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COSSA Washington Update

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REPORT SAYS U.S. CLIMATE CHANGE PROGRAM NEEDS MORE RESEARCH ON IMPACTS ON HUMANS

On September 13, the National Academy of Sciences (NAS) released a report examining the U.S. Climate Change Science Program (CCSP). Among its conclusions, the report notes: "Our understanding of the impact of climate changes on human well-being and vulnerabilities is much less developed than our understanding of the natural climate system." In addition, "the two fields have not yet been integrated in a way that would allow the potential social impacts of climate change and management responses to be addressed."

The reasons for the lack of substantial research on human drivers of climate change such as energy consumption, the impact on human systems such as political institution and economies, and mitigation and adaptation options, the report indicates, stem from the inability of the CCSP "to support a consistent and cogent research agenda" in the human dimensions area, as recommended in previous studies. The level of investment, \$25 to \$30 million of a total \$1.7 billion CCSP budget, remains substantially lower than spending on other research elements and funding is atomized across many agency programs, the investigators suggest. In addition, the report notes, that "few social scientists are in leadership positions in the federal agencies, which makes it difficult for the CCSP to increase program emphasis in this area or to establish links with the academic social science community."

Another deficiency in the CCSP, according to the NAS, is that: "Progress in communicating CCSP results and engaging stakeholders is inadequate." Admitting that the program has had some successes interacting with

scientists, federal officials, and water resource managers, its efforts to transmit results to state and local officials, nongovernmental organizations, and the climate change technology community “has been limited and ad hoc.” This has led to missed opportunities to inform decision making and policy formulation in this arena.

Furthermore, the report concludes: “Progress in understanding and predicting climate change has improved more at global, continental, and ocean basin scales than at regional and local scales.” The NAS recommends improved integrated modeling, regional-scale observations, and the development of scenarios of climate changes and its impacts, in order to for example, give a better picture of climate processes and their effect on North America.

There have been successes in documenting the climate changes of the past few decades, the report notes. We now understand better land use change, sea ice retreat, glacier melting, and atmospheric warming. The capacity to predict has also improved, especially the coupled ocean-atmospheric-land climate models used to evaluate the human impact on observed trends.

Yet, at the same time, “the use of that knowledge to support decision making and to manage risks and opportunities of climate change is proceeding slowly.” Only a few small programs have been initiated to engage decision makers. These include the Regional Integrated Sciences and Assessment program and the Decision Making Under Uncertainty centers.

The Committee on Strategic Advice on the U.S. Climate Change Science Program produced the report. Veerabhadran Ramanathan of the Scripps Institute of Oceanography, chaired the panel. Christopher Justice of the Geography Department at the University of Maryland was the co-chair. Other social scientists on the panel included: Clark University Geographer Roger Kasperson; Michigan Political Scientist Maria Carmen Lemos; University of California, Santa Barbara Environmental Economist Chalres Kolstad; and Ohio State University Geographer/Atomspheric Scientist Ellen Mosley-Thompson. Thomas Wilbanks, a geographer at the Oak Ridge National Laboratory, served as the liaison from the NAS Committee on Human Dimensions of Global Change.

The report: *Evaluating Progress of the U.S. Climate Change Science Program: Methods and Preliminary Results* is available at: http://books.nap.edu/catalog.php?record_id=11934

PSYCHOLOGIST, SOCIOLOGIST AND STATISTICIAN AMONG THE RECIPIENTS OF NIH PIONEER AWARDS

On September 19, National Institutes of Health (NIH) Director Elias Zerhouni announced the recipients of the fourth group of Pioneer Awards and the first group of NIH Director’s New Innovator Awards recipients.

The awards are part of the NIH Roadmap for Medical Research initiative that tests new approaches to supporting research. The Pioneer Awards are designed to support scientists at any career stage. The recipients will each receive \$2.5 million in direct costs over five years. They are selected through a special application and evaluation process that engages 262 experts from the scientific community in identifying the most highly complete individuals in each pool. The Advisory Committee to the Director of NIH performed the final review and made recommendations to Zerhouni based on the evaluations by the outside experts and programmatic considerations.

