From: OC GCP Questions
To: [redacted]
Subject: IRB Research
Date: Wednesday, July 23, 2014 1:01:47 PM

Good afternoon –

As permitted under the regulations found at 21 CFR 56.114, 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. FDA has issued guidance on the use of a centralized IRB review process (see FDA Guidance for Industry – Using a Centralized IRB Review Process in Multicenter Clinical Trials at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf).

Section V of this guidance document (IRB Records – Documenting Agreements and Procedures), subsection A says:

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 [emphasis added]. IRBs should report this action to the investigator and the institution, for example, by providing copies of the agreement to the investigator, and the institution. If the agreement apportions IRB review responsibilities between a central IRB and the institution's IRB, the agreement should delineate the specific responsibilities of the central IRB and the institution's IRB for the initial and continuing review of the study.

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). For example, procedures should address the following:

How the institution's IRB determines that the central IRB is qualified to review research conducted at the institution.

How the central IRB intends to communicate with relevant institutions, the institutions' IRBs, and investigators regarding its review.

How the central IRB ensures that it provides meaningful consideration of relevant local factors for communities from which research subjects will be drawn (see Section IV).

How the central IRB assesses the ability of a geographically remote site to participate in a study (e.g., whether the site has medical services appropriate to the complexity of the study).

When an institution, an institution's IRB, and a central IRB agree to apportion IRB review responsibilities between the two IRBs, each IRB must have written procedures describing how it implements its responsibilities under the agreement (21 CFR 56.108, 56.115(a)(6)).

So, while FDA's regulations don't specifically mention an agreement, FDA recommends that if an institution, its IRB, and a central IRB agree to participate in a centralized IRB review process they should document that action in an agreement signed by the parties. How the institution decides to document such agreement is up to the institution.

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

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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Wednesday, July 23, 2014 11:12 AM
To: OC GCP Questions
Subject: IRB Research

Hello,

Do you have or can you refer me to policies for facilities to conduct research that has been approved by another facilities IRB (Institutional Review Board)

Thank you
[redacted]