DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Secretary's Advisory Committee on
Human Research Protections
Washington DC 20201

JUN 15 2007

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

In accordance with the provisions of the charter for the Secretary's Advisory Committee on Human Research Protections (SACHRP), I respectfully submit for your consideration a set of recommendations relative to Department of Health and Human Services (HHS) human subjects protection regulations at 45 CFR part 46. These recommendations represent the sixth in a series of recommendations from SACHRP.

Background

On October 5, 2004, SACHRP approved a resolution establishing a Subcommittee on Subpart A. SACHRP's charge to the subcommittee was to review and assess all provisions of subpart A of 45 CFR part 46 (HHS' codification of the Federal Policy for the Protection of Human Subjects, also known as the Common Rule) and relevant Office for Human Research Protections (OHRP) guidance documents, and based on this review and ongoing assessment, to develop recommendations for consideration by SACHRP in three categories: (1) recommendations on interpretation of subpart A provisions; (2) recommendations for development of new, or modification of existing, OHRP guidance; and (3) recommendations for possible revision of subpart A.

The goals of this review and assessment of subpart A of 45 CFR part 46 are threefold: (1) to enhance the protection of human subjects; (2) to reduce, where possible, regulatory burdens that do not contribute to the protection of subjects in a meaningful way; and (3) to promote scientifically and ethically valid research. To that end, the following recommendations were developed by the Subpart A Subcommittee, and discussed and approved by SACHRP at its meeting on March 29, 2007.

Recommendations Related to the Training of Individuals Involved in the Review, Oversight, or Conduct of Human Subjects Research

(1) SACHRP strongly recommends that OHRP require that institutions ensure that initial and continuing training is provided for **IRB members**. Such training should include ethical principles and their historical foundation, federal regulations, state and local laws, written IRB procedures, OHRP guidance, and institutional policies relevant to the protection of human subjects. Training should be initiated before members review human subjects research, and IRB duties should be commensurate with the level of training completed. Ongoing training should occur in a manner appropriate to assure the continued competence of IRB members.

(2) SACHRP strongly recommends that OHRP require that institutions ensure that initial and continuing training is provided for **IRB staff**. Such training should include ethical principles and their historical foundation, federal regulations, state and local laws, written IRB procedures, OHRP guidance, and institutional policies relevant to the protection of human subjects. IRB duties should be commensurate with the level of training completed. Ongoing training should occur in a manner appropriate to assure the continued competence of IRB staff.

(3) SACHRP strongly recommends that OHRP require that institutions ensure initial and continuing training for **the Institutional Signatory Official and the Human Protection Administrator** (e.g., Human Subjects Administrator or Human Subjects Contact Person). Such training should include ethical principles and their historical foundation, federal regulations, state and local laws, and institutional policies relevant to the protection of human subjects, and the terms of the institution's federal assurance. Ongoing training should occur in a manner appropriate to assure the continued competence of these institutional officials.

(4) SACHRP strongly recommends that OHRP require that institutions ensure initial and continuing training for **investigators and other members of the research team with responsibility for conducting human subjects research**. Such training should include ethical principles and their historical foundation, federal regulations, state and local laws, professional standards, and institutional policies relevant to the protection of human subjects. Initial training should be completed before investigators are allowed to conduct research that involves human subjects. Ongoing training should occur in a manner appropriate to assure the continued competence of investigators.

Mr. Secretary, I trust you will find this report acceptable. Your committee members and SACHRP subcommittee members have worked hard in their pursuit of the charges contained in the charter. SACHRP has also worked closely with Dr. Bernard Schwetz and the rest of the

OHRP staff and has benefited greatly from their expertise and leadership. We look forward to continuing our work and providing you with recommendations which will enhance human subject protections and advance science for the benefit of all Americans.

Sincerely,

Samuel Tilden, M.D., J.D., L.L.M.
Chair, Secretary's Advisory Committee on Human Research Protections

cc: Bernard A. Schwetz, D.V.M., Ph.D., Executive Secretary, SACHRP
Catherine Slatinshek, M.A., Executive Director, SACHRP