

Consortium of Social Science Associations

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CONGRESS EXAMINES RESEARCH PROTECTION OVERSIGHT SYSTEM: LEGISLATION NEEDED

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Examination of the Federal government's oversight system for protecting human research participants continued on April 23rd as the Senate Health, Education, Labor and Pensions Subcommittee on Public Health held a hearing analyzing the issues surrounding protecting participants in research, including appraising the remaining gaps in the oversight system. The Subcommittee also considered the need for legislation to address the issue.

Senator Edward Kennedy (D-MA), the Subcommittee's Chairman, observed that a number of reports (including those issued by the National Bioethics Advisory Commission (NBAC) and the Department of Health and Human Services' (HHS) Office of the Inspector General) have identified "serious flaws" in the oversight of the human research system "that must be corrected." Noting the Committee's long-standing interest in this issue, he emphasized that correcting those flaws is an "urgent task."

According to Kennedy, legislation is necessary to accomplish this. He is currently drafting a bill that would, among other things, require all institutions to be accredited in order to conduct research involving human participants. Kennedy's legislation would retain the existing oversight framework and grant greater statutory authority to the HHS's Office of Human Research Protections (OHRP).

Ranking Minority member Bill Frist (R-TN), a heart-transplant surgeon and clinical researcher, echoed the Chairman's call for legislation to provide greater safeguards for research participants. "Unfortunately, recent, highly-publicized tragedies have shaken the public's trust and confidence," he explained. Frist, who convened two hearings in the 106th Congress on this issue while he was Chair of the Subcommittee, related that it became "clear that there had been a systematic breakdown of oversight

ranging from the investigators to the institutional review boards (IRBs) to the federal agencies responsible for ensuring the safety of patients."

Meanwhile, on the House side, Reps. Dianna DeGette (D-CO) and Jim Greenwood (R-PA), both members of the House Energy and Commerce Committee, are drafting a measure that would also work within the existing oversight framework and grant greater authority to the OHRP. Their bill would also require prior written consent for all research. As currently drafted, however, it is unclear whether the bill would allow exceptions to this requirement.

The Senate hearing's witnesses, a quartet of academic and corporate representatives, included Marjorie Speers, Executive Director of the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) and former Acting Executive Director of NBAC.

Testifying in this latter capacity, Speers noted that great strides have been made in human participants research in many fields, including the social sciences, the humanities, and the biomedical

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sciences. She recognized that "NBAC was not alone in its deliberations on the human research system," noting the work of the Institute of Medicine, the U.S. General Accounting Office, the Office of the Inspector General at HHS, and others.

Speers focused her remarks on three of the 30 recommendations made by NBAC to change the oversight system at the national and local levels that would ensure all research participants receive appropriate protections and remove unnecessary burdens. (See *Update*, June 4, 2001).

NBAC's recommendations called for the independent review of risks and potential benefits of voluntary informed consent for participants in both publicly and privately sponsored research. This recommendation is vitally important, Speers stressed, because it responds to concerns about research conducted by Federal agencies that do not follow the Common Rule or privately funded research that is not regulated by the Food and Drug Administration.

She underscored the NBAC's support for legislation that would create a "single, independent Federal office to lead and to coordinate the oversight system" outside of HHS, but noted that this is not meant as a criticism of OHRP; rather, NBAC recognizes the need for a Federal office to exist

independently and outside of any department or agency that sponsors research and be responsive to the ethical issues of all fields of research, not just those of primary concern to the HHS.

The Commission's support for a "unified, comprehensive Federal policy embodied in a single set of regulations and guidance" that would apply to all types of research involving human participants was the third recommendation highlighted. A wide variety of research, from clinical trials to social science methods, is currently regulated under the same set of Federal rules. Speers emphasized that the rules "were originally written by the National Institutes of Health and do not always appropriately address the ethical issues in research outside of the biomedical context."

'Voluntary Self-Regulation'

Also testifying in her capacity as the Executive Director of AAHRPP, Speers called for a voluntary accreditation system. She explained that while the NBAC took a stand in favor of accreditation, AAHRPP believes that "voluntary self-regulation by the research community, along with oversight by an independent accrediting body, is the best strategy for making research as safe as it possibly can be." AAHRPP, emphasized Speers, has taken governmental policy and developed it (with input from a diverse range of professionals and the public) into a clear set of accreditation standards. Those standards meet all regulatory requirements and, in some cases, exceed them, she declared.

