



January 5, 2010

Michael A. Carome, M.D.
Captain, U.S. Public Health Service
OHRP
1101 Wootton Parkway, Suite 200
Rockville, MD 20852.

Federal eRulemaking Portal: <http://www.regulations.gov>.

RE: PRIM&R's Comments on Draft Guidance on IRB Approval of Research with Conditions, Docket No. HHS-OPHS-2009-0017

Dear Dr. Carome,.

On behalf of Public Responsibility in Medicine and Research (PRIM&R), we appreciate the opportunity to submit comments on OHRP's Draft Guidance on IRB Approval of Research with Conditions.

PRIM&R is a non-profit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served the full array of individuals and organizations involved in biomedical, social science, behavioral and educational research. PRIM&R's membership community includes professionals representing human subjects protection, animal care and use, and institutional biosafety programs, as well as researchers, institutional officials, government personnel, subject advocates, ethicists, policy makers, pharmaceutical and biotechnology leaders, and attorneys. Via a wide variety of conferences and courses, PRIM&R provides balanced, well-researched, and accurate information on the range of ethical and regulatory issues affecting research, while also offering access to certification, networking, and professional development resources.

PRIM&R believes that the guidance is helpful in clarifying some ambiguities related to approval of research with conditions. However, we offer a few suggestions for further clarification:

- **General:** PRIM&R assumes that this policy is consistent with policy objectives of the FDA so that IRBs that follow this policy but which are also subject to the authority of the FDA will not be in conflict with any relevant FDA policy. If this assumption is incorrect, the new guidance will have limited effect, and a disclaimer about its applicability to FDA-regulated research should be added.
- **D. What circumstances permit the IRB to approve research with conditions? p. 6:** PRIM&R supports a policy that permits individuals other than the IRB chair to determine that the conditions of approval have been satisfied.

Procedures that allow others with the requisite expertise to verify compliance with IRB conditions provides for greater efficiency which allows IRBs and their staff to focus on the activities that pose greater risk to research subjects.

Thank you again for the opportunity to comment on this proposal.

Respectfully Submitted,

A handwritten signature in black ink that reads "Joan Rachlin". The signature is written in a cursive, flowing style.

Joan Rachlin, JD, MPH
Executive Director
Public Responsibility in Medicine and Research

Cc: Board of Directors, Public Policy Committee