From: OC GCP Questions
To: [redacted]
Subject: RE: IND waiver question
Date: Wednesday, May 27, 2015 12:07:00 PM

Dear [redacted],

Thank you for your question. Questions about the application of the IND regulations are handled by the appropriate review division (i.e., for the therapeutic area being studied) in the appropriate FDA Center. For products regulated by the Center for Drug Evaluation and Research (CDER), an inquiry concerning the application of the IND regulations should be directed to the Chief, Project Management Staff, in the appropriate CDER review division. For products regulated by the Center for Biologics Evaluation and Research (CBER), the inquiry should be directed to the applications division of the appropriate review Office.

If the relevant review division is not known, we recommend the sponsor contact CDER's Division of Drug Information (druginfo@fda.hhs.gov) or CBER's Division of Manufacturer's Assistance and Training (matt@cber.fda.gov), Office of Communication, Outreach and Development.

The information provided above is included in FDA's guidance document titled, "*Guidance for Clinical Investigators, Sponsors, and IRBs, Investigational New Drug Applications (INDs) - Determining Whether Human Research Studies Can Be Conducted Without an IND*" which can be found at the following web link http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm229175.pdf. Section VIII of this guidance document outlines the process for addressing inquiries concerning the application of the IND requirements, and provides you with information on who to contact with your specific question.

If you need further information and/or have additional questions, please feel free to contact us once again 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

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Tuesday, May 26, 2015 1:32 PM
To: OC GCP Questions
Subject: IND waiver question

Dear Sir/Madam:
We are preparing a Phase 1 study whose primary aim is to determine the maximum tolerated dose (MTD) of [Redacted] given in combination with [redacted] for children and adolescents with [redacted] Given that this is not requesting a new indication for [Redacted] and is using lower than the recommended Phase II dose in children, I would like some guidance on whether I need to have a formal waiver of the need for IND? If so, is it possible to send this information by email rather than print out 3 copies of the Investigators Brochure from [Redacted]?

Thank you very much for your advice.
Best regards,
[redacted]