Opposing a voluntary accreditation program, Cherlynn Mathias, a whistleblower of research conducted at the University of Oklahoma and the panel's first witness, pressed the case for mandatory accreditation. Based on her experience, Mathias explained that she believed that voluntary accreditation would not be adequate.

Speers stressed that AAHRPP's standards are significant in several other respects: they are broad and flexible so that they will be meaningful to a full range of research types; certainly in clinical research, but also in social science, historical, and business research. They can be applied in a variety of research settings, including universities, hospitals, government agencies, and independent IRBs.

CONSORTIUM OF SOCIAL SCIENCE ASSOCIATIONS

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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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According to Speers, the standards also make clear that protecting research participants is not the sole responsibility of IRBs, but a duty shared by everyone who conducts research. "By requiring institutions to meet an explicit set of standards for protection, AAHRPP's goals are to recognize institutions that meet these high standards. We believe this voluntary self-regulation by the research community, along with oversight by an independent accrediting body, is the best strategy for making research as safe as it possibly can be," Speers concluded.

AAHRPP was founded by seven diverse organizations, including COSSA. (See *Update*, June 4, 2001). For additional background on issues related to human subjects protection, see the COSSA webpage at www.cossa.org/hsbackground.htm.

NIH DIRECTORS TESTIFY TO HOUSE APPROPRIATORS

AS

The House Labor, Health and Human Services, and Education Appropriations Subcommittee held its final National Institutes of Health (NIH) "theme hearing" of the spring (see *Update*, March 18, 2002) on April 16th, as several NIH institute directors joined Acting NIH Director Ruth Kirschstein on a panel called to discuss disease prevention and health promotion. The directors appearing were: Claude Lenfant (Heart, Lung, and Blood - NHLBI), Francis Collins (Human Genome), Kenneth Olden (Environmental Health Sciences), Paul Sieving (Eye), Lawrence Tabak (Dental and Craniofacial - NIDCR), Patricia Grady (Nursing), Donald Lindberg (National Library of Medicine), Raynard Kington (Acting Director, Alcohol Abuse and Alcoholism - NIAAA).

Kirschstein began the testimony by giving some brief examples of the research and communication activities funded by NIH to further disease prevention and health promotion. She focused primarily on the work done at the institutes led by her fellow panelists, and she told the Subcommittee about prevention programs aimed at averting high blood pressure, maintaining vision, and avoiding asthma. Her remarks were followed by an opening statement from each of the directors that served as a more in-depth version of Kirschstein's overview.

Olden stressed that much work remains to identify the key genetic, environmental, and behavioral risk factors for varied diseases. He followed this point by noting that investment in prevention research and translation techniques is key. Grady discussed her Institute's need to fund research on teaching disease prevention and health promotion techniques to nurses and other health care professionals. Lindberg discussed the steps the Library of Medicine has taken to disseminate research results relating to health promotion on the internet.

The Subcommittee's Chairman, Ralph Regula (R-OH), asked Kington about alcohol industry advertising; Kington responded by informing the Chairman that the NIAAA is doing research as to how advertising affects alcohol consumption and related behaviors. Regula then asked Lenfant about the best methods to disseminate information about the dangers of aging as related to heart disease. Lenfant posited that the AARP (American Association for Retired Persons) could serve as such a vehicle by sharing important knowledge with its 40 million members.

Rep. David Obey (D-WI), the Subcommittee's Ranking Member, inquired whether the consideration of ethical, legal, and social questions posed by genome advances has come at a reasonable pace. Collins answered by saying that "this is one of the first times in scientific history that ethical, legal, and social research has been conducted hand-in-hand with advances in a particular field." He then discussed the risk of genetic discrimination in hiring and insurance issues and stressed that legislation is needed to protect the population from such prejudice. Obey concluded his questioning by asking Tabak about dental care discrimination against poorer individuals. Tabak assured the Congressman that the NIDCR is supporting research into how we can prevent dental health decay among those in at-risk communities.

Rep. Don Sherwood (R-PA) then pressed Collins on how soon we will be able to use genetic advances to prevent disease. Collins explained that it will take a good deal of study to apply innovations to hands-on medical therapies. Sherwood turned next to Lenfant with a question about the NHLBI's efforts to curtail obesity. The Director replied that his Institute runs "educational and translational programs to bring research to the population."

