

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

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

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The Honorable Charles E. Johnson
Acting Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Johnson:

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

Recommendation from October 2008 SACHRP meeting

SACHRP members noted the Office for Human Research Protections' (OHRP's) reduced program budget, with its resulting decrease in a capacity to perform essential duties such as oversight, compliance and education. The following motion was approved unanimously:

To enable OHRP to oversee human subject protections in the multibillion dollar clinical research enterprise in the U.S., we respectfully ask you in your capacity as Secretary to increase its program budget line to at least its 2008 level plus 15 percent.

SACHRP members also unanimously wished to convey to the Secretary their appreciation for Dr. Ivor Pritchard's leadership as Acting Director, OHRP:

SACHRP appreciates Dr. Pritchard's outstanding efforts during this time of transition. Those efforts have required balancing two critical interests: the pre-eminence of the human research enterprise and the protection of human subjects participating in research. He has partnered with

the research community in providing education, determining public policy directions, addressing difficult oversight issues, and in fulfilling challenging compliance mandates. He has ensured research integrity while also working to ensure public trust in behavioral, social science, and biomedical research. We thank him and value him for his vision, dedication and leadership.

Recommendation from July 2004 SACHRP meeting

Please note that while reviewing work done by SACHRP and the communications that have been made to the Secretary, one recommendation was found to have been inadvertently omitted: during the July 2004 SACHRP meeting, SACHRP unanimously voted to request that OHRP develop guidance on how socio-behavioral research may appropriately be conducted in accordance with Subpart B.

Further SACHRP recommendations will be conveyed later this year following the March SACHRP meeting. SACHRP committee members and subcommittee members are working hard in their pursuit of the charges contained in the charter. SACHRP has also worked closely with Dr. Pritchard and the rest of the OHRP staff and has benefited greatly from their expertise and leadership; we now look forward to working with the new Director of OHRP, Dr. Jerry Menikoff. 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,

//Signed//

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

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