

COUNCIL ON GOVERNMENTAL RELATIONS

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TO: COGR Membership

FROM: COGR Staff

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NIH Salary Cap Summary and NIH Guidance

COGR has followed the NIH salary limitation developments over the past six weeks and has reported updates to the membership via the COGR ListServe and the 2011 Holiday Update (dated December 22, 2011). As you know, the Executive Level II salary limitation became effective on December 23, 2011. Per Section 203, General Provisions of H.R. 2055: *“None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.”*

Consequently, this provision reduces the salary cap on extramural grants from Executive Level I (\$199,700 in 2011 and 2012) to Executive Level II (\$179,700 in 2011 and 2012). Also note, see the link below to the Salary Tables published by the U.S. Office of Personnel Management, which includes access to the Executive Schedule and historical salary levels:

<http://www.opm.gov/oca/12tables/index.asp>

The NIH issued guidance on January 20, 2012. Information included in COGR emails to the ListServe and the 2011 Holiday Update was consistent with the NIH guidance (see below): <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html>

COGR has consulted with NIH staff on a number of topics that have been raised by the COGR membership. While not in the position to provide official guidance or interpretation, COGR has tried to be responsive to the membership concerns. Below are COGR's most fine-tuned updates, based on the official NIH guidance and conversations with NIH staff.

- 1) H.R. 2055, or the Consolidated Appropriations Act, 2012 (Public Law 112-74), finalizes appropriations for most agencies (including DHHS, NIH) for the Federal Fiscal Year 2012.
- 2) If the Initial Issue Date of the FY12 award (competing and non-competing) is on/after 12/23/2011, Executive Level II salary is applicable.
 - For NIH competing grant awards with categorical budgets reflecting salary levels at or above the new limit, NIH will adjust the award downward for the current year and all future years.
 - For NIH non-competing grants, awards will not be adjusted downward. Unless otherwise restricted, grantees may rebudget any funds freed as a result of the lower salary level.
- 3) If the Initial Issue Date of the FY12 award (competing and non-competing) is on/after 10/1/2011 through on/before 12/22/2011, Executive Level I salary initially is applicable.
 - For NIH competing grant awards with categorical budgets reflecting salary levels at or above the new limit, the grantee may continue to apply the Executive Level I for the FY12 award period and no adjustments are required. However, for future years, NIH will adjust the award downward to reflect Executive Level II and there will no excess funds freed for rebudgeting,
 - For NIH non-competing grants, the grantee may continue to apply the Executive Level I for the FY12 award period and no adjustments are required. For future years, Executive Level II is applicable – however, awards will not be adjusted downward and unless otherwise restricted, grantees may rebudget any funds freed as a result of the lower salary level.
- 4) The treatment of the examples above assumes that the Executive Level II will remain in effect for the FY13 Federal budget year. If a Federal budget is not approved by October 1, 2012, a Continuing Resolution (CR) would be necessary to keep the Federal government open for business. Under either scenario, the Executive Level II would remain effective unless legislation provides otherwise. However, until we are closer to that date, no one can predict for sure if there will or will not be changes to the salary limitation.
- 5) As stated in the NIH guidance: *“Any grants awarded in previous fiscal years (e.g., FY 2011, FY 2010, etc.) are not impacted by the FY 2012 salary limitation. Carrying*

over previous years' funds to support salaries will remain at the salary limitation levels in effect at the time those awards were issued FY2012." If, for example, FY11 funds are carried over to an FY12 award, there are no restrictions on the FY11 funds. However, the FY12 funds are subject to the applicable restrictions. If two salary caps are to be managed on the same award, institutions will need to keep the accounts sufficiently separate and/or insure that the carryover be sufficiently documented in order to demonstrate that the institution is complying with the appropriate salary limitation.

6) As stated in the NIH guidance: *"The salary limitation provision DOES apply to subawards/subcontracts for substantive work under an NIH grant or contract."* Consequently, NIH interprets the date of issuance of the initial FY12 award to the prime awardee to be the date for application of the salary limitation – not the date that the prime awardee issues the award to the subawardee/subcontractor.

7) For new proposal applications and corresponding budgets, NIH expects to post the following guidance on grant applications: *"NIH application instructions remain unchanged. Applicants submitting an application with a detailed budget should continue to reflect the actual institutional base salary of individuals for whom reimbursement is requested. NIH will make any adjustment necessary using the applicable salary limit in effect at the time of award. In lieu of actual base salary, institutions may elect to provide an explanation in the budget justification narrative indicating that the actual institutional exceeds the current salary limitation. When this information is provided, NIH staff will make necessary adjustments to requested salaries prior to award. When preparing an application using the modular budget format, applicants should use the current salary limit when estimating the number of modules requested."*

8) All HHS operating divisions, with the exception of the FDA (funded under the USDA appropriations bill) and the Indian Health Service (funded under the Department of Interior appropriations bill), are equally affected by H.R. 2055 and the Executive Level II is applicable. Note, under prior years appropriation legislation, only NIH, AHRQ and SAMHSA were affected. Guidance from other HHS operating divisions should be forthcoming – to date, guidance from AHRQ is available: <http://grants.nih.gov/grants/guide/notice-files/NOT-HS-12-007.html>

NIH is actively providing outreach and responding to questions. If you have concerns, we encourage you to contact an NIH grant manager or program officer. COGR will continue to follow implementation questions and other issues and can further engage, as appropriate.

