From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, May 20, 2005 9:00 AM
To: [Redacted]
Subject: RE: IRB Panels, Reciprocity

Dear [Redacted]:

I am so sorry for not responding to your e-mail promptly.

In answer to your question, FDA does not have any formal guidance on setting up an IRB composed of multiple "panels," as you described in your e-mail, nor is there any regulatory prohibition against doing so.

Your plans to revise your SOPs and develop a process for assigning protocols to the panels for review sound like a practical way to handle a large workload. Devising a workable system may take some careful thought; as you develop your new procedures, you might want to give some special consideration to the following issues:

--Membership. Each panel would need to meet the membership requirements described in 12 CFR 56.107.

--Assignment process/Awareness of other panels' reviews. How will protocols be assigned to the different panels? Will each panel be responsible for specific types of protocols (e.g., behavioral, therapeutic/medical, oncology, device studies, pediatric) or will protocols be put into a single queue and simply assigned to the next available panel? If a single queue method is used, how will panels be aware of a previous review (particularly if it was negative) and any concerns that may have been raised? If a single queue method is used, how will the membership of each panel (e.g., regular members, alternates) be managed to assure that members are "sufficiently qualified through experience and expertise...and the diversity of members..(etc.)" to review the specific protocols that come before the panel? [See "Membership" above.]

--Continuing review. How will continuing review be handled? Will protocols go back to the same panel that conducted the initial review of the study to assure consistency and at least some historical knowledge or familiarity with a study? What special considerations should be made for continuing review if membership on a particular panel has changed markedly since the initial review, for example, such that none of the original members remains?

--Cooperative Review. You may want to look at FDA's Draft Guidance, "Using A Centralized IRB Review Process in MultiCenter Clinical Trials," (http://www.fda.gov/OHRMS/DOCKETS/98fr/05d-0103-gdl0001.pdf) or OHRP's guidance, "Multicenter Clinical Trials - Local IRB Review" and "General Guidance on the Use of Another Institution's IRB." [Here are links to FDA's and OHRP's websites: http://www.fda.gov/oc/gcp; http://www.hhs.gov/ohrp.]
Although these guidances were prepared to assist IRBs that are involved in multi-institutional studies reduce or avoid duplication of effort, the guidances may be helpful as you try to devise strategies for coordinating reviews under your new system, and ensuring that the various panels communicate with one another and are aware of other panels' reviews.

[Redacted]

I hope this is helpful, and again, I apologize for the delay in getting back to you.

Sincerely,

Carolyn Hommel
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-----Original Message-----
From: [Redacted]
Sent: Thursday, March 17, 2005 1:20 PM
To: 'carolyn.hommel@fda.hhs.gov'
Subject: IRB Panels, Reciprocity

Good afternoon Carolyn

I am an IRB coordinator in [Redacted].

Currently, our local area has 3 different IRBs, for 3 different facilities, with all facilities being owned by the same parent company.

We are in the early stages of exploring our options for these IRBs.

One potential plan that we are evaluating, involves the following:
- use of a single IRB intake office
- a single set of SOPs and IRB forms
- one name for the IRB
- with each facility maintaining it's own individual committee (each facility committee would then be a "Panel" under the IRB)
- reciprocity among panels, in cases where an Investigator would like to perform the research in more than one facility

We understand that this will involve, at minimum
- revising our SOPs to address reciprocity and communication among panels
- ensuring continued compliance with Federal Regulations
- developing a panel assignment process

I am contacting you to determine whether or not there is any available FDA guidance related to this concept, or one similar. Additionally, I want to ensure that FDA would not view this as an unfavorable process.

I appreciate any guidance you can provide. If you would like for me to provide additional information, feel free to contact me via phone or email.

Thanks.
[Redacted]