ACRP
ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS

MISSION:
ACRP promotes excellence in clinical research.

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Office of Clinical Research and Bioethics Policy
Office of Science Policy, NIH
6705 Rockledge Drive
Suite 750
Bethesda, MD 20892

In reference to docket number: **NOT-OD-15-026**

The Association of Clinical Research Professionals (ACRP) is the primary resource for clinical research professionals in the pharmaceutical, biotechnology and medical device industries, and those in hospital, academic medical centers and physician office settings. ACRP was founded in 1976 to address the educational and networking needs of research nurses and others who supported the work of clinical investigations. Almost 40 years later, ACRP is a global association comprised of individuals dedicated to clinical research and development. Our mission is "ACRP promotes excellence in clinical research." The Academy of Physicians in Clinical Research (APCR) is an affiliate of ACRP and is the leading professional organization, exclusive to physicians, that supports and addresses these unique issues and challenges of all physicians involved in clinical research.

ACRP appreciates the opportunity to provide the NIH with our comments on the Policy on the Use of a Single Institutional Review Board for Multi-Site Research as this issue has a significant impact on our membership. It appears the policy has adequate allowances for various exceptions, and we agree that adequate human subject protections can be obtained through a single, competent IRB review body in most multi-center trials supported with NIH funds. This policy should be adjusted in response to the public comments and staff recommendations where feasible and activated with a generous period of notice to the NIH and investigator community. The attached document provides detailed comments, suggestions, and recommendations on specific sections of the draft guidance.

We applaud the NIH's efforts on this important issue and hope that our feedback helps improve the final version of the document. Please let me know if you have any questions regarding our comments, or if we may otherwise serve as a resource on issues related to clinical research.

Sincerely,

James O Thomasell

Jim Thomasell, CPA
Executive Director

NOT-OD-15-026 : Policy on the Use of a Single Institutional Review Board for Multi-Site Research			
Page Number	**Text Line**	**Reference** *(if applicable)*	**Comments**
1	1	all	We encourage NIH to work with FDA to coordinate on policies about using a single IRB for each individual trial, and to work with FDA staff to update the existing FDA guidance (March 2006) in order to make the two policies more harmonious.
2	"Several extramural..."	CIRB	Consider the potential conflict of interest when apparently promoting the NIH NCI CIRB in this document, and provide in parallel an example of commercial IRB review that is also supported by an NIH-sponsored awardee.
2	"The draft Policy..."		The policy should state by what criteria an IRB should be considered qualified to provide this service, and whether, e.g., active registration with OHRP and a current Federal Wide Assurance (FWA) for participating institutions linked to the IRB are together adequate for this qualification, or whether additional quality criteria should apply. We recommend that the policy should specify the minimum qualifications, and should further specify that the selecting institution/awardee should have a written procedure in place to assess and document the qualifications of the selected IRB in order to fulfill their selection responsibility. This should be no different than qualifying a vendor for other key activities that are a function of the research plan. When approving the selected single IRB, the funding NIH IC must be able to review both the selection criteria and the supporting evidence of qualification before making their decision.
3	"A duplicate IRB..."	Cost	When a 2nd IRB exists by necessity at another location, how will discrepancies between approved protocols and Informed Consent materials from the Central IRB of record and Site IRB be managed by the Central IRB? How will different requirements for reporting safety and efficacy performance concerns be transmitted to the respective IRBs? How should necessary costs for differences in reporting or even continuing review frequency be addressed by the Central IRB and the awardee institution/investigator budget?
4-5	Ref 11	accountability	How will "diminished accountability for participating sites, and decreased consideration of local context..." be managed? We believe the guidance document should address this area of concern.
5	Ref 13	Example	While the word "local" appears in the cited example regarding US medical device laws, 21 USC 360j(g)(3)(A) may not be an appropriate example that restricts the application of this guidance within the US. It should be noted that this enabling legislation for IDEs presumes that each investigational site may have its own IRB. This is clearly not the case for many investigational sites in device trials (or drug trials, for that matter). Additionally, the cited language on IDEs indicates that the "local" IRBs, "established in

			accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted," can be argued to apply to any IRB "established" at any location *if* the local institution/facility has agreed to that IRB's supervision. This is because the regulations derived from this part of the FD&C Act do not give any specific indication to suggest a "local" requirement exists in that regard. In support of this, the regulations for IRBs (in 21 CFR 56 and 45 CFR 46) never use the term "local" IRB, and the definition of an IRB (in 21 CFR 56.102(g)) is written as, "any board, committee, or other group formally designated by an institution to review, to approve…" etc., with no mention or implied use of the term, "local." This definition is echoed with similar wording in 21 CFR 50.3(i). There is not even an obligation of affiliation with the institution or facility, other than by the agreement to be designated as the IRB authorized to review, approve and supervise the research activity. In addition, the regulation for IDEs in 21 CFR 812.40 et seq., while referencing 21 CFR 56, uses the term "reviewing IRB" as opposed to "local IRB," which implies a wider opportunity for where the IRB might be located. The equivalent regulations for drugs under an IND have no reference to "local" IRBs either, and also use the term "reviewing IRB" in 21 CFR 312.23. Our experience with FDA oversight for numerous INDs and IDEs indicates there are no de facto restrictions with regard to requiring "local" IRB oversight, meaning from within each institution/facility conducting the research, for device studies or otherwise. FDA normally asks only for the contact information of the relevant reviewing IRB(s), however many or wherever there are. It may be better to cast possible exceptions as they may relate to state, local and tribal laws, regulations, or rules, and not US Federal laws or FDA regulations.