



COSSA Washington Update

Consortium of Social
Science Associations

December 12, 2005

Volume 24, Issue 22

CENTRALIZING NIH'S TRANS-AGENCY RESEARCH

At its 91st meeting on December 1st and 2nd, the Advisory Committee to the Director (ACD) of the National Institutes of Health (NIH) Deputy Director Raynard Kington discussed the ongoing development of the newly created Office of Portfolio Analysis and Strategic Initiatives (OPASI). Before Kington spoke, NIH Director Elias Zerhouni explained that the Congressionally- and Administration-approved effort to develop OPASI "looks across the landscape of research," particularly at those areas that cannot be tackled by one institute individually, but not necessarily only at large initiatives.

Kington presented a detailed overview of the progress in creating OPASI's structure. Its mission is to fill a critical need to provide the NIH and its constituent Institutes and Centers (ICs) with an intellectual home for developing new methods and new techniques to manage NIH's large and complex scientific portfolios.

OPASI will not replicate or substitute what ICs do very well within their missions, Kington explained. Instead, it will be "a state-of-art organization that can provide the same perspective, resources, and analysis at the level of the agency as a whole." Within OPASI is an embedded process designed to accelerate investment in those areas that cut across the ICs or fall between their missions. The Office will also provide a structure for connecting a range of evaluation activities that occur at NIH and a feedback loop to a decision making process for setting priorities.

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CONGRESS SEEKS TO FINISH SESSION

As often happens in non-election years, Congress will remain in town into mid-December to finish its work. As UPDATE goes to press, the legislative leadership hopes to complete its work by December 15 and go home. This may be unrealistic as a number of key bills remain on the agenda.

These include the Labor, Health and Human Services, and Education appropriation bill. Since the rejection by the House on November 17th of the conference report on the latter bill, House lawmakers have tried to figure out how to make minor changes in the bill to obtain acquiescence. Senators, including Subcommittee Chairman Arlen Specter (R-PA) hoped for significant alternations to increase budgets for agencies such as NIH. House appropriators now believe that small increases to education and rural health programs will bring enough of the

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Why Does NIH Need OPASI?

According to Kington, NIH requires a mechanism to coordinate the assessment and management of its overall portfolio. There is also a need for a transparent, systematic process for coding funding related to specific diseases and conditions, along with the need to provide the ability to assess scientific opportunities within public health needs and integrating them into NIH-wide funding priorities. He emphasized NIH's need to continually evaluate the benefits and impact of NIH research investments. Ultimately, OPASI will allow the NIH "to be nimble, dynamic, and responsive to emerging scientific demands and opportunity," Kington stated.

Kington explained that a weakness of the NIH structure is the challenge to coordinate funding in areas that cut across and/or between the missions of the ICs. He cited the area of obesity as an example, noting that it had been identified as a public health challenge at least ten years ago. Yet, only recently has NIH developed a coherent trans-agency strategic plan that cut across the missions of the ICs, Kington contended.

Accordingly, this lack of coordination, Kington informed the ACD, had been the motivation for a number of earlier changes to NIH. Most notably, he explained, was the creation of the five existing appropriations-funded programmatic offices, including the Office of Behavioral and Social Sciences Research, the Office of AIDS Research, and the Office of Research on Women's Health to address a problem that cut across the ICs; the lack of a transparent process to examine important areas of research. OPASI will be a home to focus on issues similar to those examined by these programmatic offices.

Kington also suggested that NIH also needs to improve how it evaluates the benefits and impacts of its investments. These include a number of activities that cut across the NIH, such as reviews of specific programs funded through the one-percent set-aside evaluation funds, as well as broader evaluations under the Government Responsibility and Performance Act.

He then provided additional detail about OPASI's three Divisions: Resource Development and Analysis (DRDA), Strategic Coordination (DSC), and Evaluation and Systemic Assessments (DESA). Kington explained that DRDA would use new knowledge management

technology for analyzing the portfolio and analyzing data. This would, he argued, allow NIH to integrate data on public health needs, demands, and public health illness and let it "do a better job in terms of coding and funding across areas that is consistent, rigorous, and transparent." The agency would use the technology to analyze funding proposals, giving it "a better sense of where the scientific community is going in terms of ideas," Kington maintained. It would also allow the NIH the ability to assess its review process.

