



# COSSA

## Washington UPDATE



November 7, 2011    Volume 30, Issue 20A



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#### **Two Issues of Update**

COSSA is producing two issues of Update this week. The first below, focuses on the news emanating from Congress, the Agencies, and the Associations.

The second issue, which will cover COSSA's 30<sup>th</sup> Anniversary Colloquium, will be sent later in the week.

### **Senate Clears First Minibus Appropriations Bill: Expiration of CR and Report of Deficit Reduction Committee Looming**

On November 1, the Senate voted 69-30 to pass S. 2112, a Minibus Appropriations bill, which included the FY 2012 Commerce, Justice, Science (CJS), Agriculture/Rural Development, and Transportation/ HUD spending bills.

The House and Senate are now conferring in a conference committee to reconcile spending differences in the Senate Minibus legislation and the three separate bills that emerged from various stages of the House appropriations process. Although the Agriculture/Rural Development bill had passed the House in June, CJS only made it through Committee, and the Transportation/HUD bill never got past the Subcommittee level.

(In the October 21<sup>st</sup> issue of COSSA Washington Update, we stated that the House had not enacted any of the FY 2012 appropriations bills. That was a mistake for which we apologize. The House has passed six of the twelve spending bills.)

In passing the Minibus, the Senate rejected a whole host of amendments, none of which dealt with the National Science Foundation or the Census, two targets of past attempts to shift funding among the agencies in the CJS bill.

The House is on recess the week of November 7. However, upon its return both Houses of Congress will need to deal with the November 18 expiration of the Continuing Resolution (CR) that has funded the government's agencies and programs since the start of FY 2012 on October 1, 2011. The expectation is that the new CR, lasting until mid-December, will become attached to the Minibus, thus leading to the likely enactment of those three spending bills and possibly more.

The House and Senate leadership are contemplating adding some other FY 2012 spending bills to this Minibus. Homeland Security and Legislative Branch are considered the two possible additions.

Furthermore, the Senate has announced a second Minibus that would include the Energy and Water, Financial Services, and State and Foreign Operations FY 2012 spending bills.

Lurking through all of this is the November 23 deadline for the report of the Deficit Reduction (or Super) Committee.

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## SBE Releases "Rebuilding the Mosaic" Report

After soliciting the community in August 2010 for input and suggestions and receiving over 250 papers, the National Science Foundation's Social, Behavioral and Economic Sciences (SBE) directorate has released *Rebuilding the Mosaic: Fostering Research in the Social, Behavioral, and Economic Sciences at the National Science Foundation in the Next Decade*. The report is available on the COSSA Web page at [www.cossa.org](http://www.cossa.org). The 252 papers are available at: [http://www.nsf.gov/sbe/sbe\\_2020](http://www.nsf.gov/sbe/sbe_2020).

Written by Myron Gutmann, Assistant Director for SBE, and Amy Friedlander, Senior Advisor in the Office of the Assistant Director of SBE, the report, according to the Executive Summary, notes:

- Interest in the social, behavioral and economic (SBE) sciences is broad, deep, and varied, reflected both in the characteristics of the researchers and in the range of the science that they pursue and believe will be possible.
- Future research will be interdisciplinary, data-intensive, and collaborative. That vision rests on thorough grounding in the core SBE sciences that continue to present important, discipline-based research and methodological challenges.
- The research community looks to NSF/SBE to provide leadership and direction in building capacity and infrastructure, most notably in interdisciplinary training (capacity-building)

and infrastructure (data and facilities to support analysis, simulation, tools, and training in new research methods, including integration and synthesis across data, methods, and disciplines).

- Four major topic areas have been identified within the wealth of ideas received: population change; sources of disparities; communication, language, and linguistics; and technology, new media, and social networks.
- NSF/SBE's existing programs serve their communities well. New topics, especially multidisciplinary ones, may invite a more flexible structure within the directorate.
- NSF/SBE will continue to explore new ideas in the future, concentrating over the next five years on more focused planning activities that will: 1) strengthen the ability of the directorate to support interdisciplinary research, develop human capacities, and build out the data and organizational infrastructure; and 2) consider approaches required to shift resources to relevant priorities.
- The highest priorities go toward planning and implementation of the following: devote attention to evaluating and implementing ideas and recommendations in the white papers that concern existing programs; enhance interdisciplinary research with initial preference given to the four areas identified above; and develop planning activities to test ideas for new data and infra-structure services.