Regula then asked Lindberg about the NIH's dissemination of information through the internet. Lindberg told the Chairman that the Library answers thousands of questions each day posed by both health professionals and members of the public through e-mail systems. Lindberg also referred back to his earlier remarks on web-based information dissemination.

NIH SEEKS COMMENTS ON DATA SHARING POLICY BY JUNE 1

The National Institutes of Health (NIH) is seeking comments on a draft statement on sharing research data. Under the policy, NIH-supported investigators will be expected to make their data available to the scientific community for subsequent analysis by other researchers. Additionally, investigators submitting a grant application to NIH will be required to include a plan for data sharing or to explain why data sharing is not possible. The policy will apply to both extramural and intramural investigators and to cooperative agreements and contracts.

The Agency, however, recognizes that "in some particular instances sharing data may not be feasible." It is noted that studies with very small samples or those collecting particularly sensitive data "should be shared only if stringent safeguards exist to ensure confidentiality and protect the identity of subjects."

Additional information is available on the NIH website at http://grants.nih.gov/grantspolicy/data_sharing/index.htm. Comments must be received no later than June 1, 2002 and sent to the Office of Extramural Research, 1 Center Drive, MSC 0152, Building 1, Room 150, Bethesda, MD 20817 or by email to dder@nih.gov. It is expected that the new policy will be announced August 1, 2002, after consideration of public comments and appropriate revisions, with a proposed effective date of January 1, 2003.

COALITION REQUESTS INCREASED FUNDING FOR INTERNATIONAL EDUCATION

Speaking on behalf of the Coalition for International Education, of which COSSA is a

member, David Ward, President of the American Council on Education, called for significant increases for FY 2003 appropriations for international education and foreign language programs commonly known as Title VI (of the Higher Education Act) and Fulbright-Hays.

Ward told the Labor, Health and Human Services, Education Appropriations panel, chaired by Rep. Ralph Regula (R-OH), on April 23, that: "Developing the international expertise the nation needs in the 21st Century requires educational reform and sustained financing." He added: "Just as the Federal government maintains military reserves to be called upon when needed, it should invest in an educational infrastructure that steadily trains sufficient numbers and diversity of American students." However, Ward noted, "the global transformations of the last decade have created an unparalleled need in the United States for expanded international knowledge and skills, but the nation is unready."

To accomplish this, Ward asked the Subcommittee to provide sufficient FY 2003 funding to: 1) significantly increase the number of experts with high-level proficiency in foreign languages, international and area studies, especially those relating to non-Western nations and cultures; 2) expand the international knowledge of faculty and students across the disciplines, especially in professional and technical fields such as business, education, environment, crime and terrorism, economics, health, and information technology; 3) increase the diversity of students who major in international fields and foreign languages and who pursue careers in international service; and 4) expand the capacity of colleges and universities to maintain and update our international knowledge in a wide range of disciplines and fields that are vital to U.S. national interests and economic competitiveness on a continuous basis.

Rep. David Obey (D-WI), Ranking Member of the appropriations panel and a champion of Federal support for international education, remarked that if it were not for his National Defense Education Act fellowship in Russian studies shortly after Sputnik, he "would not be here." He also noted that given recent events, it was now easier to get people's attention about the importance of Federal investment in these programs. Referring to Ward's testimony that indicated the major Federal programs in this

area were currently funded at 32 percent below the FY 1967 spending level, Obey declared that Congress is long overdue in remedying this situation.

KINCANNON CONFIRMED; BARRON TO LEAVE CENSUS BUREAU

Louis Kincannon, President Bush's choice to be Census Director (see *Update*, July 30, 2001), was confirmed unanimously by the U.S. Senate on March 13th. He replaces Bill Barron, who had been serving as Acting Director since Kenneth Prewitt (a Clinton appointee) left the Bureau in January 2001.

Barron concurrently decided to retire this summer after 34 years of Federal service. He has accepted a one-year professorial appointment from the Woodrow Wilson School of Public and International Affairs at Princeton University. Prior to his term as Acting Census Director, Barron spent 15 years as Deputy Commissioner of Labor Statistics, served as a Deputy Undersecretary of Commerce, and was appointed Deputy Director of the Census Bureau in 1999.

