

HHS DISSOLVES HUMAN SUBJECTS PROTECTIONS COMMITTEE *AS*

Without explanation, the Department of Health and Human Services (HHS) has allowed the charters of at least two scientific advisory committees designed to provide guidance to Federal policy on the protection of human participants in research to expire. The committees, the National Human Research Protection Advisory Committee (NHRPAC) and the Secretary's Advisory Committee on Genetic Testing (SAGGT), were chartered by President Clinton's HHS Secretary Donna Shalala in June 2000 and June 1998, respectively. All of the committees' deliberations, including a planned NHRPAC meeting in October, have been cancelled.

Administration officials have indicated that HHS is "diligently working" to reconstitute the panels, but they have not provided any public timetable for this action. Nevertheless, NHRPAC members are troubled that the Committee's charter was allowed to expire.

"I am shocked and dismayed that NHRPAC has been permitted to lapse as a Federal Advisory Committee. It is a non-partisan body with its only intent the advancement of human research protection and the production of knowledge, including in the social and behavioral sciences, consonant with the best ethical practices. NHRPAC is a dedicated group that came together to address critical issues in human research protection system across fields of inquiry. To stop such progress in the making is sad indeed," observed NHRPAC's Social and Behavioral Sciences Working Group Co-Chair Felice Levine.

Senators Edward Kennedy (D-MA) and Hillary Clinton (D-NY) sent a letter to Secretary Thompson expressing their "deep concern about reports that the Administration is engaging in wholesale replacements of the experts on key scientific advisory committees. . . It is unimaginable, for example, that the public could be well served by the (see NHRPAC, page 6)

SENATE COMMERCE PANEL GIVES OK TO DOUBLING NSF; ADMINISTRATION EXPRESSES OPPOSITION *HS*

On September 19, the Senate Commerce, Science, and Transportation Committee, chaired by Sen. Ernest Hollings (D-SC), favorably reported S. 2817, the National Science Foundation Doubling Act, a bill that authorizes increasing the NSF budget from its FY 2002 level of close to \$5 billion to almost \$10 billion by FY 2007. Under the dual jurisdiction that governs consideration of NSF authorization bills in the Senate, the Commerce panel joins the Health, Education, Labor and Pensions Committee, which reported the bill on September 5. (See *Update*, September 9, 2002).

In a letter to Senator Ron Wyden (D-OR), chair of the Commerce panel's Subcommittee on Science, Technology, and Space, NSF director Rita Colwell expressed the Administration's opposition to the bill because "the amounts authorized in S. 2817 do not conform to the Administration's budget request for FY 2003." The letter also cites White House Office of Science and Technology Policy Director John Marburger's oft-stated contention that "any plans for increased expenditures must be supported by a specific rationale for each increase, rather than an arbitrary formula." Given this letter, Senator John McCain (R-AZ), Ranking Republican on the Commerce Committee, offered and then withdrew

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an amendment to limit the reauthorization to two years rather than five and to require a report on how NSF would spend the money if its budget was doubled in the next five years.

The NSF and the Administration also expressed their opposition to other parts of the bill. They object to a provision that would make the Math and Science Partnership (MSP) Program a formula block, rather than a competitive, grant program in FY 2006. Colwell noted, "This is inconsistent with the Foundation's exemplary merit review process and conflicts with the competitive processes that promote excellence."

In addition, "the issue of greatest concern to the Foundation" is the section of S. 2817 that would enhance the independence of the National Science Board (NSB) by granting it the right to hire and pay its own staff.

The House passed its version of the legislation on June 5th. It is a three-year authorization that presumes a doubling of NSF's budget in five years and contains the language regarding the NSB. It does not include the provision making the MSP a formula block grant program or the language regarding EPSCOR. The hope is that House-Senate staff can meet and resolve the differences before the bill goes to the Senate floor. This could expedite

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Government Affairs:	Angela L. Sharpe
Public Affairs:	John A. Wertman
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President:	Janet L. Norwood

The Consortium of Social Science Associations (COSSA), an advocacy organization for federal support for the social and behavioral sciences, was founded in 1981 and stands alone in Washington in representing the full range of social and behavioral sciences.

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passage before the 107th Congress calls it quits. However, as the NSF director's letter suggests, an Administration veto may be possible.