NIH 2012 Fiscal Policy for Grant Awards and Budgeting for Inflationary Increases

The NIH published their 2012 fiscal policy in response to implementation of the FY2012 NIH approved budget of \$30.7 billion. NIH Notice Number NOT-OD-12-036, which addresses NIH fiscal policy for FY2012, can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-036.html>

The approved budget amount of \$30.7 billion represents an increase of less than one percent. Consequently, the NIH fiscal policy includes the following:

- Non-competing awards will be issued without cost of living/inflationary adjustments in FY 2012; however adjustments for special needs (such as equipment and added personnel) will continue to be accommodated.
- The NIH will make efforts to keep the average size of awards constant at FY 2011 levels or lower.
- Inflationary increases for future year commitments will be discontinued for all competing and non-competing research grant awards issued in FY 2012, however adjustments for special needs (such as equipment and added personnel) will continue to be accommodated.
- FY 2012 awards that have already been issued will be revised to adjust the award level and future year commitments in accordance with these principles.
- For Ruth L. Kirschstein National Research Service Awards (NRSA), the NIH will implement a two percent increase at all stipend levels.
- NIH will continue to support new investigators on R01 equivalent awards at success rates equivalent to that of established investigators submitting new (Type 1) R01 equivalent applications.
- Section 203 of the Consolidated Appropriations Act prohibits payments for salaries under grants and other extramural mechanisms to rates in excess of Executive Level II.

The NIH Notice does not prohibit budgeting for future year inflationary increases in a grant application – however, under the current budget climate, it is likely that any future budget increases associated with inflationary increases will be eliminated from the approved budget. Also note, the NIH Notice also does not prohibit providing a reasonable allowance for salary increases to individuals and charging those increases to NIH grants. Since inflationary increases are not being provided by NIH, the institution would need to rebudget as permitted under allowable rebudgeting authority if it decides to charge salary increases to NIH grants.

A-21 Task Force Update: OMB to Provide Complete Update at COGR Meeting

The A-21 Task Force has completed its work and has provided its recommendations to senior leadership at the Office of Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP).

One of the afternoon sessions at the Thursday, February 23rd COGR Meeting is a presentation by OMB Controller, Danny Werfel. He will provide an update on how senior leadership at OMB and OSTP have addressed the recommendations from the A-21 Task Force and what the next steps will be for reducing the cost and burden associated with OMB Circular A-21. Mr. Werfel has indicated he will be able to be forthright on the status and respond to all questions from the COGR membership.

Costing Policies Outlook for 2012: Will Implementation of A-21 Policy Changes Carry the Year?

One of the Thursday morning sessions at the February 23rd COGR Meeting is designed to provide an overview of the hot topics on the plate of the Costing Policies Committee. Front and center are the outcomes from the A-21 Task Force, and possibly, implementation of A-21 policy changes. We will utilize the Thursday morning session to address the following:

- Status of the A-21 Task Force, from COGR's Perspective,
- Revisit the COGR July 2011 Recommendations to the Task Force, in preparation for Mr. Werfel's presentation in the afternoon,
- Effort Reporting special focus and recap of the November 9, 2011 letter to the Task Force,
- Identify primary concerns and questions that should be directed to Mr. Werfel in the afternoon session,
- Costing Policies 2012 – Speculation on the role COGR may play in implementation of A-21 policy changes,
- If applicable and time permits, other potential hot topics for Costing Policies in 2012.

The afternoon session with Mr. Werfel may be our best and last opportunity to share COGR membership questions and concerns directly with a Federal official who has a significant role in how the A-21 policy changes unfold. **We encourage you to come to the morning session prepared with those issues that are of particular concern to your institution.** Copies of the July 2011 COGR Recommendations and the November 9, 2011 COGR proposal on effort reporting are available at www.cogr.edu under Educational Materials / Financial Management.

Revisiting the A-21 Task Force Timeline

At the February COGR Meeting, we expect to learn how the work of the A-21 Task Force may translate into A-21 policy changes. While COGR's understanding is that there may be several more steps prior to final and approved changes, the Thursday afternoon presentation by OMB Controller, Danny Werfel, should more clearly define how the process should unfold. Below is a recap of some of the steps that have led to where we are, and speculation of what may lie ahead.

