From: Donnelly, Janet
To: [redacted]
Subject: FDA Contact Information
Date: Wednesday, January 14, 2015 3:26:00 PM

Hello [redacted] -

Thank you for calling today and it was nice talking to you. As you are already aware, FDA has a guidance document for Clinical Investigators, Sponsors, and IRBs titled, "Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND" that can be found at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm229175.pdf.

Section VIII (page 18) of this guidance document outlines a process for sending an inquiry to FDA about the application of the IND requirements. As we discussed, I suggest that you send your specific question to CDER's Division of Drug Information (as outlined in the third bullet on page 18, and copied here for reference):

- If the relevant review division is not known, we recommend the sponsor contact CDER's Division of Drug Information (druginfo@fda hhs.gov).

CDER's Division of Drug Information is best equipped to answer your specific question.

I also mentioned to you that FDA's Office of Good Clinical Practice (OGCP), which is the group that I work in, has a central public mailbox where we welcome GCP questions (gcp.questions@fda.hhs.gov). You can find information about OGCP and the public mailbox address at the following web location http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134476.htm. We find that it is best to send questions to the public mailbox because it is monitored and managed Monday through Friday each week. Sending a question directly to specific staff may result in a delay if that staff person is out of the office.

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. 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

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Office of Special Medical Programs, Food and Drug Administration