DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

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

OCT 13 2011

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. Sebelius:

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 recommendations relevant to the Department of Health and Human Services (HHS) human subjects protection regulations at 45 CFR part 46. These recommendations were passed by SACHRP at their July 2011 meeting.

Recommendations from the Subpart A Subcommittee

On October 5, 2004**,** SACHRP approved a recommendation establishing a Subpart A Subcommittee (SAS). SACHRP's charge to this 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 recommended guidance on informed consent (Tab A) is provided for your consideration.

Recommendations from the Subcommittee on Harmonization

On October 28, 2009**,** SACHRP approved a recommendation establishing a Subcommittee on Harmonization (SOH). SACHRP's charge to this subcommittee was to identify and prioritize areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. The Subcommittee will develop recommendations for consideration and possible adoption by SACHRP, to harmonize and simplify these guidelines and regulations. The goal of this subcommittee effort is to reduce unnecessary burdens on research efforts, thus resulting in better allocation of research resources and promoting the safety and welfare of human subjects.

SACHRP approved the following recommendations and comment from this subcommittee on July 20, 2011:

Recommendation regarding definition of a minor change in research under 45 CFR 46 and 21 CFR 56 (Attachment B)

Recommendation regarding application of 45 CFR 46 and 21 CFR 56 to early processes in research, such as identifying potential subjects, contacting subjects, and recruiting subjects (Attachment C)

FAQs, Terms and Recommendations on Informed Consent and Research Use of Biospecimens (Attachment D). Please note that this is a revised version of a document which had been previously submitted for your consideration January 24, 2011; this version now includes responses from FDA and OCR and provides more complete, robust answers to the questions posed.

On behalf of SACHRP, I would like to thank you for your consideration of this report. The committee, the Subpart A Subcommittee and the Subcommittee on Harmonization have been actively working in pursuit of their charges, and we look forward to continuing this work to enhance human subjects protections for the benefit of all Americans.

Sincerely,

/s/

Barbara E. Bierer, M.D.
Chair, Secretary's Advisory Committee
on Human Research Protections (SACHRP)

cc: Jerry Menikoff, M.D., J.D., Executive Secretary, SACHRP
Julia Gorey, J.D., Executive Director, SACHRP