DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

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

JUL 15 2009



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 a set of recommendations relative to Department of Health and Human Services (HHS) human subjects protection regulations at 45 CFR part 46. This letter represents the tenth in a series of recommendations from SACHRP.

## I. Recommendations Regarding Research Involving Individuals with Impaired Decision-making

### A. Background

Impaired decision-making capacity or impaired consent capacity occurs in a wide range of disorders and conditions that affect large numbers of Americans and cause suffering, morbidity, and mortality on a large scale. Current approaches to early detection, diagnosis, and treatment are inadequate, and there is a pressing need to advance therapeutics and understand basic mechanisms of disease and disease progression. Progress requires the inclusion of individuals with impaired consent capacity in research. However, the protections provided by free and informed consent are not available to individuals with impaired decision-making capacity; these individuals are uniquely susceptible to exploitation and research related harm. The Common Rule requires that when individuals vulnerable to coercion or undue influence take part in research, "additional safeguards are included," but the nature of these additional safeguards, the standards of capacity to consent, guidance regarding the consent process in general, the use of surrogate-based consent, and the definition of acceptable risk have not been addressed. Without a framework of regulations or guidance within which to conduct IRB review, it is evident that individuals may be unjustifiably called upon to take part in research, important ethical consideration may be missed, and valuable research may be hindered.

On August 1, 2006, SACHRP approved a resolution establishing the Subcommittee for the Inclusion of Individuals with Impaired Decision-making in Research (SIIIDR). SACHRP's charge to the subcommittee was to develop recommendations regarding whether guidance and/or additional regulations are needed for research involving individuals with impaired decision-making capacity. In making this assessment, the Subcommittee was asked to review the relevant provisions of subpart A, 45 CFR part 46, including the provisions at 45 CFR 46.111(b) (and 21 CFR 56.111(b) for FDA), and seek additional information to formulate its decision as it deems necessary.

SIIIDR was charged with developing either or both of the following products, depending on its conclusions: (1) recommendations on the interpretation of specific Subpart A provisions that will enhance protections of individuals with impaired decision-making; and (2) recommendations for a new subpart under 45 CFR part 46 (and FDA's human subject protection regulations) that would provide additional regulatory protections for this population.

**B. Recommendations**

SIIIDR's response to the question at the core of our charge is in the affirmative: new guidance and/or additional regulations are necessary to provide appropriate research protections for individuals who have impaired consent capacity. A series of ten interdependent recommendations were developed by SIIIDR and approved by SACHRP at its meetings on March 27, 2008, and March 4, 2009. Recommendations 1 through 8 call for new guidance while recommendations 9 and 10 would require new regulation. These recommendations and an explanatory preamble are presented in the enclosed final report from SIIIDR. SIIIDR has completed its charge and has been disbanded.

Individuals who have impaired consent capacity are uniquely vulnerable to exploitation and susceptible to harm, and SACHRP's primary obligation is to enhance protections with particular attention to those who are unable to protect themselves through the process of consent. This is an obligation we share with the community of researchers and professionals involved in research oversight. We believe our recommendations will move the field in the necessary direction.

## II. Recommendation Regarding the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

SACHRP members engaged in discussion regarding the current role of the Health Insurance Portability and Accountability Act (HIPAA) in research following presentations from representatives of the Institute of Medicine (IOM) and the Association of Academic Health Centers (AAHC), and commentary from a representative of the Office for Civil Rights. Both the IOM and AAHC have issued recent reports suggesting continued significant problems associated with the implementation of HIPAA in human subjects research. Please note that SACHRP previously issued recommendations on HIPAA which were communicated in a Secretarial letter dated September 27, 2004.

The following recommendation was approved by SACHRP at its meeting on March 3, 2009:

> SACHRP urges the Secretary of the Department of HHS to harmonize, within a defined time frame, policies governing research involving human subjects, in particular those aspects of the Common Rule (codified under HHS regulations at 45 CFR part 46, subpart A), Food and Drug Administration FDA regulations, and the provisions of the HIPAA Privacy Rule that govern access to and use of individualized health information and data. One option would be to consider the creation of a high-level department task force to accomplish this aim.
>
> Meaningful health care reform will require availability of health information data to compare the effectiveness of new and existing medical diagnostics and therapeutics and the utilization of personalized therapies resulting from applications in the scientific understanding of genetic and proteomic variation and susceptibility to disease.
>
> Development of a vibrant national health information technology infrastructure is provided in HR1, the American Recovery and Reinvestment Act of 2009. This will provide a unique vehicle to assemble this essential health information data which is impaired or even prohibited by current inconsistencies in federal privacy and research regulations.

## III. Recommendation Regarding Subpart A of 45 CFR part 46

### A. 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 recommendation was developed by the Subpart A Subcommittee, and discussed and approved by SACHRP at its meetings on March 3, 2009.

**B. Recommendation Regarding the Requirement to Designate IRBs in the Assurance Document**

The following recommendation was developed by the Subpart A Subcommittee and approved by SACHRP at its meeting on March 3, 2009:

> The Federalwide Assurance should be modified to remove the current requirement to designate specific IRBs (within the assurance document itself), replacing this with a commitment by the institution to rely only on registered IRBs, in satisfaction of the requirement to designate IRBs under 45 CFR 46.103.
>
> If the regulations as currently written do not allow this modification, OHRP in conjunction with other Common Rule departments and agencies should issue a Notice of Proposed Rulemaking to amend section 45 CFR 46.103 of the Common Rule by eliminating the requirement for institutions to designate individual IRBs under their assurances of compliance.

SACHRP committee members and subcommittee members are working hard in their pursuit of the charges contained in the charter. SACHRP is also working closely with Dr. Menikoff and the rest of the OHRP staff and has benefited greatly from their expertise and leadership. We hope to continue our work and provide you with recommendations which will enhance human subject protections and advance science for the benefit of all Americans.

Sincerely,

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

Enclosure

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