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**January 5, 2010 - Guidance on IRB Approval of Research With Conditions**

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January 5, 2010

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SUBJECT: Guidance on IRB Approval of Research With Conditions

Dear Dr. Carome:

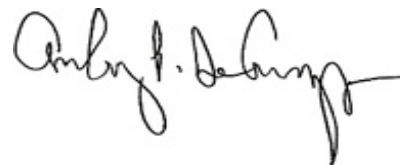
The Council on Governmental Relations (COGR) is an association of 182 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies, and practices on the performance of research conducted at its member institutions. We welcome the creation of guidance by agencies to assist the government's partners in meeting their responsibilities and ensuring the effective stewardship of federal funds or, in this case, the conduct of federally sponsored research.

We appreciate the Draft Guidance on Institutional Review Board (IRB) Approval of Research With Conditions. We understand that the key element to a conditional approval is the IRB's ability to make all the required determinations with the assumption that specific conditions are met. OHRP's definition of IRB approval with conditions is consistent with the meaning used by many IRBs and we welcome the note that IRBs may designate the chair, IRB members, or other individuals who are not IRB members to review material responsive to the conditions and/or request for clarification. This clarifies that the review of conditions is not an expedited review and, therefore does not have to be treated or documented as such. We assume that the list of examples of the types of conditions IRBs may stipulate is illustrative and not exhaustive.

The clarification on the effective date of approval – the date on which the conditions are reviewed and accepted by the IRB designee – will enable researchers to perform their studies for an entire year before submitting materials for continuing review.

We believe the research community will appreciate this guidance and encourage OHRP to finalize the Draft Guidance on Institutional Review Board (IRB) Approval of Research With Conditions.

Sincerely,



Anthony P. DeCrappeo  
President