F&A-Compliance-Regulatory Reform - COGR began advocacy efforts, in coordination with AAU and APLU, in 2009, concurrent with the beginning of the Obama Administration. External events and internal COGR initiatives helped to advance the effort, including:

- Bipartisan Congressional request for National Academies, National Research Council, "Study on Research Universities" – NRC workgroup convenes in September 2010.
- GAO Study in September 2010, "University Research: Policies for the Reimbursement of Indirect Costs Need to be Updated" (GAO-10-937).
- COGR Policy Paper in November 2010, "Federal Funding Agency Limitations on Cost Reimbursement: A Request for Consistency in the Application of Federal Guidelines."
- COGR Policy Paper in May 2011, "Improving the F&A Rate-Setting Process with the Federal Government."

Executive Order 13563, January 18, 2011, Improving Regulation and Regulatory Review - E.O. 13563 orders that the regulatory system of the country must allow for open public participation and must identify the most innovative and least burdensome tools for achieving regulatory relief, while not sacrificing important health, safety, or environmental protections.

A-133 and A-87 Task Forces - Prior to E.O. 13563, an A-133 Single Audit Task Force is tasked to look at potential improvements to OMB Circular A-133. The A-87 Task Force is created as a direct response to E.O. 13563.

A-21 Task Force - Formed in the spring 2011, soon after the creation of the A-87 Task Force. It is co-chaired by OMB, NIH, and DOD. On June 28, 2011, an NIH “Request for Information (RFI): Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Educational Institutions (OMB Circular A-21)” is issued.

COGR, AAU, APLU Responses to RFI, and up to the Present –

- July 28, 2011, COGR Submits 45-page Response to the RFI, addressing 20 topics.
- A-21 Task Force indicates over 150 responses by associations, universities, and individuals were submitted.
- August-December 2011, A-21 Task Force compiles responses and develops recommendations to senior leadership at OMB and OSTP.
- October 26, 2011 meeting between COGR Costing and RCA Committees and the A-21 Task Force to review Effort Reporting.
- November 9, 2011, COGR submits, at the request of the A-21 Task Force, a proposal to the Task Force: “Discontinuation of the Effort Reporting Requirement.”
- January 2011, A-21 Task Force submits their recommendations to senior leadership at OMB and OSTP.
- January 20, 2012, OMB Controller, Danny Werfel, updates COGR, AAU, and APLU on “Next Steps.” Our understanding is that OMB will circulate the proposed A-21 policy changes through Federal Register Notice(s) and Request for Public Comments.
- Summer 2012, depending on the results of Public Comments, COGR’s understanding is that OMB will announce A-21 policy changes.

If our understanding of the “Next Steps” is accurate, COGR expects to focus on thorough responses to Federal Register Notice(s) and Request for Public Comments over the next several months. If policy changes are announced this summer 2012, we expect to be engaged in the implementation of those policy changes. Again, the Thursday afternoon presentation by OMB Controller, Danny Werfel, should more clearly define how the remainder of the process should unfold.

Accelerating Spending on ARRA Programs: Guidance Available

We expect NSF and NIH, as well as all other affected agencies, to actively monitor all ARRA awards and spending rates. COGR reported on the status of “accelerating spending” guidance in the 2011 Holiday Update and will continue to follow this issue. The trigger came from a September 15, 2011 Office of Management and Budget (OMB) Memorandum M-11-34 (Accelerating Spending of Remaining Funds from the American Recovery and Reinvestment Act for Discretionary Grant Programs). Consequently, all affected agencies, including NSF and NIH, published notices to Revise the Terms and Conditions of ARRA awards to ensure completion of these awards by September 30, 2013 (see OMB, NSF, and NIH links below):

<http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-34.pdf>

<http://www.nsf.gov/recovery/acceleration.pdf>

The NSF and NIH Guidance take the same general approach. The COGR perspective on the primary takeaways from both the NSF and NIH Notices are:

- 1) For awards that are scheduled to end on or BEFORE September 30, 2013, No Cost Extensions will require prior approval. This will be specified via an amendment to the Standard Terms and Conditions of the award.
- 2) In those situations where a No Cost Extension is needed, and with an extension the project still will be completed on or before September 30, 2013, no amendment to the Standard Terms and Conditions is necessary. However, grantees are encouraged to responsibly accelerate spending.
- 3) In those situations where approval of a No Cost Extension is necessary, YOU MUST REQUEST THE NO COST EXTENSION BY JUNE 1, 2012. NSF and NIH will grant approvals based on the four allowable exceptions per OMB M-11-34 (i.e., the project is long-term by design, the project requires complex environmental review, contractual commitments with subs/vendors legally prevent adjusting the timeline, acceleration of spending may cause harm or risk to vertebrate animals or human subjects).
- 4) For awards that are scheduled to end AFTER September 30, 2013, NSF and NIH staff may reach out to your institution/PIs to accelerate spending, and possibly request that the award be amended to be completed on or before September 30, 2013. Several of your institutions shared correspondences with COGR where an agency staff person encouraged “accelerating spending” in a manner that was not necessarily appropriate. If you receive correspondences that seem to fall into this category, please contact COGR staff.
- 5) Construction and Renovation of Facilities awards, from a COGR perspective, would be candidates for an exception ((see 3) above). However, the guidance from both NSF and NIH is not obvious in how these types of projects are to be treated. If you receive direction from agency staff that is contrary to the nuances associated with your Construction awards, please contact COGR staff.
- 6) COGR has not seen similar guidance from other agencies, with the exception of guidance from the Agency for Healthcare Research and Quality (AHRQ). The AHRQ guidance is more restrictive than NSF and NIH guidance, and can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-HS-12-002.html>

You should note all agencies are under the same pressure to accelerate spending. COGR will continue to follow all issues related to NSF, NIH, and other agency guidance. As necessary, we will work with appropriate Federal agency staff to clarify concerns that arise.

