From: OC GCP Questions
To: [redacted]
Subject: IRB and continuing review
Date: Tuesday, September 08, 2015 10:11:58 AM

Good morning,

I would refer you to FDA's guidance document "IRB Continuing Review after Clinical Investigation Approval" which is available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf .

Section D on pages 11 -14 answers your questions.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Sunday, September 06, 2015 3:17 PM
To: OC GCP Questions
Subject: IRB and continuing review

Hi,

My question relates to the requirements for continuing review by a Canadian REB (research ethics board) of a study at a Canadian site, conducted under an IND (where no exemption from Part 56 was pursued by the sponsor). My understanding is that the sponsor maintains overall responsibility for the study, and as part of this, obtains assurance from the PI that they will obtain the necessary reviews/approvals from an REB that operates in compliance with 21 CFR part 56.

My question is what are the REBs responsibilities under Part 56? More specifically, which party should make the determination that a more-than-minimal risk IND study initially approved at full board qualifies for an expedited continuing review? Is it sufficient for the REB to ask the PI and perform the level of review they request, or is the REB itself obligated under Part 56 to make this determination?

Kind regards,
[redacted]