Emphasizing that the Pioneer Awards are part of the NIH’s ongoing efforts to enhance the NIH peer review system, Zerhouni noted that the Pioneer Awards along with newly created NIH’s Director’s New Innovator Awards, “represent experiments in new ways of identifying and funding promising but unconventional ideas.” Among the winners are:



Lisa Feldman Barrett, a professor of psychology and director of the Interdisciplinary Affective Science Laboratory at Boston College, with additional appointments at Harvard Medical School and Massachusetts General Hospital, is only the second psychologist ever to have earned the honor. She received her Ph.D. in clinical psychology from the University of Waterloo in 1992. Barrett’s research, which is interdisciplinary, addresses the nature of emotion by integrating neuroscience, social psychology, psychophysiology, and cognitive science. She plans to use her

Pioneer Award to study how the brain creates the experiences that people refer to as “anger,” “sadness,” “fear,” and “happiness.”



Peter Bearman is the Jonathan Cole Professor of Social Science at Columbia University and the first sociologist ever to receive the Pioneer Award. Bearman also directs the Institute for Social and Economic Research and Policy and co-directs the Robert Wood Johnson Foundation Health & Society Scholars Program at Columbia. He received his Ph.D. in sociology from Harvard University in 1985. His work centers on understanding how social network dynamics shape diverse adolescent health outcomes. A former COSSA seminar speaker, Bearman co-designed the National Longitudinal Study of Adolescent Health (Add Health) and has studied the structure of sexual networks and the risk of sexually-transmitted diseases, peer influence and sexual behavior, friendship structure and suicidality, and the determinants of school achievement. Bearman plans to use his Pioneer Award to understand the role of social and environmental factors in autism.



Emery N. Brown is the Massachusetts General Hospital Professor of Anesthesia at Harvard medical School and Massachusetts General Hospital, and a professor of computational neuroscience and health sciences and technology at the Massachusetts Institute of Technology. Brown received his M.D. from Harvard Medical School in 1987 and a Ph.D. in statistics from Harvard University in 1988. He is a fellow of the American Statistical Association. Brown is an anesthesiologist-statistician whose research develops signal processing algorithms to characterize how the patterns of electrical discharges from neurons in the brain represent information from the outside world. With his Pioneer Award, Brown plans to use a systems neuroscience approach to study how anesthetic drugs act in the brain to create the state of general anesthesia.

2007 NIH Director's New Innovator Awards



Zerhouni also announced the recipients of the first group of NIH Director's New Innovator Awards which are reserved for new investigators who have not received a NIH regular investigator-initiated research (R01) or similar grant. The 29 recipients of the New Innovator Awards will receive \$1.5 million in direct costs over five years. With the project entitled, *From Neighborhoods to Neurons and Beyond*, **Kristen C. Jacobson**, University of Chicago will conduct a large, multiphase, multidisciplinary study of Chicago-area adolescents to determine the effects of social, biological, and environmental factors on individual differences in problem behaviors. Jacobson is an assistant professor of psychiatry. She received her Ph.D. from the department of Human Development and Family Studies at the Pennsylvania State University.

DISSEMINATION AND IMPLEMENTATION RESEARCH: A 'CRITICAL, BUT STILL EMERGING AREA OF SCIENCE'

On September 10 -11, the National Institutes of Health (NIH), led by the Office of Behavioral and Social Sciences Research (OBSSR) held a sold-out conference on *Building the Science of Dissemination and Implementation in the Service of Public Health*. Welcoming the more than 700 registrants and those watching via NIH Videocast, OBSSR Director David Abrams explained that the conference is the result of “a growing synergy between an existing trans-NIH Funding Opportunity Announcement (FOA) in support of dissemination and implementation research (Dissemination and Implementation Research in Health) and the implementation of a new strategic prospectus of OBSSR.

According to Abrams, the prospectus identifies increasing the “science of implementation” as a key avenue for moving behavioral and social science forward. It specifically calls for research to understand the factors promoting or impeding the adoption, adaptation, implementation, and maintenance of evidence-based practices by health providers, insurers, policy makers, and the public. Accordingly, the FOA seeks to test models which will sustain evidence-based health behavior change, preventive, diagnostic, treatment, and quality-of-life improvement services into public health and clinical practice settings.

Abrams expressed his excitement at seeing the “critical mass” coming together in this area. “Behavior and behavior change have to be central to making a key impact . . . It bridges biology and the environment. We

have to embrace behavior change at every level.” He explained that OBSSR is a trans-NIH entity with the responsibility to promote that “germ of support” designed to encourage the 27 NIH institutes and centers to collaborate and participate in basic science that leads to population change at a meaningful level of impact.