Federal Reporting, Accountability and Transparency

In the 2011 Holiday Update, COGR reported on a broad range of topics that fall under the broad umbrella of Federal Reporting, Accountability and Transparency. The momentum behind enhancing accountability and transparency at the Federal government level remains strong. This

has been demonstrated over the past five years in the form of FFATA, ARRA, and most recently, the proposed DATA and GRANT Acts. Also, we constantly see agency-specific initiatives such as the expected 2013 release of a new NSF Cash Payment system and recent system/access changes with DOD's Wide Area Workflow system (WAWF).

Executive Order 13576, "Delivering an Efficient, Effective, and Accountable Government" (issued June 13, 2011) reinforced the theme of accountability and transparency – building upon the foundation of the ARRA Recovery Accountability and Transparency Board (RATB), E.O. 13576 created the Government Accountability and Transparency Board (GATB). A recent GATB report references lessons learned from ARRA reporting, and while we are not necessarily on the cusp of ARRA reporting for all Federal funds, the GATB report raises discussions that require attention. The GATB report is available at:

http://www.whitehouse.gov/sites/default/files/gat_board_december_2011_report_and_recommendations.pdf

COGR is paying attention to all of these developments and is most interested about those current Federal reporting requirements that are particularly burdensome to your institutions.

Audit Update: General

The past two COGR Updates included detailed updates on the 2012 Office of Inspector General (OIG) Workplans for HHS (specifically, NIH) and the NSF. However, as the OIGs often make clear, their workplans are subject to change based on internal and external events. Consequently, COGR tries to stay connected to all developments and update the membership on new or unexpected initiatives that affect the research community.

Below are audit-related topics that are either new developments or items we have reported on in the past and/or continue to follow.

- HHS OIG ARRA Audits. As reported previously, the HHS OIG is engaged in ARRA audits related to NIH programs. Generally, these ARRA audits of NIH programs have been grant-specific with a focus on the financial aspects of the grant (i.e., cost allowability, internal controls of financial processes, etc.), and have included lengthy information requests – jobs reporting has not been emphasized. These ARRA audits are being conducted at institutions in each of the eight HHS OIG regional audit offices. The results from a Region 6 (Dallas) audit report from January 2012 stated: *Based on our assessment, the Recovery Act costs claimed by the University for reimbursement were allowable, allocable, and reasonable and are in accordance with applicable Federal regulations. Accordingly, this report has no recommendations.* A copy of this report is available at: <http://oig.hhs.gov/oas/reports/region6/61100054.pdf>
- HHS OIG Administrative & Clerical Audits. The eight schools that were selected for this audit work (officially entitled, *College and University Indirect Costs Claimed as Direct Costs*) are at different stages of completion, and each is assigned to one of the eight HHS OIG regional audit offices. There are indications that each HHS regional audit office has employed a unique approach to its audit work. Consequently, the audit experience for each school has varied from region to region. To date, three audits reports (August 2011, October 2011, and December 13, 2011) have been released and the audit findings have not indicated any systematic or serious issues:

<http://oig.hhs.gov/oas/reports/region10/11101500.pdf>
<http://oig.hhs.gov/oas/reports/region2/21102000.pdf>
<http://oig.hhs.gov/oas/reports/region5/51100030.pdf>

COGR is following the developments related to the Administrative & Clerical audits as well as any broader repercussions that could ensue.

- NSF OIG Activity. In the 2011 Holiday Update, we summarized how the NSF OIG will approach ARRA audit work for FY2012: The Academic Research Infrastructure program will be audited, both from an NSF oversight perspective and a grant recipient/subawardee perspective and the NSF OIG also will pursue financial and compliance based audits of “high risk” recipients of ARRA awards – and unlike the HHS OIG, jobs reporting may be audited. We also reported that the NSF OIG is transitioning to a new audit approach that emphasizes data and statistical analysis (“*data analytics*”) rather than the more traditional approach of topic oriented audit initiatives (e.g., labor and effort audits).
- 2012 A-133 Compliance Supplement. We expect that the 2012 A-133 Compliance Supplement will be available, shortly. We will keep the membership posted.

COGR is interested in audit experiences at your institution so that we can update the general landscape for the membership. We have most access to HHS OIG and NSF OIG initiatives, but also are interested in activity related to the OIGs at other agencies. Please contact David Kennedy if your institution has been contacted by any agency to conduct an audit or review. We will keep all correspondences confidential.

