From: OC GCP Questions
To: [redacted]
Subject: RE: IND new protocol question
Date: Wednesday, October 25, 2017 11:47:09 AM
Attachments: [redacted]

Dear [redacted] -

Thank you for your questions. The Office of Good Clinical Practice (OGCP) is able to offer assistance with general questions about good clinical practice regulations and policy, but not study design or study product questions. However, I wanted to share with you that FDA has a 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*" – see https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm229175.pdf.

I hope this guidance is helpful to you. Because determining whether an IND is needed is an important step in the process, if after reviewing this guidance document, you still have questions about whether or not you need an IND, please follow the instructions in Section VIII "*Process for Addressing Inquiries Concerning the Application of the IND Requirements*". Specifically, you may wish to send an email to CDER's Division of Drug Information at druginfo@fda.hhs.gov to assist you, as they are most familiar with the relevant review divisions who should be able to help you. You may also wish to discuss your questions with the appropriate individuals at your institution.

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
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Tuesday, October 24, 2017 3:12 PM
To: OC GCP Questions
Subject: IND new protocol question

Dear Officer,

My research group is going to use [redacted] in humans. This experiment has been performed previously by other groups, and IND number is reported by some of them.

My questions are:
- does this protocol still require an IND application?
- if yes, can we refer to the IND application of a previous study? Indeed, one of our collaborator has conducted and published this study in the past and made him available to use his IND.

The test is not aimed to have the drug approved neither to change its indications of use. It's a [redacted] using an [redacted].

Best regards
[redacted]