CONSORTIUM OF
INDEPENDENT REVIEW BOARDS

June 3, 2009

Via E-Mail IRBaccountability@hhs.gov

Dr. Jerry Menikoff
Director
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Re: Comments on Advanced Notice of Proposed Rulemaking to Enable OHRP to Hold Institutional Review Boards and the Institutions or Organizations Operating the IRBs Directly Accountable for Certain Department of Health and Human Services Regulatory Requirements (74 Fed. Reg. 9578, March 5, 2009)

Dear Dr. Menikoff:

The Consortium of Independent Review Boards ("CIRB®") commends the Office for Human Research Protections ("OHRP") recent notice to consider pursuit of changes to its compliance policies as they relate to activities performed by an external institutional review board ("IRB"). As OHRP knows, CIRB is a consortium of independent institutional review boards ("IRBs") located in the United States and Canada that provide IRB services to institutions external to their individual member institutions. The membership has a central mission of promoting the protection and rights of human research subjects, while providing an understanding of how independent IRBs support this goal. Approximately 75% of clinical research in the United States is conducted in non-academic settings, and independent IRBs review a majority of this research. Independent IRBs also provide services to the academic community. While most research under the oversight of independent IRBs is regulated by the Food and Drug Administration ("FDA"), the independent IRBs' involvement in the review of federally-funded research is steadily growing. As a result, CIRB has a significant interest in the extension of accountability measures.

As an initial matter, CIRB welcomes recognition of IRB accountability for IRB responsibilities in connection with federally-funded research. CIRB already demands the highest standards for its members, including agreement to conform with a code of ethics. Among other things, the CIRB Code of Ethics requires members to comply with both the

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letter and spirit of all laws and regulations pertaining to the protection of human subjects. Further, CIRB recently modified its membership requirements to impose a commitment to IRB accreditation. Most of CIRB's members are already accredited through the Association for the Accreditation of Human Research Programs, and the remaining members have committed to becoming accredited within the next two years. Finally, as OHRP recognizes, independent IRBs are already held accountable for responsibilities associated with the review of FDA-regulated research, and, as to federally-funded research, they must enter into agreements with the research institutions to comply with the institution's Federal Wide Assurance. Thus, OHRP's recognition of compliance oversight as it relates to the external IRB would make it clear that OHRP, like FDA, is holding the IRB, as a separate organization, responsible for assuring the protection and the rights of human research subjects.

The compliance change being considered by OHRP is an overdue progression of OHRP's general acceptance that IRBs external to a research institution are authorized, under 45 C.F.R. part 46, to review an institution's federally-funded research. The acceptance of independent IRB oversight commenced in the 1990's when OHRP's predecessor organization, the Office for Protection from Research Risks ("OPRR"), agreed that institutions can rely on review provided by an external IRB. Then came the implementation of the Federal Wide Assurance ("FWA") process in December 2000, along with OHRP's creation of a model IRB Authorization Agreement which contractually commits the external IRB to compliance with an institution's FWA. CIRB clearly believes that current regulations allow OHRP to implement the compliance change through a guidance document. However, it is not averse to new regulations that formally recognize the IRB's accountability similar to those found in FDA regulations set forth in 21 C.F.R. part 56.

CIRB wishes to express its deep appreciation to OHRP for the opportunity to comment on this Notice and looks forward to providing any assistance it can in connection with any proposed OHRP guideline or regulation formalizing external IRB accountability.

Sincerely,

Cami Gearhart
Chair

cc: CIRB Membership