Other Costing Developments and Discussions

Below are topics that are either new developments or items we have reported on in the past and/or continue to follow. If there are cost-related or financial topics that you would like to discuss with COGR, please contact David Kennedy at dkennedy@cogr.edu.

NIH and Genomic Arrays (GAs) – Request for Input. COGR has revisited this topic with officials from NIH. The NIH Office of Policy for Extramural Research Administration (OPERA) is interested in publishing clarification FAQs, including addressing those types of research where the GAs that are utilized are more F&A intensive and would not be characterized as a “*high-throughput commodity and service*” (as was defined in the May 13, 2010 NIH Notice, “Budgeting for Genomic Arrays for NIH Grants, Cooperative Agreements and Contracts”). Please contact COGR if you have examples of research at your institution where an exemption from the current NIH policy could be appropriate. The original NIH Notice can be found at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-097.html>

NIH and Efficient Spending for Conferences and Meetings. NIH published NOT-OD-12-041, “New NIH Policy on Efficient Spending Related to Grants Supporting Conferences and Meetings,” on January 27, 2012. Per the Notice: “*Effective with grant awards issued on/after the date of this Notice, a new term and condition which prohibits food/meal costs from being supported or charged to NIH-supported conference grants will be included on all competing and noncompeting NIH R13 and U13 awards.*” The Notice goes on to state:

“The policy does not apply to research grants and other mechanism that are not awarded specifically to support conferences ... the allowability of food-related costs is governed by the respective cost principles and the terms of award which include references to the NIH Grants Policy Statement.” The NIH Notice can be found at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-041.html>

Forest Service ARRA Awards and USDA OIG Audit. In the 2011 Holiday Update we reported on a May 2011 audit by the USDA Office of Inspector General (OIG) that found some grant recipients covered under OMB Circular A-87 (*Cost Principles for State, Local, and Indian Tribal Governments*) did not comply with the salary allocation requirements outlined in Circular A-87. One repercussion of the audit was for grantees to begin certifying on their Federal Financial Report (SF-425) that: *“The salary component of the amounts on lines e and g complies with all OMB Circulars applicable to my organization and accurately reflects the actual time personnel spent working on the award.”*

COGR contacted representatives from the Forest Service to contend that this certification statement is inappropriate for institutions covered under OMB Circular A-21. After conferring with the USDA OIG, the Forest Service updated the certification as follows: *“The salary component of the amounts on lines e and g complies with all OMB Circulars applicable to my organization and represents an appropriate after-the-fact determination of the work performed by the personnel working on the award.”* The official clarification can be found under Question and Answer Transcript, Follow-up to the December 7, 2011 webinar (see page 14, Question #44) at: http://www.fs.fed.us/spf/webinar_questions.pdf

Also note, COGR has raised the question as to whether the certification statement represents an addition of a data element to the SF-425, which if so, would require OMB approval. The position of the Forest Service is the certification statement is included in the existing block 12 “Remarks” section of the SF-425 and is not an addition of a data element. If there is any follow-up on this issue, we will update the membership.

USDA, National Institute of Food and Agriculture (NIFA) F&A Cap Increased. In recent COGR Updates, we reported on this change. Section 720 of the General Provisions to the Consolidated and Continuing Appropriations Act, 2012 (Public Law 112-55), enacted November 18, 2011, states that: *“None of the funds in this Act shall be available to pay indirect costs charged against any agricultural research, education, or extension grant awards issued by the National Institute of Food and Agriculture that exceed 30 percent of total Federal funds provided under each award ...”*. This represents an increase from the 22 percent limitation that previously was in effect. However, some NIFA programs may be authorized under legislation that supersedes Section 720 of Public Law 112-55. Below is a link to the “Indirect Costs Chart” published on the NIFA website. Also, in recent COGR Updates we described a possible concern as to how the “30 percent of total Federal funds” requirement should be treated when there are subrecipients on a NIFA award. COGR can provide additional insights on this issue to the membership, upon request.

http://www.csrees.usda.gov/business/awards/indirect_cost.html

2011 COGR Survey of F&A Rates. The Data Tables that contain institutional data are available. There are two data tables, both in XLS format, that are available: Historical Rates and Components. The data in the tables is “Confidential and for Internal Institutional

Purposes Only.” Our intent is for the survey to have a “real-time” element and to regularly update the tables, so please keep COGR posted on any updates.

Workplace Flexibility (“Family-Friendly”) Science Policy. This issue was addressed in COGR Updates throughout the Fall of 2011. We are following up on a recent NSF FAQ related to this topic (FAQ #4). Specifically, FAQ #4 is inconsistent with how many institutions account for sick leave, vacation time, and other leave time.

NIH and Costing on Core Facilities. After COGR responded to an NIH request for comments in December of 2010, internal reorganizations at NIH resulted in this topic being put on hold. Our understanding is the NIH will revisit this topic in 2012.

