From: OC GCP Questions
To: [redacted]
Subject: Ref- Requirement for having local IRB in a acute care medical center
Date: Friday, October 14, 2016 1:18:00 PM
Attachments: [redacted]

Good afternoon –

IRB regulations require the IRB to "be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice" (21 CFR 56.107(a)). The responsibilities of a central IRB for consideration of local concerns are discussed in FDA's Guidance for Industry, Using a Centralized IRB Review Process in Multicenter Clinical Trials:

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf

This guidance notes that the requirements for IRB membership in 21 CFR 56.107(a) specify that the membership of an IRB must have sufficient experience, expertise, and diversity to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. This requirement was intended to implement a recommendation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that IRB members be "men and women of diverse backgrounds and sufficient maturity, experience, and competence to assure that the Board will be able to discharge its responsibilities and that its determinations will be accorded respect by investigators and the community served by the institution or in which it is located."

As mentioned above, the guidance states that, IRB members must "be able to ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and practice" (21 CFR 56.107(a)). Thus, IRB review, through its membership, is intended to provide meaningful consideration of various local factors in assessing research activities, including the cultural backgrounds (e.g., ethnicity, educational level, religious affiliations) of the population from which research subjects will be drawn, community attitudes about the nature of the proposed research, and the capacity of the institution to conduct or support the proposed research. Inter-community differences could influence, among other things, assessments of whether mechanisms of subject selection will be equitable, whether adequate provision is made to minimize risks to vulnerable populations, and the adequacy of the informed consent process.

Whether this assessment is made by the local IRB or the central IRB depends on the agreement between the institution (as applicable) and the two entities. FDA guidance on use of a centralized IRB review process states that "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 . . . 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." The location of the central IRB is not germane to whether it is required to consider the applicable laws of the state in which the research will be conducted.

Reviewing the guidance cited above should also be helpful to you. Please also see FDA regulation 56.114
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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 also best to check with the sponsors of your research studies.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, October 13, 2016 10:19 PM
To: OC GCP Questions
Subject: Ref- Requirement for having local IRB in a acute care medical center

Hello Madam,

Our research site is a medical center which is pretty new to research. Currently we have several studies in pipelines and only one of them has started recently.

Initially our hospital board member decided to establish local IRB and use it for various studies.They established local IRB structure but later they found that using central IRB is really efficient and convenient process which can minimize the duplicate efforts

Now our Hospital administrator, medical directors, and local IRB members would like to use only central IRB for research study approval and complete study oversight. They found its very convenient process to use only central IRB instead of using both local and central IRB

They wanted to know if we can terminate our medical center local IRB so that we can use only central IRB for various research study approval and oversight of study conduct.

Your early response will be highly appreciated.

Thanks and Regards
[redacted]