From: OC GCP Questions
To: [redacted]
Subject: Form 1572 - Listing multiple IRBs
Date: Monday, August 10, 2015 7:23:14 AM

Good morning –

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

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/RegulatoryInformation/Guidances/ucm127004.htm).

It appears from the information you provided that only the central IRB needs to be listed on the 1572 form.

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: Friday, August 07, 2015 12:09 PM
To: OC GCP Questions
Subject: Form 1572 - Listing multiple IRBs

Hi,

I have a situation where a site is using a central IRB for a study. Their local IRB has approved the use of the central IRB.

The site wants to list both the central and the local IRBs on their form 1572.

Since only one IRB performs the official review and approval of the study, wouldn't there be only one IRB listed on the form?

Thanks for your guidance,

[redacted]