NRC “Study on Research Universities” Update. It’s been almost one-year since COGR began reporting on the study to be completed by The National Academies, National Research Council (NRC), to address the top ten actions that research university stakeholders and the nation can take to ensure U.S. global competitiveness. We initially reported that the study would be completed in the Summer 2011. Our current understanding is that a version of the report is being formally reviewed. After clearing review, it may be several months before release of a final version.

NSB Release Reports on Digital Data and Merit Review

The National Science Board (NSB), which serves as the policy and advisory board to the National Science Foundation (NSF), issued two reports in December 2011. The first report, *Digital Research Data Sharing and Management* (December 2011) from the NSB Task Force on Data Policies will be discussed during the February COGR meeting. José-Marie Griffiths, Vice President for Academic Affairs at Bryant University (Smithfield RI) and chair of the Task Force, will join the COGR membership to discuss the NSB’s recommendations to refine NSF’s policies on the sharing and management of digital data – data generated or converted to digital formats as well as digital metadata resulting from NSF supported research. This examination by the NSB complements a similar, on-going review initiated by the Office of Science and Technology Policy (OSTP) with regard to public access to digital data. The NSB report is available at: <http://www.nsf.gov/nsb/publications/2011/nsb1124.pdf>. COGR’s comments in response to the OSTP request concerning public access to scholarly publications and digital data are on the COGR website at: www.cogr.edu.

The report outlines key challenges and makes recommendations to address those challenges including: to ensure reproducibility, grantees should be required to make data and methods accessible for verification and the expansion of scientific ideas; to support sustainability of data, NSF should convene a panel of stakeholders to develop a variety of business models and recommendations; and to expand the development of a workforce of computational and data-enabled investigators and cyber-infrastructure professionals, NSF should continue support for scientific and engineering research in related fields. We encourage you to review this brief report in anticipation of the discussion on data and publications at the COGR meeting.

The final report from the NSB’s review of NSF’s merit review criteria, *The National Science Foundation’s Merit Review Criteria: Review and Revisions* (December 14, 2011), doesn’t recommend changes to the criteria – intellectual merit and broader impacts – but, rather, offers a refinement of the criteria and demonstrates how the criteria are linked to each other and express

the core principles that inform NSF's support of research. Throughout the process of the NSB's consideration of the criteria, COGR has offered comment – comment informed by timely and candid interactions with NSF/NSB staff members assisting the Board, notably Joanne Tornow, Executive Secretary. Thus, there is nothing new, as such, but the Board's articulation of the Merit Review Principles and how those principles are used in the review of applications submitted to the Foundation will assist applicants in understanding the process. There is specific guidance to NSF on the use of the criteria including changes to the Grant Proposal Guide that emphasize the importance of both criteria. We will look forward to the Foundation's response to these recommendations. We encourage members to review the interesting data and thoughtful consideration of the information provided in the NSB's report. The report is available at: <http://www.nsf.gov/nsb/publications/2011/meritreviewcriteria.pdf>

NIH Data and Informatics

The National Institutes of Health (NIH) Advisory Committee to the Director (ACD) is investigating the management of large biomedical datasets as well. On January 10, 2012, the ACD's working group issued a request for information (RFI) to inform its deliberations. The RFI, *Input into the Deliberations of the Advisory Committee to the Director Working Group on Data and Informatics* (NOT-OD-12-032) includes a list of the challenges or issues that the group wants to consider in developing recommendations to NIH concerning the management, integration and analysis of data. The identified issues include appropriate data standards; secondary and future use; and accessibility, sharing and support including personnel and infrastructure. Responses to the RFI are due March 12, 2012. As with the recommendations from the NSB and the on-going deliberations of the OSTP, NIH hopes to formulate policies and procedures that ensure a robust system that allows scientists to continue to explore and expand the scientific knowledge supported by NIH.

Avian Flu and the Management of Risk

You are aware of the recent debate over the National Science Advisory Board for Biosecurity's (NSABB) recommendation that two research groups withhold key details from their pending publications in *Science* and *Nature* on the avian influenza H5N1 virus. Asked by the U.S. government to assess the dual-use research implications of the two as-yet-unpublished manuscripts, the NSABB considered the risks and benefits of communicating the research results and “found the potential risk of public harm to be of unusually high magnitude.” The NSABB recommended that the manuscripts be edited to limit the information on experimental design and research results.

The scientists and publishers agreed but call for the federal government to identify how those elements – design and results – could be shared with other scientists working on avian flu. At the same time, the scientific community including the scientists whose papers were the subject of the NSABB review called for a 60 day moratorium on any research involving highly pathogenic avian influenza H5N1 virus to provide time for the scientific community and affected organizations and governments to meet and to address the concerns. Since the announced moratorium on January 20, 2012, the World Health Organization (WHO) is sponsoring a conference with selected scientists – flu experts – this month. The similarities to the moratorium on recombinant DNA research in 1975 that led to a meeting in Asilomar, California, where scientists proposed safety guidelines for genetically engineered molecules have led some to refer to this as virology's “Asilomar moment.”

