CONSORTIUM OF
INDEPENDENT REVIEW BOARDS

January 6, 2016

Submitted electronically via www.regulations.gov

Jerry Menikoff, MD, JD
Director, Office for Human Research Protections
US Department of Health and Human Services
1101 Wooton Parkway, Suite 200
Rockville, MD 20852

RE: Document 2015-21756, *Federal Policy for the Protection of Human Subjects* (80 *Federal Register* 53931)

Dear Dr. Menikoff:

The Consortium of Independent Review Boards ("CIRB") is pleased to provide comments on the notice of proposed rulemaking issued by the Department of Health and Human Services ("DHHS" or "Department"), which proposes for public comment certain modifications to the existing regulations (the "Common Rule") "designed to continue to uphold the ethical principles upon which the Common Rule is based, as applied to the current social, cultural, and technological environment." See Federal Policy for the Protection of Human Subjects, Notice of Proposed Rulemaking, 80 Fed. Reg. 53,933 at 53,937 (September 8, 2015) (the "NPRM"). CIRB has served as the only professional trade association representing the independent institutional review board ("IRB") community since its founding in 1993. Its members, all of which are accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. ("AAHRPP") provide IRB services to external institutions and research sponsors.

The NPRM proposes changes across many aspects of the current regulations. As a general matter, CIRB shares DHHS' goal of modernizing the regulatory framework applicable to its members' work. CIRB has focused its specific comments on the issue of single IRB review and associated regulatory liability for unaffiliated external IRBs. As independent IRBs, all of CIRB's members have served as the central IRB of record for multi-site studies under their purview. CIRB has provided previous comments on the issue of streamlined IRB review both in response to the advanced notice of proposed rulemaking that preceded the NPRM (see 76 Fed. Reg. 44,512 (July 26, 2011) (the "ANPRM")), and the

Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research, Notice No. NPT-OD-15-026 (the "NIH Draft Policy").

To the extent our comments are responsive to a specific question posed in the Federal Register we so indicate in parentheses.

Requiring Single IRB Review Increases Protections to Human Participants

CIRB strongly supports the NPRM's proposal to require, with limited exceptions, single IRB review for cooperative research engaged in by United States institutions and believes that the research community is currently primed for such a requirement. (Question 74) In the commentary to the NPRM, DHHS notes that there is no evidence that duplicative review, as is currently typical for multi-site research, compounds protections to participants in a proportionate manner, see 80 Fed. Reg. at 53,982, and CIRB concurs with this conclusion based on its own experience. Inconsistency among competing IRB reviews, delays, and de-centralized reporting lines are inherent obstacles in our current system that detract from comprehensive and thorough participant protections. When reviews are centralized, with one IRB empowered to exercise authority and decision-making judgment across the entire study including every study-site, study participants are the ultimate beneficiaries. The articulated exceptions permit recognition of circumstances where the default rule would not be appropriate. (Question 77) CIRB supports the development of further guidance by DHHS as to when an exception is warranted. (Question 76)

The most obvious concern with the proposed mandate is that it will undermine the role of institutions in providing human research protections in a way that devalues and weakens the home-grown culture of compliance that many institutions have successfully cultivated, converting human research protections into an externally imposed, top-down model. However, that concern fails to appreciate the relatively discrete set of responsibilities that would be centralized in a single IRB under this proposal. The regulatory role of an IRB, and its required function, is narrow in relation to the wide spectrum of human subject and privacy protections that institutions oversee and implement. Many of these important human research protection oversight activities – ancillary to the regulatory role of an IRB – are often housed in the institutional IRB as a result of administrative ease and resource efficiency. Institutions can – and should – continue to serve a vital role in managing their human research protection programs, even if the subset of functions required to be performed by an IRB must be delegated centrally for most cooperative studies. CIRB encourages DHHS and the Office for Human Research Protections to develop guidance to further delineate and explore the role of the single IRB as compared to the critical human subject protection role of the assurance-holding institutions where the research occurs. This guidance should include model (but not mandatory) reliance agreements apportioning responsibilities accordingly. (Question 75)

Direct Enforcement Jurisdiction Over External IRBs Should be Secondary to Articulated Standards for Selecting Qualified Single IRBs of Record

The members of CIRB stand by the ethical integrity and legal compliance of the review services that they provide to the research community. Accordingly, CIRB members would willingly accept direct accountability to regulatory agencies to the extent it furthers

the underlying goals of streamlined IRB oversight. However, the primary rationale that has been offered for extending enforcement jurisdiction to IRBs providing review on behalf of assurance-holding institutions is that it would help assuage such institutions' concerns related to reliance on external IRBs and therefore create appropriate incentives for a more streamlined system. With a single IRB mandate, regulatory compliance arguably provides sufficient incentive. However, CIRB recognizes that DHHS may wish to construct the single IRB mandate within a framework that attaches liability to the entity serving a specific regulatory function. If regulatory liability for unaffiliated IRBs remains a valuable compliance tool from DHHS' perspective, CIRB reiterates the importance of guidance and model reliance agreements exploring in more detail how responsibilities can be apportioned between assurance-holding institutions and single IRBs. Parties to such agreements may always negotiate an apportionment of responsibility that goes beyond that required by the regulatory mandate. However, CIRB notes that unaffiliated IRBs may be less willing to assume delegation of responsibilities beyond the required IRB review role absent assurances that such contractual assumptions of liability will not translate into greater regulatory liability.

CIRB recommends that DHHS consider whether regulatory liability and direct enforcement against unaffiliated IRBs remains the only or best way to address institutional willingness to comply with what is proposed to be a mandatory requirement. CIRB strongly encourages DHHS to develop guidance around the required standards and performance criteria for single IRBs, as well as a framework for the selection process itself. (Question 75) Consensus on the factors and characteristics that demonstrate capacity to serve as a single IRB of record may produce more productive and meaningful assurances of quality and reliability than extending the potential of legal liability to unaffiliated IRBs.

Conclusion

In summary, CIRB, along with many of its colleagues in the independent IRB community, enthusiastically supports the NPRM's recognition that requiring single IRB review for collaborative research will significantly improve the oversight of human subjects research. The articulated exceptions allow for discretionary deviations from the default rule as necessitated by a given study.

CIRB recognizes and endorses the comments submitted by Quorum Review IRB ("Quorum") related to the single IRB of record requirement, and notes that Quorum has similarly endorsed CIRB's position. In addition to Quorum, CIRB circulated these comments to several other independent IRBs that are not currently members and is pleased to attach additional letters of support to this submission.

Respectfully submitted,

Matt Baker, Chair
Consortium of Independent Review Boards

Attachments

Chesapeake IRB

Human Connection >>> Technology Driven

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RE: Comments by the Consortium of Independent Review Boards ("CIRB") on Document 2015-21756, *Federal Policy for the Protection of Human Subjects* (80 *Federal Register* 53931)

Dear Dr. Menikoff:

We understand that you will be receiving comments on the notice of proposed rulemaking to the Common Rule (the "NPRM") from the Consortium of Independent Review Boards ("CIRB").

As an independent IRB providing services to the research community, we wish to indicate our support and endorsement of the comments provided by CIRB (although we are not currently a member).

We also would like to voice our own support of the NPRM's proposal related to the requirement for single IRB review as an important step in strengthening the protections for human participants in multi-site cooperative research in the United States.

Sincerely,

Jeffrey Wendel
President/CEO
Chesapeake IRB

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Sincerely,

Rebecca Ballard

Rebecca Ballard, JD, MA, CIP
Vice President of Compliance and Board Operations
Schulman Associates IRB