ACADEMY HEARS ADVICE ABOUT GRADUATE DOCTORAL STUDY *HTS*

As it moves closer to conducting its once-a-decade study of research doctoral programs in the United States, the National Academy of Sciences (NAS) convened a methodology panel to hear from representatives of the higher education and disciplinary communities on April 15. Witnesses, including COSSA Executive Director Howard J. Silver, shared with the panel their ideas for improving on the efforts of the previous study published in 1995.

NAS President Bruce Alberts said the study was an "important thing to do" and that the survey is taken enormously seriously. In fact, he suggested, the results "drive behavior [of schools] to a frightening extent." David Ward, President of the American Council on Education, raised concerns about how the study sometimes pushed, what he called, "the wannabe movement." This is where smaller, non-comprehensive doctoral institutions feel compelled to try to compete with the major research doctorate institutions in all subjects.

Lawrence Martin, a member of the panel and Dean of the Graduate School at SUNY-Stony Brook, suggested that the institutions should be asked what their missions are, and perhaps the study could make some differentiation. In addition, most of the witnesses deplored the ranking of departments and the "who's number one mentality," but could not suggest any useful way to get around this problem.

Council of Graduate Schools' President Debra Stewart summed up the views of most of the participants by noting: "We are half way home, with a long way to go." Stewart, who was on the NAS Committee for the last study, touched on one issue foremost in the minds of many -- what disciplines and programs should be included, and how the study will deal with new fields and interdisciplinary areas. Stewart called for "objective, threshold criteria" for inclusion that would be clear to all parties. Alberts, Silver, and a number of others noted complaints about the omissions in the previous study.

Judith Ramaley, Assistant Director for the National Science Foundation's Education and Human Resources Directorate, told the Committee that "replicating the 1995 study would be hopelessly out-of-date." Pouring out ten years of frustration (she was President of Portland State University, which was neglected by the previous study), Ramaley encouraged the panel to think much more about "quality" of graduate programs. That would entail, she declared, more than measuring reputation and citations. She asserted that the basic question the study needs to address is: "What should we expect from a Ph.D?"

What did students do with the Ph.D?

Almost all the other witnesses also focused on the importance of measuring outcomes. Silver and others asked the committee to concentrate more on those doctorates who do not take academic positions and how well the programs are preparing these students. Jerry Ostriker, Chair of the Committee and Professor of Astronomy at Princeton, expressed understanding about the desire to assess outcomes, but voiced skepticism about finding good measures to get meaningful results for the study.

Other witnesses included: Peter Magrath, President of the National Association of State Colleges and Universities; Nils Hasselmo, President of the Association of American Universities; Phyllis

Franklin, Executive Director of the Modern Language Association; and Rob Townsend of the American Historical Association.

The methodology panel will make recommendations on how to carry out the study. A separate committee will then oversee the actual study. The NAS hopes to publish the results in 2005.

DECADE BRIEFING HIGHLIGHTS HUMAN RESPONSE TO DISASTER RESEARCH *JW*

The American Association of Geographers (AAG), American Psychological Association, American Sociological Association (ASA), and Human Factors and Ergonomics Society jointly sponsored a Congressional briefing on April 24 to address the question: How do people, governments, and institutions prepare for and respond to disaster? The event was held under the guise of the Decade of Behavior, a multidisciplinary initiative stretching from 2000-2010 to focus the talents, energy, and creativity of the social and behavioral sciences on meeting many of society's most significant challenges.

Moderator Felice Levine, Executive Officer of the ASA, opened the session by describing the Decade of Behavior and briefly discussing the speech given by John Marburger, Director of the White House Office of Science and Technology Policy, at an April 11 American Association for the Advancement of Science (AAAS) Colloquium. Marburger's remarks declared "the importance of the social sciences." (See *Update*, April 15, 2002). Levine then turned the podium over to the speakers.

Baruch Fischhoff, Professor of Social and Decision Sciences at Carnegie Mellon University, made remarks that were similar to his presentation at the April 11 AAAS event. (See *Update*, April 15, 2002).

Geographical Dimensions of Terrorism

Fischhoff was followed by Douglas Richardson, Director of Research and Strategic Initiatives at the AAG, who used his allotted time to unveil "The Geographical Dimensions of Terrorism: A Research Agenda for the Discipline." This project was recently initiated by the AAG and the National

Science Foundation (NSF) as part of the NSF's urgent call for research associated with the September 11 terrorist attacks on the United States. Richardson explained that the project will focus on three key areas of research: 1) Geospatial Data and Technologies Infrastructure Research; 2) Regional and International Research Related to the Root Causes of Terrorism; and 3) Vulnerability Science and Hazards Research.