He cited the decline in smoking in one generation as an example of such a change in population behavior. Similarly, the incidence of AIDS over the past 15- 20 years has been cut in half as a result of changes in behavior and risk taking, he added. “If we use the rules of behavior, we can change behavior large scale,” says Abrams. According to Abrams, we are not going a good job of putting what we know in practice and policy with respect to what we could do to change population health behaviors in large numbers, especially for the chronic diseases. Both the persistent problems we have struggled with for decades, including health disparities and tobacco, and the new and emerging challenges such as the well-known obesity epidemic and its associated downstream consequences, are why this is a critical time for the new initiative, Abrams argued.

While primarily supported by the OBSSR, the conference was also partially supported by the National Cancer Institute, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, and the National Institute of Mental Health. Abrams also noted that there are also entities outside of the NIH that are interested in the area of research as well. Conference supporters viewed it as “an initial effort to pool the momentum, insights, and efforts around issues of dissemination and implementation research across a broad range of NIH institutes.” It is hoped that the event will be the first in a series of research conferences devoted to this “critical, but still emerging, area of science.”

The Definition of Dissemination and Implementation (D & I) Research

Conference planners defined dissemination and implementation as:

Dissemination is defined by conference conveners as the *targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to spread knowledge and the associated evidenced-based interventions. Research on dissemination addresses how information about health promotion and care interventions are created, packaged, transmitted, and interpreted among a variety of important stakeholder groups.*

Implementation is defined as the *use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings. Research on implementation addresses the level to which health interventions can fit within real-world public health and clinical service systems.*

The committee emphasizes that the distinction is made “because interventions developed in the context of efficacy and effectiveness trials are rarely transferable without adaptations to specific settings.” Accordingly, “research is needed to examine the process of transferring interventions into local settings, settings that may be similar to but also somewhat different from the ones in which the intervention was developed and tested.”

The goals of the conference were four fold:

1. To explicate the state of the theory, methods, and practice of dissemination and implementation research;
2. To highlight where increased conceptual, empirical, and methodological development is still needed, thus identifying challenges for the field;
3. To foster dissemination and implementation science with the ultimate goal of improving public health through the availability, adoption, adaptation, and sustained maintenance of efficacious approaches that improve the quality of health and human services; and
4. To recruit additional researchers and develop a diverse community of scientists, thus fostering the interdisciplinary collaborations necessary to pursue such complex and multidimensional dissemination and implementation research.

Improving the Scientific Basis of Health Care Research D & I

The meeting’s keynote speaker, Jeremy M. Grimshaw, University of Ottawa, noted that D & I is a new field and congratulated the NIH for sending a “clear signal to researchers” in the U.S. but also more globally. Grimshaw expressed his hope that the agency will be able to sustain these efforts over time.

Grimshaw began his remarks by calling attention to a 2006 *Washington Post* op-ed by Steve Wolfe, entitled *All Breakthrough, No Follow Through*, which stressed that without equal emphasis on dissemination and implementation research we are wasting our resources on discovery research. According to Grimshaw, we have reached the breakthrough point. We have made such advances in discovery research that we now need to move into an era where we give as much focus to dissemination and implementation research for the benefits of patients. He contended that it is his belief that the U.S. has, in fact, reached that point where much of its "investment in biomedical and health research is wasted because of dissemination and implementation failures." One of the most consistent findings of health services research, explained Grimshaw is that the health care system and health care professionals fail to deliver the quality of care they aspire to" deliver. He cited emerging knowledge surrounding the ineffective delivery of care for diabetes as an example.

He referenced Richard Grol, a psychologist in the Netherlands and a leader in D & I research, who insists that "evidence-based medicine should be complemented by evidence-based implementation." According to Grimshaw, we should be trying to build and use a robust evidence base to make sure we don't waste our resources. He also noted that in most health care settings approaches adopted to change clinical practice were more often based on beliefs of the actors in the room rather than on scientific evidence. Lots of people are sure that they know how to change behavior and improve quality and very few of them refer back to evidence to support the change, he asserted. He explained that there are many different issues under the umbrella of D & I research:

- Knowledge synthesis;
- Research into the evolution and critical discourse around research evidence;
- Research into knowledge retrieval, evaluation and knowledge management infrastructure;
- Development of methods to assess barriers and facilitators to D&I;
- Development of the methods for optimizing D&I strategies;
- Evaluation of the effect and efficiency of D&I strategies;
- Development of D&I theory; and
- Development of D&I research methods.