DATA SHARING AND CONFIDENTIALITY BILL MOVES FORWARD

On September 17, following a hearing that praised the legislation, the House Subcommittee on Government Efficiency, Financial Management, and Intergovernmental Relations favorably reported "The Confidential Information and Statistical Efficiency Act of 2002" (H.R. 5215). The bill represents a long-time effort by Subcommittee Chairman Rep. Stephen Horn (R-CA) and Rep. Tom Sawyer (D-OH) to improve the nation's statistical system. Both members will be leaving the Congress after this year; they hope the bill can become law before the session ends.

According to Horn, H.R. 5215 has two primary objectives. One is to enable the Bureau of the Census, the Bureau of Labor Statistics (BLS), and the Bureau of Economic Analysis (BEA) to share the business data they collect. The legislation would not permit the sharing of data on individuals. The second objective is to ensure that confidential data citizens and businesses provide to Federal agencies for statistical purposes are subject to rigorous statutory protections against unauthorized use.

Sawyer, who started the hearing in the witness chair and then moved to become a member of the committee, stressed the importance of the second objective. He noted how the legislation "replaces the current patchwork of rules" to provide "information shielded by the force of law." He noted that confidence in confidentiality is "fragile," especially among immigrant populations. He believes that the new provisions protecting individually identifiable information should lead to greater cooperation with government surveys. The legislation does this by providing clear and uniform statutory restrictions on the use of confidential statistical data for the 70 government agencies that collect information from individuals.

Also commenting on the second objective, Robert Rector of the Heritage Foundation laid out three standards for improving Federal statistical policy: (1) protection of individual identity for responders who provide original data; (2)

production of useful, timely information for data users, and (3) independent evaluations of the data for decision-makers. He expressed concern that the legislation, while effective in meeting the first standard, has problems because "it does not clearly distinguish between the *identity* of the individual respondent and the *information* they provide" (Rector's emphasis). Horn amended the bill to resolve the issue. Rector also strongly argued: "...if non-government researchers are to provide an independent evaluation of official government data, they must have access to information that is similar to that used by government statisticians."

With regard to the sharing of business data for statistical purposes among the three Federal agencies, William Nordhaus of Yale University and Chair of the American Economic Association's Committee on Economic Statistics joined Kathleen Cooper, Undersecretary of Commerce for Economic Affairs, Kathleen Utgoff, Commissioner of the BLS, Randall Kroszner of the Council of Economic Advisers, and Maurine Haver of the National Association for Business Economics, in supporting the legislation.

Nordhaus called it "an important step in improving the quality of Federal economic statistics" because it will overcome the problem where "the government has important data in the left pocket but that data cannot be moved to the right pocket." He suggested that the bill would greatly improve the National Income and Product Accounts by providing "more accurate early estimates of quarterly GDP by comparing publicly available company data with microdata on shipments and other series available from Census surveys." The data sharing would also reduce annual GDP revisions by allowing the BEA to identify discrepancies earlier, Nordhaus noted.

Cooper argued that the data sharing provisions would lead to an improvement in the accuracy of state personal income. BEA would also be able to improve its estimates of profits and wages and salaries by comparing corporate financial reports with BLS and Census surveys. Also important to both Cooper and Kroszner is that the sharing could lead to the abolition of duplicative surveys that would in turn boost response rates from businesses. From Utgoff's perspective reconciling discrepancies between the BLS and Census Bureau business registers "is one critical example of why enhanced data sharing matters." It would also allow BLS to

improve sampling and reduce respondent burden for the Producer Price Index, she noted.

Kroszner declared the Bush Administration's support for the bill, calling it "good, common-sense government" that will lead to "more accurate descriptions of the economy," and lower burdens on the private sector. Best of all, he noted, "all this would happen at no additional cost to the taxpayer."

At the moment, H.R. 5215 has no companion Senate bill. However, since there appear to be no major objections to the legislation, the hope is to get the Senate to accept the House bill before the 107th Congress adjourns.

NAS CONTINUES TO ANALYZE THE ORGANIZATIONAL STRUCTURE OF NIH AS

On September 10, the National Academy of Sciences Committee on the Organizational Structure of the National Institutes of Health (NIH) held its second in a series of five scheduled meetings. Chaired by Harold Shapiro, president emeritus of both the University of Michigan and Princeton University, the Committee heard from NIH administrators, including Ruth Kirschstein, NIH Deputy Director, Donald Poppke, Acting NIH Budget Director, Duane Alexander, Director of the National Institute of Child Health and Human Development (NICHD), and Charles Leisure, NIH Deputy Director for Management.

Poppke provided the Committee with a snapshot of the NIH budget process. He stated that the NIH budget is a series of 26 separate allocations. The Director, with input from the Institutes and Centers (ICs), identifies the underlying philosophy and NIH priorities for proposed allocation of funding including "specific areas of emphasis," a term coined by former Director Harold Varmus. Current Director Elias Zerhouni's focus will be on major trans-NIH priorities, related Poppke.