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## NIH Director: 'Agency is at a Paradoxical Point'

On October 26, reporting to the National Institutes of Health (NIH) Scientific Management Review Board (SMRB) director Francis Collins pointed out that since its inception, the SMRB has "plunged into its agenda with energy and vigor" and has produced [four reports](#) in a "rapid fire" fashion. Three of the reports, Collins noted, require substantial investigation of the organizational structures of NIH. He also acknowledged that some of them turned out to be more complicated than those who had been at the agency for awhile anticipated.

Collins gave the Board a "broader view" of where things are in terms of the scientific opportunities at NIH and some of the stresses they are facing. The NIH, Collins explained, is "at a paradoxical point." Noting that he had been at the agency for 18 years, he stated that the scientific opportunities "have never been more exhilarating" with potential for revolutionizing medicine - across-the-board - and making major breakthroughs with profound implications for human health. At the same time, the "NIH is faced with a historic challenge in terms of resources - that is the paradox," he explained. He further noted that there has not been a time that people at the agency can remember where support for biomedical [and behavioral] research has been under as much stress; a consequence of the way the United States and much of the world is struggling now with the difficult economic situation and large deficits that have to be addressed.

According to the director, the NIH is more than ever in the circumstance of "having to choose priorities carefully," including "having to scale back in order to do new things because if [the agency] ever stopped innovating then [it] probably would not deserve to be supported." We have to

be out there "on that leading edge of the new potential of new things." He lamented that it was not an easy time to try to make such difficult decisions.

The NIH is also in the circumstance where it has to "be more effective in articulating the value of what we do and not just assuming that it speaks for itself," he continued. That implies the need to articulate both the medical advances and to explain the economic consequences of the enterprise in a way that "makes it clear that dollars invested in NIH are also a good pathway towards recovery of the economy. Collins emphasized that the economic analysis that have been done are "extremely compelling in terms of the return on investment that occurs from NIH investment."

Noting that the agency was in "the throes of trying to make a case for the FY 2013 budget even though it does not have a FY 2012 budget", Collins shared with the Board scientific opportunities that reflect the case that the NIH is making.

NIH is emphasizing four themes for FY 2013:

- 1. Investing In Basic Research** - According to Collins, 52 percent of the NIH's budget goes to basic research that will not get done if it is not supported by the agency. Basic research, he reported, is flourishing, and the agency wants to motivate investigators to seek funding for this research.
- 2. Accelerating Discovery Through Technology** - The NIH is playing an increasing role in this area.
- 3. Advancing Translational Science** - He noted that the translational agenda has been a part of the NIH portfolio which the agency is looking at in new ways. He pointed out that he had accepted the SMRB's recommendation to create the National Center for Advancing Translational Science (NCATS). The NIH is "energized by NCATS' potential and grateful to the SMRB for helpful and important recommendations." Responding to a question regarding the fair amount opposition to NCATS, Collins responded that as the concept and the goals have been made clear embracement of the plan has grown and there is a lot of receptivity. He recognized that there was a lot of misunderstanding initially.
- 4. Encouraging New Investigators And New Ideas** - This theme is most important. According to Collins, supporting new investigators and new ideas is a constant source of struggle and anxiety for him.

### **NIH Woefully Short on Diversity**

He addressed the recent NIH-commissioned study regarding the agency's major challenge surrounding diversity. The NIH is woefully short of where it would like to be, explaining that he was not certain that the agency was recruiting the best and the brightest from all groups. The number of African Americans supported by the NIH is quite low when compared to the population. That means the agency is missing out on talent and needs to work on recruitment despite having invested in this effort over the decades. He posited that it is not clear that the agency has the best recruitment practices. The situation, he stressed, is unacceptable. The Advisory Committee to the Director (ACD) of NIH Workgroup on Diversity is expected to have interim recommendations for Collins at its meeting in December and final recommendations at the June 2012 meeting (see [Update, September 12, 2011](#)).

