From: OC GCP Questions
To: [redacted]
Subject: Multiple contracted IRB"s/protocol
Date: Thursday, May 14, 2015 2:18:00 PM

Good afternoon –

Thank you for the clarification.

The FDA regulations at 21 CFR 56.114 (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.114) state:

Sec. 56.114 Cooperative research.

In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

It is important that your institution understand and discuss whether it is acceptable to allow for cooperative review arrangements for studies being conducted at your institution. What type of centralized review arrangement is acceptable to your institution (e.g., joint review, reliance on the review of another qualified IRB, or other arrangement aimed at reducing duplicative efforts)? As noted in the guidance document on central review that I sent you earlier, if an institution, its IRB, and a central IRB agree (under 21 CFR 56.114) to participate in a centralized IRB review process, they should document that action in an agreement signed by the parties. Also, when an institution and an institution's IRB rely on review by a central IRB, both IRBs must have written procedures in place to implement the centralized IRB review process (21 CFR 56.108, 56.114).

I recommend that you discuss this topic and your question internally at your institution with all of the appropriate institutional officials.

Please see the guidance on cooperative research.

Search for FDA Guidance Documents > Cooperative Research - Information Sheet

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: Wednesday, May 13, 2015 1:07 PM
To: OC GCP Questions
Subject: FW: Multiple contracted IRB's/protocol

Just a further clarification

From: [redacted]
Sent: Tuesday, May 12, 2015 1:25 PM
To: gcp.questions@fda.hhs.gov
Subject: RE: Multiple contracted IRB's/protocol

Dear Ms Kezer,

Thank you for responding so quickly and apologies for any confusion. My query is rather.. can a sponsor contract with 2 IRB's simultaneously (have 2 IRBs as their central IRB) on 1 protocol. Would you foresee any conflict? Usually, if a sponsor is using a central IRB, it's 1 central IRB/protocol

Thank you again,
[redacted]