He then went through each of these three areas to highlight selected priority action items, which include:

- Establish a Geography Division in the (White House) Office of Homeland Security to advise on issues such as geospatial data sharing, integration of geospatial data, data security, back up systems and operations, and overall needs assessment for homeland security.
- Develop a national research center designed to better understand and anticipate the geographically variable regional economic and social impacts of terrorist acts.
- Develop and implement a major multi-institutional, interdisciplinary research program on the root causes of terrorism.
- Conduct a regional studies needs assessment to determine the status of training and teaching in area studies, international studies, and global studies, as a basis for identifying priorities for strengthening these programs in our universities and schools.
- Establish a Quick Response program (funded by NSF or some other agency and administered by the AAG) that enables researchers to get into the field quickly after a major world event in order to secure critical geographical data and information that would otherwise be lost.

Eduardo Salas, Program Director for Human Systems Integration Research at the University of Central Florida's Institute for Simulation and Training, took the podium next to discuss the science of team performance under pressure. He opened by explaining that the military, specifically in the area of aviation, has had a long-standing interest in the science of team performance. Salas defined a team under pressure as containing two or

more individuals and having meaningful task interdependencies; coordination among members; common, valued goals; a hierarchical structure; and specialized member roles and responsibilities.

He then told the audience that a team under pressure will face complex, multi-component decisions, rapidly evolving, ambiguous situations, information overload, severe time pressure, severe consequences of error, adverse physical conditions, performance/command pressure, and distributed, multi-operator problems. He continued by explaining the research methodologies that go into studies done by cognitive psychologists and human factors experts to identify optimal team training methods. Salas concluded by displaying statistics showing the effectiveness of enhanced team training.

The final speaker was Kathleen Tierney, Director of the Disaster Research Center at the University of Delaware. She led-off her remarks by giving some background on her Center and referring the audience to a list she had compiled of similar research institutions from around the country. She noted that hazards and disaster research has a long tradition dating back to the 1940s and that there has been significant Federal investment in the field. She also explained that the research focuses on varied social units, ranging from individuals to entire societies.

Tierney then turned to the study she conducted on the attacks in New York City on September 11. She opened the discussion of her findings by relaying that behavioral patterns following the attacks were consistent with those observed after other types of disasters (e.g. hurricanes, earthquakes...). She continued, however, by pointing out significant differences:

- There were very broad and diffuse impacts of the 9/11 attacks.
- It was an unprecedented event that presented a high degree of complexity.
- The attacks were followed by long-term, ongoing, multiple, and ambiguous threats.

Tierney then concluded by explaining how research-based approaches can help society prepare for future crises.

More information about the Decade of Behavior can be found at its website, www.decadeofbehavior.org. A draft write-up of the AAG/NSF project is on the internet at www.aag.org.

SOURCES OF RESEARCH SUPPORT *HS*

COSSA provides this information as a service and encourages readers to contact the sponsoring agency for further information. Additional application guidelines and restrictions may apply.

Law School Admission Council Research Grants

The Law School Admission Council funds empirical research related to legal education in the United States and Canada. The program welcomes research proposals proceeding from a variety of methodologies, a potentially broad range of topics, and time frames that range from students' undergraduate consideration of legal education to their first jobs following law school. Eligible investigators need not be members of law school faculties, but collaborations are encouraged. Deadlines are September 1 and February 1. For further information contact Lillian Worthington at (215) 968-1198 or Lworthington@LSAC.org. The web site address is www.lsac.org.

Environmental Protection Agency

The Environmental Protection Agency's Office of Research and Development and the U.S. Department of Health and Human Service's Agency for Toxic Substances and Disease Registry are seeking application for research on lifestyle and cultural practices of Tribal populations and risks for toxic substances in the environment. They are particularly interested in the development of: 1) exposure and effects assessment methods that can be broadly applied across geographic regions and Tribal populations; and 2) risk management strategies and options that will lead to reduction in risk from exposure. Applications are due July 10, 2002. Potential funding is \$150,000 per year for three years. For more information contact Nigel Fields at (228) 688-1981 or fields.nigel@epa.gov. The web address is http://es.epa.gov/ncer/rfa/02trib_risk.html.

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