He also noted that there is a separate ACD workgroup looking at discerning the right size of the biomedical workforce. Unfortunately, there is mindset that the only acceptable pathway for a biomedically trained researcher is to end up with a tenured-track position in a top tier research university, a disservice to the trainees and the community, said Collins. We clearly need a better

understanding of the dynamics of the workforce. Especially with those dynamics changing very quickly on the international front, we can't continue to rely on the remarkable flow of talent coming from other countries. Even if it continues to come, we cannot count on it staying, he explained. Why is it that American students are disinterested in becoming a part of our workforce, he asked. Can the NIH come up with a model for increasing doctoral training for a more diverse population? (See *Update*, [June 13, 2011](#)).

Despite these scientific opportunities, the reality check of NIH's eroded buying power since 2003 is a concern. With the exception of the funding from the American Reinvestment and Recovery Act, the agency's budget is where it was ten years ago. As a consequence, the agency's success rate is "deeply disturbing" and has become less healthy, Collins pointed out. At the same time, the cost of research is increasing. For the first time in history the rate is less than 20 percent; 17.4 percent in 2011.

He noted that much is dependent on the Super Committee deliberation which is co-chaired by Sen. Patty Murray (D-WA) and Rep. Jeb Hensarling (R-TX). Should it fail to come up with a plan, and a sequester or an automatic across-the-board (ATB) cut occurs in 2013, the NIH, like the rest of the government could see an "extremely draconian outcome." The Super Committee's deadline is November 23, 2011 for its proposed solution and according to the provisions of its establishment. Congress must vote up or down on these by December 23, 2011. Failure to adopt the Committee's recommendations would also lead to ATB spending cuts that would take effect in FY 2013.

Collins stressed that the current state of affairs requires that the NIH look at all of the possible strategies for dealing with these budget challenges, including making the case for NIH and trimming spending across-the-board. He reported that in FY 2011, the agency reneged on its out-year commitments to recipients of multi-year grants. Additionally, the Institute and Center directors are reevaluating and rearranging their research portfolios. The NIH director also emphasized that the agency is thinking about more controversial ways of managing NIH resources. Accordingly, the agency has posted data on its website and is seeking feedback from the NIH community (see *Update*, [October 24, 2011](#)).

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## **COSSA Responds to Office of Human Research Protection Proposal to Revise the Common Rule**

In July, the Office of Human Research Protection (OHRP) in the Department of Health and Human Services (HHS) issued an Advanced Notice of Proposed Rulemaking (ANPRM) to begin the process of revising the Common Rule that governs the protection of subjects in human research (see *Update*, [July 25, 2011](#)). The Office sought comments from the affected research and patient communities.

On October 26, COSSA joined many other organizations in responding to the ANPRM. A White Paper drafted by Felice Levine of the American Educational Research Association, former University of Michigan Law Professor Richard Lempert, and Paula Skedsvold of the Federation of Associations on Behavioral and Brain Research (FABBS), covered a myriad of issues raised by the notice and attempted to answer the 70 questions it posed. The White Paper was signed by 22 organizations. Many others, including some who signed the COSSA response, sent their own documents to OHRP.

The 72 page response also includes an appendix prepared by Connie Citro, Director of the Committee on National Statistics (CNSTAT), which focuses on the recommendations from a host of reports produced by CNSTAT and the National Academies on the issue of data access, privacy, and confidentiality.

While noting that COSSA and its co-signees "strongly support the aims and ambition of this project to revise the Common Rule," there are a number of criticisms on the proposal embodied in the White Paper. At the same time, the groups expressed their pleasure "to see specific attention to SBS [Social and Behavioral Science] research and ways that it differs from biomedical research whose potential for physical harm led to the development of the Common Rule."

First, COSSA supports the recommendation to "separate informational risks from physical and psychological risk and the proposed plan to remove the evaluation of information risk from the purview of Institutional Review Boards (IRBs)."

The response calls for clarification of the definitional language in the Common Rule "to meaningfully distinguish for IRBs the difference between and the implications of the probability or likelihood that a harm of a certain type might occur and the magnitude of the harm." The White Paper cites the Social and Behavioral Sciences Working Group on Human Research Protections (which Levine chaired) of the National Human Research Protections Advisory Committee, "which called attention to the need to separately evaluate the probability of a harm and its likely severity." Since the current regulations conflate the implications of likelihood or probability of harm and the magnitude of harm, the White Paper argues for revision of the Common Rule's language to avert this confusion.

