



January 30, 2007

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852.

Submitted electronically to: engagementohrp@hhs.gov.

RE: Draft Guidance on Engagement of Institutions in Human Subjects Research

Dear Sir/Madam,

On behalf of Public Responsibility in Medicine and Research (PRIM&R), we appreciate the opportunity to comment on the above referenced Draft Guidance.

PRIM&R is an educational organization dedicated to creating, implementing, and advancing the highest ethical standards in the conduct of research. Its members represent a diversity of institutions and individuals throughout the world whose research efforts vary significantly. The membership includes a range of professionals from research administrators, government officials, and academic deans, to members and chairs of Institutional Review Boards (IRBs), Institutional Animal Care and Use Committees (IACUCs), and Institutional Biosafety Committees (IBCs).

PRIM&R congratulates OHRP on the Draft Guidance on Engagement of Institutions in Human Subjects Research. We believe that the document makes many improvements over the current policy and eliminates various contradictions and ambiguities. We request, however, two points of clarification as follows:

1. Page 6, A. Examples of Institutions Engaged in Human Subjects Research, par. (1)

The first sentence of the paragraph refers to institutions that receive "support" from HHS, while the example refers to direct "awardees". This results in ambiguity. Is it intended that the awardee institution is engaged in research, regardless of where the research actually takes place? If so, we suggest that the word "support" be replaced with "an award". However, the sentence as currently stated may suggest that if institutions receive any support from HHS, then they would be engaged in research, which seems to be overbroad.

2. Page 11, B. Examples of Institutions Not Engaged in Human Subjects Research, par. (4)

PRIM&R requests clarification of the term “non-collaborative.” The examples of the 1999 Guidance included qualifying language (“non-collaborative services meriting neither professional recognition nor publication privileges”) that had provided some guidance on the meaning. The deletion of that language, and the explicit removal of authorship as an example of “engagement,” raises new questions about the meaning of “non-collaborative.”

Thank you for your consideration of these comments.

Respectfully submitted,

A handwritten signature in cursive script that reads "Joan Rachlin". The signature is written in black ink and is positioned below the text "Respectfully submitted,".

Joan Rachlin, JD, MPH
Executive Director
On behalf of PRIM&R