Evaluations: Intellectual Home Needed

DESA would provide a home for the fair amount of data on public health demand that cuts across a number of areas, but lacks a central place to store the information. These would include cooperative data collection activities between NIH and the Centers for Disease Control and Prevention as well as the NIH-funded public health surveillance studies, such as Monitoring the Future supported by the National Institute of Drug Abuse, and the Surveillance Epidemiology and End Results (SEER) supported by the National Cancer Institute. This OPASI division would also serve as an intellectual home for how NIH analyzes the data that help it set priorities for the agency.

Kington further explained that DESA would also house the trans-government evaluations that feed into the budget process, such as the Program Assessment and Review Team (PART). In addition, this division would include the labor-intensive activities at the trans-NIH level in which the agency evaluates the success of the agency in addressing important scientific areas as well as the use of the one-percent set-aside evaluation fund.

The most complex division within OPASI is DSC, which will be an institutionalized version of the NIH Roadmap for Medical Research, said Kington. DSC, on a regular basis, will "scan the scientific horizon for scientific opportunity and make strategic investments, particularly those areas that cut across and between the missions of the ICs." DSC will serve as a home for this "incubator activity," Kington explained, whereby initiatives will be funded for a period of time, where there is an identified need for strategic, targeted investment and in a particular area of science to advance the mission of the agency as a whole.

Identifying Trans-Agency Research

Building on the example and the experience of the Roadmap, NIH, Kington proclaimed, has developed a preliminary process for identifying important trans-agency research areas. The process begins with the receipt of nominations for topics from a number of sources. The NIH would consult with leading scientists across the country with clear directions regarding the criteria for initiatives that would fall within OPASI's domain.

Other sources from which nominations would come include stakeholders, scientific analysis/burden of illness data, IC directors, the Office of the Director's programmatic offices and IC level evaluation processes, which would identify areas where there might be a need for targeted, strategic investments for the agency as a whole. Kington explained that NIH would initially evaluate the nominations for responsiveness to the initiatives that fall within OPASI's mission, with further fleshing out by staffs in OPASI, the ICs, and the program offices.

NIH has created two mechanisms to provide the broader scientific community and public input into the process. For the first cut, there is a proposed Council of Councils which would consist of representatives from all the NIH advisory councils. Each IC would nominate two scientists and one public member and OPASI would create a council from that pool with assurances that there will be a sufficient range of scientific expertise and public representatives.

OPASI staff, working closely with the IC staff, and the programmatic offices in some instances, would further develop those initiatives that survive the first cut to determine what mechanisms will be used, how much it would cost to fund the research, and how to staff the administrative structure to oversee the initiative over a period of time.

That shorter list of much more developed ideas, said Kington, would then go through another round with IC directors, as well as through the ACD which would function in a way similar to that of the councils at the institutes' level when new programs are proposed. The NIH Director would make the final decision.

A lead IC(s) would be designated and would have administrative oversight for seeing the initiative put into operation. NIH would support the chosen initiatives

through a common fund (see Update, October 24, 2005), through the usual mechanisms for the agency, and in five-year cycles. The award would face a major review in the third or fourth year with a decision about what would happen in year five. In some instances, Kington explained, the research grant would end, having achieved its goals. In other instances, the initiative could continue, but transferred to a specific IC. For a limited number of cases, the initiative would be renewed for a second five-year cycle with the understanding that no initiative would remain in OPASI for more than 10 years. The NIH, stressed Kington, wants "to have sufficient churn to fund new scientific opportunities and public health challenges that come about every day." He concluded by stressing that so far this is a skeleton process that will be "fleshed out over the first few years of operation of the office."

CONGRESS FINISHING

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dissenters in line to obtain passage. If the new conference report survives the House, the Senate should agree, and certain dire situations such as a full-year Continuing Resolution will have been averted.

Also on the agenda is Defense Appropriations bill, which may include emergency flu-preparation spending and an across-the-board cut to all spending bills. Although two percent has been floated as the level of the cut, one percent is now under discussion, with some members arguing for no cut at all. These folks are upset at the already low levels of funding for many programs in the spending bills, particularly for social programs, as well as the significant cuts in entitlement spending proposed in the reconciliation bill. This piece of legislation also remains on the agenda, with House-Senate negotiators trying to reach agreement on how to force reductions in spending over the next five years on the sick elderly and poor, and students. Additional spending on hurricane clean-up and rebuilding is also part of the discussions.

