



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RE: PRIM&R's Comments on Draft Guidance on IRB Continuing Review of Research
Docket No. HHS-OPHS-2009-0016

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of Public Responsibility in Medicine and Research (PRIM&R), we appreciate the opportunity to submit comments on OHRP's *Draft Guidance on IRB Continuing Review of Research*.

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 *Continuing Review* guidance is helpful in clarifying some ambiguities. However, we offer a few suggestions for further clarification:

- **Section B(5). Evaluating Research Progress:** The section titled "Total Subject Enrollment" states that it "may be appropriate for the IRB to consider assessing the distribution of enrolled subjects by sex, race, ethnicity, or any other relevant demographic factors, taking into account variations in the prevalence of any disorder or condition under study across different demographic groups" (page 9). While demographic data on subject enrollment may be valuable information for some studies, PRIM&R is concerned that the statement could be misunderstood as a recommendation to routinely collect such data for all studies. Therefore, PRIM&R suggests that the language "for certain studies" be inserted after "may

be appropriate” so that the sentence states “...it also may be appropriate for certain studies for the IRB to consider assessing the distribution of enrolled subjects...”

- **Section F. Determining the Frequency of Continuing Review:** This section reviews the factors to consider when defining a timeline for continuing review. Specifically, it states “OHRP recommends that the IRB consider the following factors when deciding on an appropriate interval for continuing review ...” (page 26). PRIM&R supports defining these factors, but suggests changing the wording to read “OHRP recommends that the IRB consider factors like the following when deciding on an appropriate interval for continuing review...” This suggestion is proposed to provide broader flexibility to IRBs to identify additional justifications for requiring more frequent reviews than annual.
- **Section G(2). Determining the *First Continuing Review Date for Research Reviewed by the IRB at a Convened Meeting at the Time of Initial Review and Approved for One Year*:** This section redefines the effective date of the initial approval of research that is approved by the IRB with conditions. This language delays the effective date of the research to the date by which the IRB chairperson (and/or any other individual(s) designated by the IRB) has reviewed and accepted as satisfactory all changes to the protocol or informed consent documents required by the IRB from the investigator. This is a later date than the date of the convened meeting. This change provides welcome flexibility and carries the potential to improve administrative practices, allowing IRB staff to focus on more pressing matter concerning the protections of human subjects in research.
- **Section H. Lapses in IRB Approval:** This section describes the investigator’s responsibility to determine whether it is in the best interests of already enrolled subjects to continue study participation when IRB approval has expired. The section states, “The determination regarding whether it is in the best interests of already enrolled subjects to continue to participate in the research after IRB approval has expired may be made initially by the investigator, but the investigator should seek confirmation that the IRB agrees with this determination as soon as possible.” PRIM&R supports the investigator’s ability to make this determination pending timely IRB approval, but would recommend specification of when IRB confirmation is required. The term “as soon as possible” may be too open ended for the optimal protection of human subjects. We suggest that investigators seek confirmation from the IRB agrees no later than two weeks after expiration.

Thank you again for the opportunity to comment on this draft guidance.

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