Grimshaw also summarized the current available evidence and highlighted what he thinks are the key methodological and conceptual weaknesses within that evidence base. He maintained that randomized controlled trials will provide the best evidence of effectiveness of the dissemination interventions. He closed by stressing that there is a substantial evidence base out there that we should learn from if we want to move the field forward.

To accommodate the overwhelming interest the conference the conference planners decided to videocast which is now available for viewing on the NIH website at <http://videocast.nih.gov/PastEvents.asp?c=998>. For more information on possible funding opportunities see: "Dissemination and Implementation Research in Health," PAR-07-086, PAR-06-520, and PAR-06-521; <http://grants.nih.gov/grants/guide/pa-files/PAR-07-086.html>; <http://grants.nih.gov/grants/guide/pa-files/PAR-06-520.html>; <http://grants.nih.gov/grants/guide/pa-files/PAR-06-521.html>

CULTURE CHANGE: NIH LAUNCHES INTERDISCIPLINARY RESEARCH CONSORTIA

Continuing its efforts to lower the "artificial organizational barriers" and advance science, on September 6 the National Institutes of Health (NIH) through its Roadmap for Medical Research announced that it will fund nine interdisciplinary research consortia. According to the agency, the funding of these consortia represents a fundamental change in both the culture within which biomedical and behavioral research is conducted and the culture within the NIH where research projects are normally managed by the 27 individual institutes and centers (ICs).

Interdisciplinary research integrates elements of a wide range of disciplines, often including basic research, clinical research, behavioral biology, and social sciences so that all of the scientists approach the problem in a new way, as opposed to multidisciplinary research which involves teams of scientists approaching a problem from their discipline.

The intent is for these consortia to not only develop new ways to think about challenging biomedical problems, but to provide a stimulus for academic research culture changes such that interdisciplinary research becomes the norm. They address several current barriers to interdisciplinary research: (1) departmental boundaries within institutions; (2) recognition of team leadership within the projects; (3) cross training students in multiple disciplines; and (4) the NIH approach to interdisciplinary research administration.

“These programs are designed to encourage and enable change in academic research culture to make interdisciplinary research easier to conduct for scientists who wish to collaborate in unconventional ways,” said NIH Director Elias Zerhouni.

Echoing Zerhouni, Alan Krensky, newly appointed Director of the Office of Portfolio Analysis and Strategic Initiatives (OPASI), noted that these consortia represent a new paradigm for NIH administration that will manage interdisciplinary programs through multiple NIH ICs in a truly trans-NIH manner.” OPASI provides the funding for NIH Director’s Roadmap initiatives. Management of the interdisciplinary research consortia will allow the agency to act as a single entity rather than a collection of 27 individual ICs. OPASI and the National Center for Research Resources (NCRR) will oversee the entire program.

The consortia will be funded at a level of \$210 million over five years. The missions of the consortia range broadly from probing the relationship between self-control and addictive behavior, to understanding the fundamentals of the aging process, and to developing new approaches to drug discovery and targeted gene therapy. It will integrate numerous disciplines including basic biological sciences, genomics, proteomics, bioinformatics, biostatistics, biophysics, chemistry, gene therapy, stem cell biology, mechanical and tissue engineering, reproductive endocrinology, neurology, behavioral research, and the social sciences. Members and their principal investigators include:

- **Consortium For Neuropsychiatric Phenomics-Coordinating Center**, Robert Bilder, University of California, Los Angeles
- **Interdisciplinary Research Consortium in Geroscience**, Dale Bredeesen, The Buck Institute for Age Research, Novato, California
- **NeuroTherapeutics Research Institute**, Paul Hagerman, University of California, Davis
- **Taskforce For Obesity Research At Southwestern (TORS)**, Jay Horton, University of Texas Southwestern Medical Center, Dallas, Texas
- **SYSCODE: Systems-Based Consortium for Organ Design And Engineering**, Richard Maas, Brigham and Women's Hospital, Boston, Massachusetts
- **Northwest Genome Engineering Consortium**, Andrew Scharenberg, Children's Hospital and Regional Medical Center, Seattle, Washington
- **Genomic Based Drug Discovery**, Edward Scolnick, Broad Institute of MIT and Harvard University, Cambridge, Massachusetts
- **Interdisciplinary Research Consortium On Stress, Self-Control, And Addiction**, Rajita Sinha, Yale University, New Haven, Connecticut
- **The Oncofertility Consortium: Fertility Preservation for Women**, Teresa Woodruff, Northwestern University, Chicago, Illinois

