From: OC GCP Questions
To: [redacted]
Subject: Multiple contracted IRB"s/protocol
Date: Tuesday, May 12, 2015 12:49:58 PM

Good afternoon –

I am unclear what you mean by "sponsor-IRB". However please see the information below on central IRBs. Please also see the second link to the guidance on central IRB review.

The 1572 form guidance states
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

30. Does the IRB reviewing and approving the clinical study have to be at the same location as where the research is conducted?
The regulations permit review of research by IRBs at locations other than where the research is being performed (e.g. independent or non-institutional IRB; use of a cooperative IRB review process; see 21 CFR 56.114). Therefore an IRB may review clinical studies that are not performed on-site as long as requirements in 21 CFR Parts 50 and 56 are met. For more information on cooperative research arrangements, see the FDA Guidance for Industry-Using a Centralized IRB Review Process in Multicenter Clinical
Trials.http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf

The Central IRB guidance states –

C. Sponsor
For studies conducted under an IND, 21 CFR part 312 provides that a sponsor is responsible for obtaining a commitment from each investigator that he or she will ensure that requirements in part 56 relating to IRB review and approval are met with respect to the research conducted by the investigator (21 CFR 312 .53(c)(l)(vi)(d)) . Sponsors can also initiate plans for use of a centralized IRB review process and facilitate agreements and other necessary communications among the parties involved.

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

Kind regards,

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

From: [redacted]
Sent: Monday, May 11, 2015 3:35 PM
To: OC GCP Questions
Subject: FW: Multiple contracted IRB's/protocol

Dear FDA GCP ,

Can you tell me if it is acceptable for a sponsor to use > 1 centrally contracted (sponsor-IRB) (aka “Central”) IRB/protocol. Is there any conflict?
Thank you,

[redacted]