GEOGRPAHY TRANSCRIPT AVAILABLE

The edited transcript of the COSSA Congressional briefing *Building Geographic Management on Systems: Tackling Critical Policy Needs for the Nation's Future* is now available. If you would like a copy, please contact COSSA at: www.cossa.org.

NEW HSD COMPETITION ANNOUNCED

The National Science Foundation's (NSF) priority area in Human and Social Dynamics (HSD) has announced its competition for FY 2006. This year's solicitation continues the three emphasis areas: Agents of Change, Dynamics of Human Behavior, and Decision Making, Risk, and Uncertainty. NSF anticipates spending \$50 million on the priority and hopes to make over 100 awards.

HSD awards will go for different kinds of activities. NSF notes that full research projects will support multidisciplinary teams of three or more investigators from at least two different fields in projects that use multidisciplinary approaches to advancing fundamental understanding of human and social dynamics. These project proposals should have significant educational or other broader impacts. These awards will be made for three years and have total award sizes ranging up to \$750,000, including indirect costs. **These proposals are due on February 21, 2006.**

The priority area will also provide support for exploratory research projects that will enable team to perform preliminary activities that provide the basis for more elaborate work. These projects could include, according to NSF, preliminary work on untested and novel ideas, ventures into emerging and potential transformative research ideas, and application of new expertise or new approaches to 'established' research topics.

In addition, NSF will fund HSD research community development projects that will support interdisciplinary educational activities and other broad-ranging efforts, including research workshops and training activities that aim to increase awareness, capabilities, and networks within and across scholarly communities to help promote interdisciplinary collaborations and increase the quality of HSD research.

Both the exploratory research and community development grants will be for one or two years, with the total grant not exceeding \$125,000 including indirect costs. **These proposals are due on February 14, 2006.** For more information contact: Keith Crank kcrank@nsf.gov 703/292-4880 or Rachele Hollander rholland@nsf.gov 703/292-7272. The full solicitation is available by going to: <http://www.nsf.gov/dir/index.jsp?org=SBE>.

NO NIH REAUTHORIZATION BILL THIS YEAR

NIH Associate Director for Legislative Policy and Analysis Marc Smolonsky told the Advisory Committee to the Director on December 2 that although congressional interest in the NIH remains extremely high, enactment of a reauthorization bill will not happen this year.

Smolonsky explained that the Section 301 of the Public Health Service Act provides the NIH with its permanent authorities. Specific program authorizations are not needed because of this broad generic authority. Accordingly, there is no urgent need for regular reauthorization of NIH, which was last reauthorized in 1993. Consequently, the "appropriations" process has subsumed the authorization's process for more than a decade," he contended.

According to Smolonsky, with the exception of restrictions on embryonic stem cell research, NIH faces no prohibitions from the appropriators. This includes NIH's ability to create new Institutes, citing the creation of the recently created National Institute of Biomedical Imaging and Bioengineering (NIBIB), as an example. He noted that this institute was established without hearings, floor debate, or a vote by Congress.

The scrutiny of NIH by Congress, Smolonsky observed, began at the end of the five-year doubling of NIH's budget. The authorizers in the House, specifically the House Energy and Commerce Committee, became interested in reviewing agency's activities. This entailed holding nine hearings between June 2002 and July 2005, a joint House/Senate survey of NIH stakeholders taken in 2002, and a review by Congress of the congressionally-mandated Institute of Medicine Report on the structure of NIH in 2002. In addition, the Committee interviewed 23 of the 27 directors of the NIH institutes and centers and has circulated two discussion drafts on reauthorizing NIH.

Despite that fact that no bill has been introduced during this congressional session, Smolonsky explained that the "most frequent" Congressional concerns that have emerged from those drafts include: inadequate explanation by NIH regarding how it sets its priorities; unbalanced research priorities "reflected by investments in sexuality studies and other inappropriate research;" the inability to fund collaborative research; the inability to respond quickly to new public health priorities by shifting resources; and the setting of NIH priorities by Institute and Center (ICs) directors and not the director of NIH.

Smolonsky informed the Committee that only one person seems interested in reauthorizing NIH, Rep. Joe Barton (R-TX), who happens to chair the Energy and Commerce Committee. Barton, Smolonsky claimed, is “mainly concerned about restoring the Committee’s purview and prestige.” Barton wants to address three major issues in a bill: 1) expanding the authority of the NIH Director to improve portfolio management and facilitate trans-NIH research; 2) realigning budget authorities to foster collaboration; and 3) streamlining and improving public reporting of research results.