COSSA also supports the recommendation to separate informational risks from physical and psychological risk and the proposed plan to remove evaluation of information risk from the purview of Institutional Review Boards (IRBs).

With regard to data protection and confidentiality, the ANPRM suggested using rules set up by the Health Insurance Portability and Accountability Act (HIPAA). COSSA strongly opposes the use of HIPAA for these purposes. The White Paper argues that HIPAA's standards are unsuitable for several reasons: "HIPAA is designed to provide privacy protection for administrative health records related to specific categories of Personal Identifiable Information (PII) and has failings even as a mechanism for permitting health research consonant with privacy protection; HIPAA was not intended to identify data security and data protection mechanisms that would reduce risks of advertent or inadvertent data disclosure while allowing appropriate research use, nor is it well suited to this end; and, because HIPAA was drafted with an eye to protecting patient medical records, it is particularly ill-suited to the kinds of data security and subject protection issues that SBS researchers encounter in wide-ranging research beyond health and beyond the use of administrative records (e.g., census data)."

Rather than using HIPAA, COSSA recommends "an examination of options available for researchers, establishing data protection plans, and for oversight of those plans that are efficient, flexible, and in accord with the data being collected, and an independent study of these options drawing upon expert sources," such as the National Research Council (NRC) of the National Academies. In addition, the Rule should "exempt from further specification, review, or registration of data protection plans, research using only data derived from public use files that have been already vetted through a disclosure review board, data archives, survey/data centers, or federally approved data archives or other federally approved system of access." At same time, the OHRP should hold researchers who seek excused status for restricted data use accountable in accord with their data security and protection plans.

### **Changes to Expedited Review**

COSSA supports all three areas of change (revising the criteria for expedited review, eliminating continuing routine review of expedited studies, and streamlining submission requirements) contemplated in the ANPRM. The plan to expand the research activities appropriate for expedited review and to increase the clarity of what qualifies as minimal risk is long overdue, according to the response. Specifically, COSSA: supports updating the list of research activities that qualify a study for expedited review and for periodically considering further expansion based on empirical assessment of the levels of risk; supports the default assumption that research that falls under one of the listed activities is by definition minimal risk and thus qualifies for expedited review; and appreciates that there may be a need for reviewers to be able to determine that listed research should receive full IRB review. COSSA strongly recommends that such decision should be documented and subject to auditing to avert the migration from expedited to full review.

COSSA also agrees that annual or continual review of expedited studies is not a good use of an IRB's

(or a researcher's) time and strongly supports eliminating continuing review of expedited studies and a streamlined documentation for expedited studies.

In one of its strongest criticisms of current practice, COSSA emphasized that the language inviting IRBs to determine whether research procedures are "consistent with sound research design" should be stricken or modified, since they are not directly germane to human subjects' protections and are beyond the expertise of IRBs.

The ANPRM offered a new category of "excused" research that would significantly streamline the research review process. However, it was coupled with the imposition of additional regulations relating to data protection and consent policies. COSSA expresses concern about the coupling of these two concepts.

The White Paper notes: "The introducing of an excused category for research that, apart from possible information risks involves no more than minimal risk, is attractive because it largely removes from IRBs the burden and distractions of review tasks that do little if anything to protect human subjects."

Once again, COSSA recommends an independent study by the NRC to determine: 1) what exemption should mean and means in practice; 2) the appropriateness of exempting studies of various sorts from IRB review; 3) whether or not oversight under the Common Rule is appropriate when research is exempt; and 4) what principles and procedures should be used in determining what research should be exempt.

With regard to the proposed consent rules for "excused" research, COSSA strongly advises that "any revisions to the consent rules with respect to use of preexisting data focus on the objectives of the consent process and confidentiality protections put in place and on whether researchers using existing data do so consonant with consent agreements, rather than seeking to assess on a project-by-project basis the extent to which consent sufficiently anticipates the scope of scientific uses by the initial researcher or subsequent researchers."

### **Informed Consent Issues**

COSSA strongly recommends that a revised Common Rule should set forth what needs to be accomplished through the consent process and the alternative approaches to obtaining meaningful consent, rather than emphasizing the default of written forms as the requirement.