As many of you know, the Asilomar Conference refers to the February 1975 International Congress on Recombinant DNA Molecules that met at the Asilomar Conference Center in California to examine how to self-govern the safe use of recombinant DNA (rDNA) molecules in research. In a way similar to the events that triggered the recent moratorium, concerns in the scientific community led to a 1974 National Academy of Science committee review and call for a moratorium until the hazards of rDNA could be carefully considered. In addition to the moratorium, the NAS called for federal guidelines to provide oversight of rDNA research. The Asilomar meeting did not address the ethical issues surrounding genetic alteration; rather it focused on safety. At the end of the conference, the group articulated a set of safety principles or guidelines that involved working with disabled bacteria that could not survive outside the lab. The guidelines allowed the research to resume and helped persuade Congress that legislative restrictions were not needed—that scientists could govern themselves. The conferees also endorsed the NAS recommendation for federal guidelines and an oversight committee. The resulting *NIH Guidelines for Research Involving Recombinant DNA Molecules* with the national Recombinant DNA Advisory Committee in the NIH Office of Biotechnology Activities and the related establishment of local Institutional Biosafety Committees is a result of this 1974-75 consideration. Many hope that a similar outcome of scientific self-governance can be achieved concerning avian influenza.

The information about the controversy and the moratorium statement are on *Science*'s website at: <http://www.sciencemag.org/site/feature/data/hottopics/biosecurity/index.xhtml>

In the short-term, the controversy and moratorium have drawn attention to the 2007 recommendations by the NSABB on providing oversight of dual use research of concern. COGR has brought the various publications, recommendations and work of the NSABB to your attention over several years. It may be appropriate to reexamine the NSABB's *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* (June 2007) available at: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html. We are likely to see guidelines and/or policies addressing the oversight of dual use research in the near future and we encourage you to become re-acquainted with these documents and begin discussions with your scientific staffs to identify the most effective way to build the NSABB-recommended "culture of compliance" on your campus. The NSABB website is at: <http://oba.od.nih.gov/oba/index.html>

Other RCA Updates and Recent Comments

As discussed in the December 2011 Update, COGR submitted brief comments on the Position Statements prepared by the NIH Office of Laboratory Animal Welfare (OLAW) on the implementation of the 8th Edition of the *Guide for the Care and Use of Laboratory Animal* (NAS, 2011). Specifically, COGR made a general comment on how the management of costs may be reflected in an institution's implementation of the *Guide*; discouraged OLAW's endorsement of the *Guide*'s space recommendations as a "starting point;" and, finally, called for a clarification that IACUCs must review adverse consequences with the use of non-pharmaceutical-grade substances when these substances are used as medications rather than research test substances.

COGR asked the US Fish and Wildlife Services to retain the "threatened" status for all chimpanzees (*Pan troglodytes*) and endorsed the more extensive comments on the consideration

of a change in status from “threatened” to “endangered” provided by our colleagues at the National Association for Biomedical Research (NABR).

President’s Jobs Council Issues Final Competitiveness Report

On January 17 the President’s Council on Jobs and Competitiveness issued its 2011 Year-End Report. The Report may be found at www.jobs-council.com/2012/01/16/2902/.

The Report strongly recommends increased federal support for R&D. In the context of a broad recommendation for fostering a climate for innovation to thrive, it states:

“Given the federal government’s central role in funding basic research, the prospect of constrained federal budgets in the years to come could put at risk a generation of new ideas. Because the societal benefits of early innovations are far greater than those that accrue to any individual inventor, government has long provided a large share of basic research funding, ranging from 50 to 70% over the years. In the corporate world, where companies are looking for technology that they can develop directly into products, basic research plays a much smaller role, accounting for less than 20 percent of corporate R&D spending even at its peak.

Given this context, reducing federal support for basic research would be a terrible mistake. The Council endorses President Obama’s call for significant new investments in R&D and urges the nation to set an overall R&D investment goal of 3% of GDP or more. We should also consider expanding the role of novel research agencies such as the Department of Energy’s new ARPA-E, modeled after DARPA. These innovative agencies stretch our research budgets further (by using new techniques to spur invention) and help make late-stage innovations more successful by targeting them to the needs of a final customer—our nation’s energy system and our military, respectively.” (See note on ARPA-E below).

Other major recommendations are to improve education at all levels to prepare the workforce to participate in the global economy; promoting an “all-in” strategy on energy supply, innovation, and efficiency; revitalizing the U.S. manufacturing sector, including by reforming U.S. export controls; instituting “smart” regulatory reforms, such as better aligning U.S. regulations and international regulatory standards; and reforming the tax system to better promote innovation. The regulatory reform material among other things calls for regulatory ombudsmen and for OMB/OIRA to develop guidelines for how agencies should respond to petitions for reconsideration of final rules (timely in view of COGR’s recent request for NIH to reopen the financial disclosure rule with regard to travel disclosures).