NIH FUNDS SECOND ROUND OF CTSAs

On September 18, National Institutes of Health (NIH) Director Elias Zerhouni announced the recipients of the second round of the Clinical and Translational Science Awards (CTSAs). Twelve additional academic health centers join the first 12 centers announced in October 2006. Ultimately, when fully implemented in 2012 the goal is to fund 60 linked institutions designed to energize the disciplines of clinical and translational science.

Led by the National Center for Research Resources (NCRR), the CTSA program is designed to fund diverse and far reaching approaches related to all aspects of the research enterprise. According to Zerhouni, the CTSA consortium represents NIH's "investment in the future as it prepares the next generation of clinical researchers to meet tomorrow's health care challenges."

The goal is to extend the CTSA philosophy of interdisciplinary interactions and connectivity to generate partnerships and collaboration beyond the consortium to organizations involved with health care throughout the nation, said Barbara Alving, NCCR Director. "It is through multiple partnerships that CTSAs will transform clinical and translational research and bring new scientific advances to health care."

This round of awards include: partnerships with three minority research centers and three institutions led by women principal investigators. Institution receiving awards in the second round include: Case Western Reserve University; Emory University partnering with Morehouse School of Medicine; Johns Hopkins University; University of Chicago; University of Iowa; University of Michigan; University of Texas Southwestern Medical Center; University of Washington; University of Wisconsin, Madison; Vanderbilt University partnering with Meharry Medical College; Washington University, St. Louis; and Weill Cornell Medical College partnering with Hunter College.

The CTSA initiative is part of the NIH Roadmap for Medical Research. Funding for the CTSA initiative comes from redirecting existing clinical and translational programs and from Roadmap funds. Through the CTSA consortium and other collaborations, NCCR supports all aspects of translational and clinical research, connecting researchers with one another and with patients and communities across the nation. Information about current members and the new grantees can be viewed on the CTSA Consortium Web site at www.ctsaweb.org.

Applications for the third round of funding are due November 7, 2007, with the awards expected in June 2008. For more information see: www.ncrr.nih.gov/ctsa.asp

HUMAN BEHAVIOR IMPORTANT IN MILITARY CONTEXTS: MORE RESEARCH NECESSARY SAYS NAS REPORT

On September 17, the National Academies' Committee on Basic Research in the Behavioral and Social Sciences for the U.S. Military released its report *Human Behavior in Military Contexts*. Quoting former North Vietnamese Commander General Vo Nguyen Giap on how human beings are the decisive factor in winning wars, the Committee argued for enhanced funding for new research in six key areas relevant and timely for military needs.

The areas are, according to the report:

Intercultural Competence: The ability of military personnel to adapt to different cultures. Two key components are learning a second language and cross-cultural negotiation;

Teams in Complex Environments: Understanding team behavior and functioning, their dynamic nature, and leaders' behaviors are critical to military activity;

Technology-based Training: Using technology to train military personnel should be based on evidence-based knowledge about learning and not simply driven by the available technology;

Nonverbal Behavior: A key aspect of people's reactions and behavior, such nonverbal activities and cues directly affect military leadership, persuasion, negotiation, cultural fluency, training, and learning;

Emotion: Intense emotions such as euphoria or grief, often take place in the military in stressful situations. These affect almost every aspect of people's behavior and performance and also can have long-term effects on their health and functioning; and

Behavioral Neurophysiology: New noninvasive research techniques have made possible trying to understand the interplay among the biological underpinnings of motivational, affective, and cognitive processes as they affect human behavior. This is important for military procedures for personnel selection, training, and performance evaluation.

The U.S. Army Research Institute for the Behavioral and Social Sciences (ARI) asked the NAS to provide an agenda for basic research for both the near (5-10 years) and far (more than 10 years) terms. The Committee recognized that currently funds for this research agenda appear limited. The Department of Defense budget for behavioral and social science is \$37.6 and has been declining. The ARI basic behavioral research funding is approximately \$4 million. Giving these data the report also recommends doubling or more of basic and applied research in the behavioral and social sciences across U.S. military research agencies. This would support approximately 40 new projects per year across the Committee's recommended research areas.