Turning the discussion to the August 22 discussion draft circulated by the Committee, Smolonsky outlined the key provisions. The bill would create two budget categories for Institutes and Centers characterizing them as “mission-specific” or “science enabling.” This does not pose any legal problems for NIH, he related. The draft creates a budget authorization ceiling, which remains unspecified on these two categories. That provision gives NIH stakeholders “heartburn,” said Smolonsky. A ceiling in the Public Service Health Act for the ICs would prevent the appropriators from exceeding that amount, he explained.

The draft affirms the existing IC statutory authorities. Smolonsky emphasized that Barton has no interest in changing the missions of the ICs. However, it would limit the number of ICs by capping them at current levels and any newly created ICs would have to replace existing ICs. According to Smolonsky, there is a misunderstanding about this section of the draft by the community. “It is really just a restatement of existing authorities,” with added requirements for public hearings, he said.

The bill creates a coordination unit within the Office of the Director with IC input and advisory body review. It is patterned after the newly created Office of Policy Analysis and Strategic Initiatives (OPASI) (see related article). That is the only provision of the draft that the NIH Director Elias Zerhouni has publicly supported, he emphasized.

According to Smolonsky, the draft has implications. Program coordination will bring rigor to the research collaboration process and provide a mandatory funding mechanism. While it categorizes the ICs budget, it does not create any legal changes to the existing appropriations process. The most significant implication of the draft is that it signals the end of structural growth at NIH for the near future, a

key congressional concern, said Smolonsky. This is different because all of the previous NIH reauthorization bills have grown the NIH.

The NIH’s main position, said Smolonsky, is that whatever the Congress does it should maintain the heart of NIH’s authority. This include keeping the current peer review process, preserving the emphasis on investigator-initiated research, continuing the policy of minimal congressional directives, retaining the general research authorities, and enhancing scientific freedom.

A number of things have deterred the reauthorization process so far. There is a lack of stakeholder interest in a bill, it has not been a priority for the Congressional leadership, the Senate does not appear interested, and the Administration has “tacitly opposed” it by not publicly commenting on the draft legislation. However, with Barton continuing as chair of the key House panel for the foreseeable future, the push for legislation will not go away.

Zerhouni’s Concerns

Following Smolonsky’s presentation the Council discussed its concerns, specifically the lack of sufficient funding to maintain the momentum created by the doubling of the agency’s budget. Zerhouni lamented that he is concerned about the message that Congress receives from the advocacy community is that the NIH is not suitably addressing specific diseases. It is a message that hurts the NIH and impacts its ability to get sufficient funding.

Zerhouni further expressed frustration with the desire for “quick cures.” There is a “disconnect.” There is also a lack of understanding by some in Congress of the scientific process, said Zerhouni. It is an “incremental” process. “It’s hard, it is not easy, and it is getting more and more difficult,” the director lamented.

Echoing Zerhouni, Smolonsky explained that the Congress wants something that “is more tangible than what they are seeing. They have unrealistic expectations of NIH. . . They still don’t quite understand the scientific process.”

THE NEW AMERICAN NATIONAL ELECTION STUDIES

The National Science Foundation (NSF) announced in late October that it has awarded \$7.6 million to continue funding the American National Election Studies (ANES) for another five years. ANES will study the causes of voter participation and candidate choice in the 2008 U.S. presidential election. The principal investigators (PIs) for the project will be Arthur Lupia of the Institute for Social Research at the University of Michigan and Jon Krosnick of the Institute for Research in the Social Sciences at Stanford University.

The major component of the study, as it has been for over 50 years, will be pre- and post-2008 presidential election face-to-face interviews. The survey will ask respondents questions to measure their opinions on a wide array of political issues, their assessments of the health of the nation, their hopes for government action in the future, their perceptions of the candidates and their platforms, their behavioral participation in the campaign and in politics more generally, and much more. The key to the ANES is that it has been asking many of these questions identically every two years since the 1950s, allowing scholars to track changes in the American electorate over time.

In addition, the ANES will now include a panel component allowing measurement of changes of candidate preferences during the primary and general election campaign as well as how people react to the election outcome into the start of the new presidential term. To accomplish this, the ANES will recruit a nationally representative sample of American adults during 2007 and interview them once a month over the next 21 months into early 2009.