Specifically, the White Paper argues, consent forms should have straightforward language that satisfies the requirements for a general consent that allows for future data use. The focus should be on informational risk in the consideration of subsequent use of non-research as well as research data, COSSA declared, and "in the SBS sciences, de-identified, data even if collected for non-research reasons, are public-use data and research should proceed without further consent."

COSSA opposes the proposed extension of the federal regulations to all research in the belief that there are too many complexities involved to use the Common Rule as "the best way to achieve the protections that are desired."

For the full White Paper, including the appendix, go to:

<http://www.cossa.org/advocacy/2011/SBS-White-Paper-ANPRM-10-26-11.pdf>.

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## **Ladson-Billings Delivers AERA's 2011 Brown Lecture**

On October 27, Gloria J. Ladson-Billings, Kellner Family Chair in Urban Education at the University of Wisconsin-Madison, gave the American Education Research Association's (AERA) Eighth Annual Brown Lecture in Education Research.



The lecture series is designed to feature the important role of research in advancing understanding of equality and equity in education. It was inaugurated in 2004 to commemorate the 50th anniversary of the *Brown v. Board of Education*, a decision in which the Supreme Court cited social science research on race. Each year a distinguished scholar notable for producing significant research related to equality in education is invited to give a public lecture in Washington.

Ladson-Billings, who was President of AERA in 2004-05, is the author of *The Dreamkeepers: Successful Teachers of African-American Children* (now in its second edition). In her lecture, she posited that education (particularly literacy) has been tied to race for centuries. She explored the various ways this occurred using examples from the world and deeply personal imagery from her own family history.

Ladson-Billings has argued for "culturally relevant pedagogy," and did so again in her Brown lecture. She began with a discussion of her family member born in South Carolina in the late 1800s. In one census, this woman was deemed "mulatto" in the next she was "black." Ladson-Billings could only conclude that the woman was given the "mulatto" classification almost as an honor in recognition of her literacy.

Racial identification underscores the way research functions, according to Ladson-Billings, and we must rely on empirical data to tell us the truth about a time. The links between education and race have been part of the nation's heritage for centuries. From laws making it illegal to teach blacks to read, to eugenics courses taught in universities, education and science have never been safe from built-in racism, she added. Ladson-Billings pointed out that the American Sociological Association has indicated that race is central to societal organization, thus making its study obligatory.

In closing, Ladson-Billings used a narrative about a black family with three incredibly intelligent and motivated children. Despite every effort of the family, the children still faced disadvantages that could not be overcome in an education system that was not crafted for them.

For more information on AERA's Brown lectures please look [here](#).

## Karen Cook Named to AAHRPP Board



The Association for the Accreditation of Human Research Protections Systems (AAHRPP) has named Stanford sociologist Karen Cook to its Board of Directors. COSSA is one of the Founding Members of AAHRPP.

AAHRPP promotes high quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HRPPs). As an independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection.

Cook, who also serves as an At-Large member of the COSSA Board of Directors, replaces Steven Smith, Dean of the California Western School of Law, in the AAHRPP Board slot chosen from COSSA nominees. Smith served for nine years, completing three three-year terms.

Cook is the Director of the Institute for Social Science Research and Vice Provost for Faculty Development and Diversity at Stanford. She has also served as an Associate Dean for the Social Sciences and Humanities and Chair of the Department of Sociology. Cook has been at Stanford since 1998, having previously taught at Duke and the University of Washington, where she was also department chair.

She has edited a number of books in the Russell Sage Foundation Trust Series she co-edits with Margaret Levi and Russell Hardin, including *Trust in Society*; *Trust and Distrust in Organizations*:

*Emerging Perspectives* (with Roderick Kramer); *eTrust: Forming Relations in the Online World* (with Chris Snijders, Vincent Buskens, and Coye Cheshire), and *Whom Can Your Trust?* (with Margaret Levi and Russell Hardin, 2009). She is a Member of the American Academy of Arts and Sciences and the National Academy of Sciences. She has been Vice President of the American Sociological Association.

Her B.A., M.A. and Ph.D. in Sociology are all from Stanford.

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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.

UPDATE is published 22 times per year. ISSN 0749-4394.

