator Initiated Studies (e.g. IIT) and get an IND since he is using a drug in for a new indication via a different route of administration (e.g. intrathecal versus IV)?

Thanks in advance for your help. I sure miss [Redacted] as I learned so much and enjoyed meeting everyone.

Kind regards,

[Redacted]