CONSORTIUM OF
INDEPENDENT REVIEW BOARDS

January 29, 2015

Via email: SingleIRBpolicy@mail.nih.gov

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

Re: Comments on Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research, Notice No. NOT-OD-15-026

Dear NIH:

The Consortium of Independent Review Boards ("CIRB") is pleased to provide comments on the National Institutes of Health (NIH) Draft Policy on the Use of a Single Institutional Review Board for Multi-Site Research ("NIH Draft Policy"). CIRB is a professional organization that was founded in 1993 and since that time it has served as the only professional trade association representing the independent institutional review board ("IRB") community. CIRB is a consortium of independent institutional review boards ("IRBs") that provide services to institutions external to their individual member institutions. All of CIRB's members are accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. ("AAHRPP"). Additionally, all of the members of CIRB have either served as a central IRB on some research studies and/or as a single IRB on some studies. Accordingly, CIRB feels that it is in a unique position to provide comments on the NIH Draft Policy.

CIRB applauds NIH's Draft Policy to require the use of a single IRB for NIH conducted or supported multi-site studies ("NIH research"). CIRB agrees that the Draft Policy will result in significant benefits and time savings for NIH research. The benefits will include the following: (1) the empowerment of the Single IRB to provide a thorough and substantive IRB review which can improve the protection of human subjects; (2) the consistency of initial and continuing IRB review; and (3) the time savings and elimination of delays created by the prevention of numerous lengthy and duplicative IRB reviews of the same research.

As an illustration, under the IRB review system proposed by NIH, the designated single IRB will be able to decide during initial and/or continuing review if the research is approvable. Accordingly, the decisions of the single IRB will have a substantive impact on the research and must be considered by the sponsor or the research cannot begin. Additionally, the single IRB will have initial and continuing safety and other relevant data which will position it to determine if additional protections are necessary for the

research. In contrast, under the current duplicative IRB review system, IRBs frequently feel that their reviews have little or no impact on the research since it has generally already been approved by other IRBs. In other words, their IRB review decision is often limited to either approving the research as submitted or preventing the research from being conducted at their institution.

It is well documented that duplicative IRB reviews of multi-site research add costs and delays but do not meaningfully add to enhanced human subject protection. In the recent article, The Harvard Catalyst Common Reciprocal IRB Reliance Agreement: An Innovative Approach to Multisite IRB Review and Oversight, the authors noted the following: "In multi-site studies, review by several IRBs is burdensome and the burden and expense of conducting multiple and duplicative ethics reviews at several institutions has been cited as a major barrier to research, manifest in delays in research conduct in the absence of demonstrable enhanced human subjects protections."[1] The lack of value of duplicative IRB review was also highlighted in an article several years ago by Dr. Jerry Menikoff and Dr. Joseph Millum as follows: ".... different IRBs mandate different, often minor, changes to consent documents or the protocol and researchers go back and forth...."[2] Menikoff and Millum also noted another problem stemming from wasteful duplicative IRB reviews. They stated as follows: ".... there are always constraints on IRBs' time and resources. Time spent reviewing one protocol takes away time from reviewing others." Ibid.

Accordingly, CIRB believes that NIH Policy for Single IRB review will add efficiencies to the IRB process and help reduce burdens on the local IRB and delays in the conduct of research.

Additionally, the NIH Draft Policy expressly states that it will not relieve research sites from their traditional regulatory obligations for such things as obtaining informed consent and reporting unanticipated problems and adverse events to the single IRB of record. The reporting of these events from all research sites to a single IRB of record also enhances the likelihood of a consistent IRB review since the single IRB will receive all of the unanticipated problems and safety information and will be much better positioned to make informed review decisions than under today's piecemeal approach. This approach will also eliminate duplicative IRB review of the same adverse events and unanticipated problems and thus reduce the burden on institutions and their IRBs who rely on the single IRB.

Lastly, if there are truly local issues which are relevant to the research such as applicable local laws or regulations, the Draft Policy allows for one of two approaches. In the first approach, the research site can notify the single IRB of these relevant local issues so they can be considered by the IRB. The second approach allows for an exception to the single IRB review but only where local IRB review is "... required by federal, tribal, or state laws or regulations."

In conclusion, CIRB submits that the Draft NIH Policy on Use of a Single Institutional Review Board for Multi-Site Research is very beneficial as it provides significant efficiencies and cost savings and reduces the burdens and delays of duplicative IRB review of multi-site research.

CIRB has circulated these comments to additional IRBs and is pleased to attach additional letters of support from those IRBs.

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[1] Winkler, S.J., Witte, E, Bierer, B.E., *The Harvard Catalyst Common Reciprocal IRB Reliance Agreement: An Innovative Approach to Multisite IRB Review and Oversight*. Clinical and Translatiol Science. 2014:10.1111/cts.1220.

[2] Millum, J., Menikoff, J., *Streamlining Ethical Review*, Annals of Internal Medicine. 2010:153 (10):655-657.

CIRB thanks the NIH for issuing this Draft Policy and for the opportunity to submit comments. CIRB looks forward to additional opportunities to provide NIH with its collective experience in advancing the protection and welfare of human subjects involved in clinical research.

Sincerely,

Matt Baker

Matt Baker, Chair
Consortium of Independent Review Boards

Attachments

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January 27, 2015

Via email: SingleIRBpolicy@mail.nih.gov

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Re: Comments on Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research, Notice No. NOT-OD-15-026

Dear NIH:

We understand you will be receiving a response to the proposed NIH rule making on the Draft NIH Policy on Use of a Single Institutional Review Board for Multi-Site Research, Notice No. NOT-OD-15-026, from the Consortium of Independent Review Boards ("CIRB").

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

We also would like to voice our own support of the NIH proposed Policy of centralized IRB review as an important step in strengthening the ability of the single, central IRB to protect participants effectively in multi-site trials.

Sincerely,

Cami Gearhart, CEO
CG/dkr

Chesapeake IRB
Human Connection >>> Technology Driven

January 28, 2015

Via email: SingleIRBpolicy@mail.nih.gov

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As an Independent Review Board providing services to the research community, we wish to provide comments in support of this proposed policy and although not a current member of CIRB, we agree with the comments provided by CIRB and acknowledge support of the NIH proposed Policy.

Sincerely,

Jeffrey W. Wendel

Jeffrey W. Wendel
Chief Executive Officer

Cc: Matt Baker, Chair
Consortium of Independent Review Boards

Full Accreditation