Poppke noted that the NIH director is able to put his or her personal stamp on the NIH budget. One way to do this is to take advantage of the director's powers of influence in the initial allocation of resources among ICs during the Administration's budget formulation process. The director, said Poppke, negotiates with the Department of Health and Human Services (HHS) and the Office of

Management and Budget on the final distribution of funds among ICs and among funding mechanisms. Finally, the Congress consults the Director in allocating either increases or decreases relative to the President's budget during the marking up of House and Senate bills as well as conference legislation. The director, Poppke observed, "ultimately decides which ICs will get what [funding]."

According to Poppke, there are also direct methods of fiscal control available to the NIH director. These include the Director's Discretionary Fund, which is authorized at a level up to \$25 million. For FY 2002, the Congress appropriated \$10 million. There is also the one percent transfer authority which is provided in annual appropriations language. The director may transfer up to one percent of the total NIH appropriations (\$237 million in FY 2002). Finally, there is the Office of the Director (OD) Appropriation, an annual amount to operate the office and program of OD.

Kirschstein told the Committee that in her 46 years at NIH, she has been part of all the organizational studies. She noted that there were enormous similarities between them and that many of the recommendations made over the years have not been taken. According to Kirschstein and others who have come before the Committee, NIH is a remarkably effective institution because of the people it gets to work for it.

She also stated that management of the organization is not nearly impossible; it depends on the interaction of the leadership at the top. Kirschstein noted that there has been a "sea change" in how the Institute and Center directors interact. Once they were so independent they hardly spoke to each other. Now they assemble themselves in groups by subject areas. She added that changes are needed in the organizational structure that will help to facilitate that type of interaction.

Kirschstein noted that she is loathe to suggest that a major change be made for the sake of making change. NIH may be unwieldy but that does not mean that it is not working effectively. She also emphasized that she thought it was important that the NIH director weigh in on whether a new institute should be created.

Alexander cautioned the Committee that many of the current ICs are derivatives of other ICs. He

explained that NICHD, which has the broadest mission and scope of any of the ICs, was created for political reasons and that there was a lot of resistance from NIH. He also explained that he was opposed to the creation of a women's health institute. Coordination of research across the ICs is a more regular occurrence now, Alexander stated, and he added that there is a high spirit of cooperation across the NIH.

He also noted that there may be problems with the idea of clustering, which would put another layer between IC directors and the NIH director. He then questioned what criteria would be used to determine the clusters. Alexander also called for established criteria for the creation of any new institute.

'One HHS'

The Administration's efforts to restructure the Department of Health and Human Services into "one HHS" are on schedule, Leisure told the Committee.

Eight areas have been considered for consolidation by HHS Secretary Tommy Thompson: human resources, public affairs, legislative affairs, information technology, grants acquisition management, finances/accounting, budget, and facility management funds.

According to Leisure, effective October 1, the personnel offices of the 27 NIH Institutes and Centers will be coordinated through the HHS' Bethesda personnel office. For the time being, these offices will report to NIH, but eventually they will report to HHS.

Meanwhile, the Senate Labor, HHS, and Education Appropriations Subcommittee denied a request by HHS to transfer staff and budget from the various public and legislative affairs offices of HHS agencies to the Secretary's office. Observing that services are best provided by those close to the researchers, Leisure noted that "there are a number of things going on at various stages."

APPOINTMENTS

AS

Zerhouni names NIMH, NIAAA Directors

Newly confirmed National Institutes of Health (NIH) Director Elias Zerhouni has begun to fulfill the promise he made at his confirmation hearing to make "finding great leaders" to fill the vacancies at the Agency a top priority.

Making the rounds of the Federal advisory committees to the 27 institutes and centers, Zerhouni introduced newly appointed Directors of the National Institute of Mental Health (NIMH) and the National Institute of Alcohol Abuse and Alcoholism (NIAAA) to their respective advisory committees. Their appointment leaves only three institutes with acting directors: the National Institute on Drug Abuse, the National Institute on Neurological Disorders and Stroke, and the National Institute of General Medical Sciences.

Introducing Thomas R. Insel to the NIMH Council, Zerhouni noted that he believes that Insel has a way of bringing logic to the field of research and the ability to build teams, both which are "very valuable" qualities in a leader. "After a thorough and careful search process, it became clear that Dr. Insel's ability to communicate a compelling vision for mental health research, his outstanding scientific record and proven leadership skills have made him the natural choice for this important directorship," Zerhouni further observed.

