From: OC GCP Questions
To: [redacted]
Subject: RE: IRB Deferral Letter Inquiry
Date: Monday, October 20, 2014 11:14:00 AM

Dear [Redacted]-

Thank you for your question. 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.*

FDA also has guidance titled, "*Using a Centralized IRB Review Process in Multicenter Clinical Trials*" that can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf. This guidance describes the roles of the participants in a centralized IRB review process, offers guidance on how a centralized IRB review process might consider the concerns and attitudes of the various communities participating in a multicenter clinical trial, makes recommendations about documenting agreements between a central IRB and the IRBs at institutions involved in the centralized IRB review process concerning the respective responsibilities of the central IRB and each institution's IRB, recommends that IRBs have procedures for implementing a centralized review process, and makes recommendations for a central IRB's documentation of its reviews of studies at clinical trial sites not affiliated with an IRB.

Section III of the guidance discusses the roles and responsibilities of the institution, the institution's IRB, the sponsor, investigator and central IRB when considering whether to establish a cooperative review arrangement.

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, 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.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [Redacted]
Sent: Thursday, October 16, 2014 11:34 AM
To: OC GCP Questions
Subject: IRB Deferral Letter Inquiry

To Whom This May Concern:

The Institutional Review Board of [Redacted] is in need of FDA guidance. Specifically, we are being asked to defer oversight of a study that was recently approved through our local IRB. Attached is the deferral letter that the principal investigator is asking our IRB to sign. This would authorize oversight to the [Redacted] Institutional Review Board.

Does the FDA have any policies regarding study deferrals? Our institution does not currently have any policies in place.

Thank you for any assistance you are able to provide in this matter!

Sincerely,

[Redacted]