The ANES will also collaborate with the National Longitudinal Survey of Youth, to measure political opinions and behavior of a representative sample of thousands of young adults every two years. This should allow scholars and policy makers to focus on patterns of long-term change of individuals across elections.

The ANES has always served as an incubator of new techniques in the election survey field. For the 2008 face-to-face interviews, the ANES will use laptop computers to confidentially display questions and answer choices, thus allowing for secret responses akin to the way most people vote these days. The computers will also show respondents election-related photographs and videos to enhance measurement of what voters learn during the campaign.

Using the latest techniques from social and cognitive psychology the study will use the computers to measure the speed with which respondents make judgments. According to Lupia, response speed measurement is one way to elucidate automatic processes that occur unconsciously in the brain and guide political thinking and action. "By combining self-reports that measure opinions and measurement of response speed, we can better understand the impact of sensitive attitudes, including prejudice and stereotyping," he explained.

For further information about the ANES go to: <http://www.electionstudies.org>

NIH SEEKS APPLICANTS FOR PIONEER AWARD PROGRAM

Following the success of its 2005 NIH Director's Pioneer Award program, the National Institutes of Health is seeking applications for a third round. The award is a key component of the NIH Roadmap for Medical Research, a series of initiatives designed to transform then nation's medical research capabilities and speed the movement of research discoveries from the laboratory bench to the patient's bedside (see Update October 10, 2005 and October 25, 2004).

The Pioneer Award, unlike other NIH grants, supports individual scientists. It provides recipients the intellectual freedom to pursue new research directions and highly innovative ideas that have the potential for unusually great impact. The program is open to scientists at all career levels. Scientists may be currently engaged in any field of research provided they are interested in exploring biomedically-relevant topics and are willing to commit the major portion of their effort to Pioneer Award research.

NIH expects to make five to ten new Pioneers of up to \$2.5 million in direct costs over a five-year period in September 2006. Thirteen scientists, including a behavioral scientist, received awards in September 2005 and nine individuals received awards in 2004.

National Institute of General Medical Sciences director Jeremy Berg and National Institute on Drug Abuse director Nora D. Volkow are co-chairs of the NIH committee that oversees the Pioneer Award program.

Applications for the award may be submitted between January 15 and February 27, 2006. For more information see: <http://grants1.nih.gov/grants/guide/rfa-files/RFA-RM-06-005.html>.

CDC SEEKS PUBLIC COMMENT ON RESEARCH AGENDA

On November 18th, the Office of the Director at the Centers for Disease Control and Prevention (CDC) officially released the public comment draft of the CDC Health Protection Research Guide, 2006-2015 requesting members of the health and research communities to review and respond to the plan.

The public comment draft of the Research Guide was developed with extensive input from a wide range of federal, state, tribal, academic, and non-profit partners, as well as the public-at-large. CDC staff and its external advisory committees also provided input. After integrating this input to produce the current draft, the Director of the CDC approved the move to the public comment phase.

According to the CDC, the Research Guide will serve as a blueprint for research areas that should be addressed during the next decade by CDC and its partners in response to current and future needs and events. The Research Guide will also be used to help define the research priorities that support CDC's new Health Protection Goals, and will enable the creation of a shorter-term research agenda that stems from the goals' implementation activities currently underway.

The 60-day public comment period will run from November 18 through January 15, 2006. Individuals wishing to submit a written, public comment will be able to do so in one of three ways; either by entering comments directly at the CDC's Website, http://www.rsvpBOOK.com/custom_pages/50942/index.php, emailing comments to ResearchGuide@cdc.gov, or sending them to the following address:

Office of Public Health Research
U.S. Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Mail Stop D-72
Atlanta, GA 30333.

After the public comment period, the CDC will consider the comments they receive and revise the Research Guide to produce the final version. If you have any questions, please contact either Bob Spengler, Robin Wagner, or Jamila R. Rashid in CDC's Office of Public Health Research/Office of the Chief Science Officer at 404-639-4621.

EDITOR'S NOTE

This is the final issue of UPDATE for 2005. We will return in mid-January for what should be a very interesting 2006.

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Update is published 22 times per year. Individual subscriptions are available from COSSA for \$80; institutional subscriptions - \$160; overseas mail - \$170. ISSN 0749-4394. Address all inquiries to **COSSA**:

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*Happy Holidays from the
COSSA Staff!!!*