Insel is currently a Professor of Psychiatry and Director of the Center for Behavioral Neuroscience at the Emory University School of Medicine. He is the founding director of the Center, a science and technology institute funded by the National Science Foundation. His research continues to study the role of oxytocin in social attachment and behavior, and under an NIMH grant he is involved in the development of an autism research center.

Insel is a graduate of Boston University, where he received a B.A. and an M.D. from the Medical School. He did his internship at Berkshire Medical Center in Pittsfield, Massachusetts and his residency at the Langley Porter Neuropsychiatric Institute at the University of California, San Francisco. Insel joined NIMH in 1979 as a clinical associate in the Clinical Neuropharmacology Branch and went on to hold several administrative and leadership posts

prior to going to Emory. He is expected to begin his appointment in mid-November.

Zerhouni also announced the appointment of Ting-Kai Li as the new Director of the NIAAA and introduced him to the Institute's Council. "Dr. Li has been at the forefront of discovery in alcohol research throughout his illustrious career," emphasized Zerhouni. "His unparalleled scholarship and proven leadership abilities will enable NIAAA to continue to capitalize on the diverse scientific opportunities in biomedical, clinical, and prevention research," he added.

Li succeeds Raynard Kington, Director of the NIH Office of Behavioral and Social Sciences Research (OBSSR), who has served as Acting Director of NIAAA since January 2002 following the retirement of Enoch Gordis, NIAAA Director from 1986-2002.

Li received his medical degree from Harvard University in 1959. He joined the faculty of the Indiana University School of Medicine in 1971 and served as the Associate Dean for Research from 1986-2000.

Anderson Named CEO Of APA

Former OBSSR Director Norman B. Anderson has been named the next Executive Vice President/CEO of the American Psychological Association. He will begin the position on January 1, 2003 with the retirement of current CEO Raymond D. Fowler.

Anderson is currently a Professor of Health and Social Behavior at the Harvard University School of Public Health. During Anderson's tenure as Director of OBSSR and Associate Director of the NIH from 1995-2000, OBSSR grew from a \$2 million program to a \$19 million program and organized the funding of more than \$90 million in health research initiatives.

BUSH ANNOUNCES U.S. WILL REJOIN UNESCO

JW

In his September 12 address to the United Nations (UN) General Assembly, President Bush announced that the United States will return to the UN's Educational, Scientific, and Cultural Organization (UNESCO) after an 18-year absence.

The U.S. withdrew from the organization in 1984, citing poor management and philosophical disagreements.

UNESCO was created in 1946, currently has 188 member states, and is headquartered in Paris. It promotes collaboration among nations in education, science, culture, and communications. Among its key work areas are expanding educational opportunities, protecting world heritage sites, developing reliable world scientific standards and statistics, and promoting freedom of expression and human rights.

(NHRPAC, from Page 1)

dismissal of the National Human Research Protections Advisory Committee after the tragic deaths of patients involved in clinical trials.” Kennedy and Clinton urged the Secretary to “reconsider these decisions.”

Theories regarding the reason for the dissolution abound. According to the September 17 edition of the *Washington Post*, many believe that HHS allowed NHRPAC, SAGGT, and possibly several other panels to disband as a result of the pressure the Administration was receiving from conservative groups that would like the advisory panels to pursue policies such as establishing rights as research subjects for the unborn.

While HHS has indicated that it feels that there is a need to broaden the purview of NHRPAC, the disbanded committee’s previous charter clearly stated that “NHRPAC will provide expert advice and recommendations to the Secretary of HHS, Assistant Secretary for Health (ASH), the Director, Office of Human Research Protections (OHRP), and other departmental officials **on a broad range of issues and topics** (emphasis added) pertaining to or associated with the protection of human research subjects.”

In the meantime, members of the committees are concerned that not only have their efforts been wasted, but there is now a void in the discussion of human participant protection in research.

NHRPAC’s Progress

Since its inception in 2000, NHRPAC has met on a quarterly basis, and its next meeting had been planned for October 2002. In addition, the Committee established several working groups to address a variety of issues, including: children, genetics, social and behavioral sciences, decisionally impaired, informed consent, and conflicts of interest. Most recently, the panel established a working group on prisoners and another to examine whether all disciplines should come under the Common Rule.

