From: Lee, Bonnie on behalf of DE: GCP Questions
Sent: Friday, December 24, 2004 3:52 PM
To: [purged]
Cc: CDER DRUG INFO
Subject: FW: Draft Comments Form FDA/CDER Size

Dear [purged],

I was overseas, so reading you email, whether you were asking about IRBs, RERCs, and/or DSMCs, so I have provided information about each.

In March 1998, FDA published a final guidance on the use of a centralized Institutional Review Board (IRB) process in multi-center trials. If you go to the Internet, you can find that document at: http://www.fda.gov/OHRMS/DOCKETS/98fr/03-5785.htm I believe, that may for what you are referring to when you asked about "the central image review process." I apologize if I am incorrect. If you were referring to an IRB, it's requirements are stated in 21 CFR part 56, available on the web at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56. In membership requirements are

Sec. 56.107 IRB membership.
(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall 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. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
(d) Each IRB shall include at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Other requirements for the IRB are described at the web site that I referenced above.

I am not sure, but you could also be referring to an RERC (radioactive drug research committee). Guidance on RERC's is available at: http://www.fda.gov/cder/regulatory/RERC/requestfdrfdata.htm. The regulations are at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=312.1.

I am unaware of any guidance on "central critical events committee" unless you are referring to a clinical trial data monitoring committee. If you are, we do have guidance, which you can find at: http://www.fda.gov/OHRMS/DOCKETS/98fr/03-4220.pdf; it was published in March 2003.

I hope this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Cosmf/Clinical Practice Programs, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: CDER DRUG INFO
Sent: Wednesday, November 15, 2006 6:01 PM
To: [purged]
Cc: CDER DRUG INFO
Subject: FW: Draft Comments Form FDA/CDER Size

Thanks,
Larry
DDI

-----Original Message-----
From: drugsinfo@fda.hhs.gov [mailto:drugsinfo@fda.hhs.gov]
Sent: Wednesday, November 08, 2006 7:37 AM
To: CDER DRUG INFO
Subject: Draft Comments Form FDA/CDER Size

Name: [purged]

E-Mail: [purged]

Comments: I would like to know if specific FDA guidelines exist regarding the central image review process when applied for use in clinical trials on therapeutic medicinal agents. In particular, I am seeking information regarding the recommended composition of the review committee (for example, how many reviewers are necessary as a minimum, do the reviewers have to have a minimum board certification, can neuroscgeons function as a central reviewer) and its functioning (e.g., how must independent reviews be carried out, what clinical information can be provided to the reviewers), etc.

I would also be interested in similar guidelines for the composition and functioning of a central critical events committee (a group of clinicians who judge whether a patient qualifies for a specified study endpoint).

I have read the guidance for industry on the development of Medical Imaging Drug and Biological Products, but these guidelines refer to contrast agents and radiopharmaceuticals. If no other guidelines exist, is one to assume that the recommendations in the forementioned document are to be applied to clinical trials on therapeutic medicinal agents as well?

ORL.