CONSORTIUM OF
INDEPENDENT REVIEW BOARDS

January 5, 2010

Michael A. Carome, M.D.
Captain, U.S. Public Health Service
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Re: Comments on Draft Guidance on IRB Continuing Review of Research – Docket ID Number HHS-OPHS-2009-0016 and Draft Guidance on IRB Approval of Research with Conditions – Docket ID Number HHS-OPHS-2009-0017

Dear Dr. Carome:

The Consortium of Independent Review Boards ("CIRB®") appreciates the opportunity to comment on the Office for Human Research Protections ("OHRP") draft guidance documents, entitled "Guidance on IRB Continuing Review of Research," and "Guidance on IRB Approval of Research with Conditions." 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. While most research under the oversight of independent IRBs is regulated by the Food and Drug Administration, the independent IRBs' involvement in the review of federally-funded research is steadily growing. Consequently, CIRB has a significant interest in both of these draft guidance documents.

CIRB is pleased that OHRP has issued these two draft documents, and in particular would like to commend OHRP for developing such an extensive draft guidance addressing many aspects of the continuing review process (e.g., approval criteria, process, and frequency of continuing review. We believe that both guidance documents will be very helpful to the IRB community.

Because the draft guidance documents do not raise any real concerns or issues in our view, our comments are very limited. With regard to the guidance on IRB approval of research with conditions, CIRB reads the guidance as providing IRBs with sufficient flexibility to determine when research may be approved with conditions, the types conditions that may be required, and to determine the type of individual or group of individuals that may

Consortium of Independent Review Boards
1601 K Street, N.W.
Washington, DC 20006-1600

Phone: (202) 778-9294
Fax: (202) 778-9100

be designated to verify whether the required conditions for approval have been satisfied. Given CIRB's understanding that the examples in the guidance are examples only, and that they do not represent the universe of conditions that an IRB can impose in the context of "approval with conditions", CIRB is comfortable with this draft guidance. CIRB would appreciate clarification from OHRP if the Office intends for the guidance to suggest a more restrictive position because, in that case, CIRB may have additional comments on the draft guidance.

Other than seeking to assure that CIRB's understanding of the guidance on IRB approval with conditions is correct, CIRB has no other comments. CIRB wishes to express its deep appreciation to OHRP for the amount of work that was put into these guidance documents and for the opportunity to submit comments. We look forward to continuing to work with OHRP to assure the protection and welfare of human subjects involved in clinical research as to these draft guidance documents and other OHRP activities.

Sincerely,

Cami Gearhart

Cami Gearhart
Chair

cc: CIRB Board