James Blascovich of the Department of Psychology at the University of California, Santa Barbara chaired the panel under the auspices of the NAS' Board on Behavioral, Cognitive, and Sensory Sciences. Former National Science Foundation division director and now President of Haskins Laboratories Philip Rubin chairs the Board. Christine Hartel is its Executive Director.

The report is available at: http://www.nap.edu/catalog.php?record_id=12023 . It includes not only the Committee's findings, but papers reviewing findings related to the six key areas noted above.

BROOKINGS EXAMINES NEW ANTIPOVERTY POLICIES TO HELP BLACK MALES

On September 20, The Brookings Institution held a briefing in conjunction with its release of the latest edition of the *Future of Children* Journal that focuses on "The Next Generation of Antipoverty Policies." The Journal, co-produced with Princeton University's Woodrow Wilson School, focuses on policies that could alleviate poverty among adolescent and young males through incentives and mandates.

The Journal's contributors believe more progress is needed to fight poverty among young men, especially black males. The social problems of delinquency, crime, dropping out of school, unemployment, and out-of-wedlock births are all disproportionately associated with poor young men.

Ron Haskins of Brookings, who moderated the session, reported that half of all children and eighty-five percent of black children spend a considerable part of their childhood in a female-headed household. However, despite this disintegration of the nuclear family, it is not solely responsible for the rise in poverty or the other problems associated with disconnected young males. Many of the supplemental socialization efforts that were provided by schools, churches, peer groups, and civic groups that provided positive values and behavior to children are now in decline especially in low-income communities.

One of the journal contributors Gordon Berlin, President of MDRC, argued that at the heart of the debate on disconnected youth is the dismal growth record of wages and annual earnings for those at the bottom of the distribution level. He also believes that focusing on economic incentives is a useful approach to reaching these young men. Berlin proposes changes to the Earned Income Tax Credit (EITC) which would make all low-income earners eligible even if they had no children.

Unlike Berlin, Lawrence Mead, Professor of Politics at New York University, contends that cultural factors have a bigger influence. He asserts that young poor men no longer associate with mainstream culture. Their alternative culture deemphasizes the value of work. Mead maintains that youth who subscribe to this culture resist working even when jobs are available. Mead said "youths often believe that those [low income] jobs are beneath them, they have problems taking orders from bosses, and they react to perceived slights by quitting their jobs."

The panelists' ideas for solving the problem involved a variety of carrot and stick approaches that would provide economic or social incentives to lure these males back into school and/or the workforce, and punishment for

those who fail to live up to their responsibilities. Although the incentives as well as the level of punishment vary among the contributors all have the end goal of reducing poverty and reconnecting these males to society. Harry Holzer of Georgetown University concluded: "Since many forces have contributed to the collapse of employment among lower-income young black men, no single policy remedy will turn the situation around."

For more information about the journal and project go to:
<http://www.brookings.edu/es/research/projects/foc/default.htm>

OHRP SEEKS INFORMATION AND COMMENTS ON RESEARCH THAT INVOLVES ADULTS WITH IMPAIRED DECISION-MAKING CAPACITY

The Office of Human Research Protections (OHRP) in the Department of Health and Human Services' (HHS) Office of Public Health and Science is seeking information and comments regarding "whether guidance or additional regulations are needed to adequately protect adult individuals with impaired decision-making capacity who are potential subjects in research." The request for information and comments "stem from the recommendations of an HHS working group, generated in response to the report published by the National Bioethics Advisory Commission (NBAC) entitled "Research Involving Person with Mental Disorders That May Affect Decision-making Capacity" (December 1998), and from subsequent recommendations by the National Human Research Advisory Committee (NHRPAC). NHRPAC was disbanded in 2002 and replaced by the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP is currently considering whether guidance or additional regulations are needed.