The Committee, chaired by Mary Faith Marshall, a Professor of Medicine and Bioethics at the University of Kansas Medical Center, operated in such a way that once it achieved consensus on an issue, its recommendations were posted on NHRPAC’s website (<http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm>) and transmitted to the appropriate HHS officials and agencies. A number of reports and documents, charting the progress being made, are posted on the Committee’s website, including:

- Comment letter to HHS on 45 CFR 46 Subpart B – September 2001
- Recommendations on HHS’s draft Interim Guidance on Financial Relationships in Clinical Research – October 2001
- Clarification of the Status of Third Parties – Revised April 24, 2002
- Comment Letter on HIPPA NPRM – April 2002
- Report to NHRPAC from Social and Behavioral Science Workgroup on Public Use Data Files – April 2002
- Draft work product from Genetics Workgroup – July 2002
- Final Report to NHRPAC from Children’s Workgroup
- Final Report to NHRPAC from Workgroup on Decisional Incapacity on Informed Consent and the Decisionally Impaired
- Final NHRPAC Recommendations on Confidentiality and Research Data Protections, and Illustrative Overview of Federal Confidentiality Statutes and Codes

SBS Working Group

What does this the dissolution of NHRPAC portend for the Social and Behavioral Science Working Group (SBS) co-chaired by Levine, Executive Director of the American Educational Research Association, and Jeffrey Cohen of OHRP? According to Levine, the group hopes to continue to address the numerous issues that were a part of its schedule and are associated with the protection of human research participants. "It would be a shame to lose such a formidable agenda," Levine related.

Levine was appointed to NHRPAC by Shalala at the suggestion of COSSA and the social and behavioral science community. COSSA urged the expansion of the Committee to include a greater presence for social and behavioral scientists that have a different set of experiences and knowledge than biomedical researchers. Originally, the composition of NHRPAC included only one social scientist – Jennie Joe, University of Arizona, an anthropologist with public health and nursing training.

Other members of the SBS working group include: **Christine Bachrach**, National Institute of Child Health and Human Development; **Richard Campbell**, University of Illinois; **Robert M. Hauser**, University of Wisconsin-Madison; **Robert Levine**, Yale University School of Medicine; **Sally T. Hillsman**, American Sociological Association; **Raynard Kington**, National Institutes of Health Office of Behavioral and Social Sciences Research; **Philip Rubin**, National Science Foundation; **Caroline Miner**, U.S. Department of Justice; **Jonathan D. Moreno**, University of Virginia Health System; **Ivor Pritchard**, U.S. Department of Education; **James Shelton**, U.S. Agency for International Development; and **Joan Sieber**, California State University-Hayward.

The goals of the SBS working group were "to develop guidelines to help Institutional Review Boards (IRBs) review social and behavioral research involving human participants," and to make "specific recommendations regarding additions or changes to the Common Rule relevant to the social and behavioral sciences."

SBS completed several reports, two of which are posted on a website on the American Sociological Association's homepage (www.asanet.org): 1)

Public Use Data Files and 2) Third Parties, both accepted by NHRPAC at its January, 2002 meeting. Final edits were underway on two statements, on confidentiality and risk and harm, for NHRPAC review and discussion. Other key issues marked for discussion by SBS focused on issues of scientific substance, the human subjects protection system, and researchers. They included:

- Identification of risk (type and levels) in the social and behavioral sciences
- Relationship between risk, methods, substance of study, and subject populations
- Consent and written consent (timing and amount of disclosure)
- IRBs and their readiness to review social and behavioral research
- Knowledge of social and behavioral science research
- Composition of IRBs and other issues relating to expertise
- Knowledge and educational needs regarding ethical practices
- Educational needs relating to the Common Rule and role of IRBs

Reports planned for the future included addressing several new areas: informed consent, international research, classroom research, observations in public places and field research, and ethnographic and qualitative research.

In addition to the reports, the SBS Working Group members have given presentations at the various scientific societies' annual meetings and have held special sessions with department chairs at others.

Correction: The story *Academy Report Probes 'What Do Terrorists Value?'*, featured in our September 9 issue, listed an incorrect website address. To access the report, please visit:

<http://www.nap.edu/catalog/10489.html>

We apologize for any confusion this may have caused.

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Population Association of America

CONTRIBUTORS

Harvard University
Howard University
University of Illinois
Indiana University
Institute for Social Research, University of Michigan
Institute for the Advancement of Social Work
Research
Institute for Women's Policy Research
University of Iowa
Johns Hopkins University
University of Kansas
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Washington University in St. Louis
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University of Wisconsin, Madison
University of Wisconsin, Milwaukee
Yale University

Consortium of Social Science Associations

1522 K St., NW, Suite 836, Washington, D.C. 20005