According to the *Federal Register* notice, the scope of the request is limited to research involving adult subjects because additional protections for children involved as subjects in research already exists under the subpart D regulations. The notice is also not directed toward consideration of emergency research involving the decisionally-impaired that would be covered under the HHS' Secretarial waiver under 45 CFR [Code of Federal Regulations] 46.101(i) on the exception of informed consent requirements for emergency research. **Comments are due by December 4, 2007.**

OHRP is specifically seeking information and comments on:

1. What are investigators and institutional review boards' (IRBs) current practices in regard to the conduct, review, and approval of research involving decisionally impaired adult individuals.
2. What problems or concerns have arisen for investigators, IRBs, or research subjects in the conduct or review of research involving decisionally impaired individuals as subjects?
3. The current requirement for IRB approval under the HHS regulations at 45 CFR 46.111(b), states: When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. Please describe the additional safeguards you have included in studies to protect the rights and welfare of subjects with impaired decision-making capacity.
4. How should the population of adults with impaired decision-making be defined for the purposes of guidance or regulation?
5. In some circumstances, certain adult subjects may develop impaired decision-making capacity (e.g. persistent, fluctuating, or progressive decisional impairment) after consenting and enrolling in research. In such cases, is guidance needed, or are additional regulations necessary, in order to adequately protect adult subjects who become decisionally impaired during their participation in research? For example, should guidance or additional regulations address when it would be appropriate for investigators to seek the consent of the subject's legally authorized representative to enable the subject's continued participation?

6. If guidance or additional regulations are needed to adequately protect the rights and welfare of subjects with impaired decision-making capacity, should such guidance or regulations address the issue of assent? Note that the subpart D regulations generally require that IRBs determine that adequate provisions are made for soliciting the assent of children when in the judgment of the IRB the children are capable of providing assent. (See 45 CFR 46.408.)

Submit written comments to REQUEST FOR INFORMATION ON RESEARCH THAT INVOLVES ADULT INDIVIDUALS WITH IMPAIRED DECISION-MAKING CAPACITY, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to impairedcapacityohrp@hhs.gov, or via facsimile at 301-402-2071.

For further information contact: Julie Kaneshiro, 240-453-6900; e-mail julie.kaneshiro@hhs.gov.

CONSORTIUM OF SOCIAL SCIENCE ASSOCIATIONS

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The Consortium of Social Science Associations (COSSA) is an advocacy organization promoting attention to and federal support for the social and behavioral sciences.

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1522 K Street, NW, Suite 836
Washington, D.C. 20005
Phone: (202) 842-3525; Fax: (202) 842-2788

GOVERNING MEMBERS

American Association for Public Opinion Research
American Economic Association
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American Historical Association
American Political Science Association
American Psychological Association
American Society of Criminology
American Sociological Association
American Statistical Association

Association of American Geographers
Association of American Law Schools
Law and Society Association
Linguistic Society of America
Midwest Political Science Association
National Communication Association
Rural Sociological Society
Society for Research in Child Development

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Association for Asian Studies
Association for Public Policy Analysis and Management
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Council on Social Work Education
Eastern Sociological Society
International Communication Association
Justice Research and Statistics Association
Midwest Sociological Society
National Association of Social Workers
National Council on Family Relations

North American Regional Science Council
North Central Sociological Association
Population Association of America
Social Science History Association
Society for Research on Adolescence
Society for the Psychological Study of Social Issues
Society for the Scientific Study of Sexuality
Sociologists for Women in Society
Southern Political Science Association
Southern Sociological Society
Southwestern Social Science Association

COLLEGES AND UNIVERSITIES

Arizona State University
Brown University
University of California, Berkeley
University of California, Davis
University of California, Irvine
University of California, Los Angeles
University of California, San Diego
University of California, Santa Barbara
Carnegie-Mellon University
University of Chicago
Clark University
Columbia University
Cornell University
Duke University
George Mason University
George Washington University
University of Georgia
Harvard University
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University of Kentucky
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Rutgers, The State University of New Jersey
University of South Carolina
Stanford University
University of Tennessee
State University of New York, Stony Brook
University of Texas, Austin
Texas A & M University
Tulane University
Vanderbilt University
University of Virginia
University of Washington
Washington University in St. Louis
West Virginia University
University of Wisconsin, Madison
University of Wisconsin, Milwaukee
Yale University

CENTERS AND INSTITUTES

American Academy of Political and Social Sciences
American Council of Learned Societies
American Institutes for Research
Brookings Institution
Center for Advanced Study in the Behavioral Sciences
Cornell Institute for Social and Economic Research
Institute for Social Research, University of Michigan

Institute for the Advancement of Social Work Research
Institute for Women's Policy Research
National Bureau of Economic Research
National Opinion Research Center
Population Reference Bureau
Social Science Research Council