We noted in the COGR October 2011 Meeting Report that the Interim Report of the Council included a recommendation that university faculty be allowed “to shop discoveries to any technology transfer office, other than solely to their own university’s technology transfer office.” Subsequently COGR, AAU and APLU representatives met with the Executive Director and Deputy Director of the Jobs Council and an OSTP representative to express concerns about the recommendation. This recommendation does not appear in the final report (except in a summary of the interim recommendations).

The report does call for “cultivating a supportive environment for entrepreneurs and promoting innovation clusters around our world-class universities” and for providing “better access to markets for new technologies through more liberal technology transfer policies.” It also cites the

need to bolster private R&D through a competitive R&D tax credit, speedy tech transfer and strong IP enforcement. University programs at MIT and the University of Michigan are specifically singled out for praise.

The Report was editorially criticized by the NY Times (Jan. 22) as a “corporate wish list,” citing its emphasis on lower tax rates, less regulation, and for assuring the education system meets the needs of corporations. For these reasons the Council’s two union representatives dissented from the Report. However, many of the themes in the Report were sounded by President Obama in his January 24 State of the Union address.

Note: a recent GAO report on ARPA-E concluded that most ARPA-E projects could not be funded solely by private inventors since they involve unproven technological concepts and there is a lack of successful venture capital investments in new energy technologies. However, in response to Congressional concerns, the report recommended that applicants provide documentation from private investors explaining why they are not willing to fund the projects. NIST has a similar requirement for some programs. The GAO report highlights are available at <http://www.gao.gov/assets/590/587665.pdf>.

Commerce Releases Report on Competitiveness

On January 6 the Commerce Department in consultation with the National Economic Council released a report on *The Competitiveness and Innovative Capacity of the United States* (<http://www.commerce.gov/americancompetes>). The report was mandated by the American COMPETES Act (Section 604).

A number of recommendations in the report closely mirror recommendations made by a group of five higher education associations including COGR, in a letter dated April 1, 2011 in response to the Department’s February 2011 Request for Information on the Administration’s Strategy for American Innovation (see COGR February 2011 Meeting Report; letter available at www.aau.edu –Innovation and Competitiveness-Government University Partnership). That letter attached earlier comments from the associations on improving the commercialization of university research (see COGR May 2010 Recent Developments).

The report is along similar lines as the Jobs Council Report. It discusses the importance of federal support for basic research, the importance of STEM education for economic growth, the need for infrastructure investments, the need to revitalize U.S. manufacturing, and the need to support regional clusters for innovation, reduce barriers to entrepreneurship, and accelerating lab to market innovations through proof of concept centers, etc.

With the exception of an unfortunate footnote to a questionable study purporting to show a slowdown in university patenting, licensing and startups in the early 2000’s, there is nothing in the Report that should raise issues or concerns for COGR members.

Patent Reform: Prior User Rights and Proposed Implementing Rules

House Judiciary Subcommittee Holds Hearing on PTO Prior User Rights Report -
One of the key compromises in last year’s America Invents Act (AIA) was to expand the defense to patent infringement for prior commercial use of the claimed invention. Previously the defense was available only for business method patents. Universities had

opposed further expansion on the grounds that the defense favors trade secrets over public disclosures required by patents, and thus does not encourage innovation. We also were concerned about an adverse effect on universities' ability to license their patented inventions, which tend to be early-stage, high-risk technologies. Prior user rights protection of trade-secret technologies decreases patent certainty and may discourage private sector companies from licensing university patents or investing in startups.

However, in the course of the prolonged discussions and negotiations over patent reform, we came to recognize the importance to some private sector companies of the availability of a prior use defense to patent infringement. In complex products and manufacturing processes it may not make sense to patent every component or process. But such unpatented products or processes, often developed under trade-secret procedures, could become vulnerable to a charge of infringement from a later-granted patent on the same subject matter, threatening an entire product or process based on an unpatented component. This is of particular concern with the move to the "first inventor to file" system in the AIA, since the prior secret art would not invalidate the patent. An important concession to universities in the AIA was a carveout from the assertion of the defense for university-owned inventions. In addition, to be eligible for the prior user rights defense the product or process must have been in commercial use for at least one year before the effective filing date of the patent application (or disclosure qualifying for the one-year grace period).

Given the controversy, the AIA mandated that the U.S. Patent and Trademark Office (PTO) provide a report on the operation of prior user rights, including a comparative study of the patent laws in other countries, the effect on innovation and the ability of startups to attract venture capital, the effect on small business and universities, legal and constitutional issues, and an analysis of the need for prior user rights with the change to a first inventor to file system. The PTO report was released on January 17. It found that the AIA treatment of prior user rights "strikes the right balance," with no substantial evidence of negative impacts. It recommended that the defense be maintained with no change for now, but should be reevaluated by PTO as part of its required 2015 report to Congress on the implementation of the AIA. (The report is available at www.uspto.gov/news/pr/2012/12-05.jsp . It contains a comprehensive and helpful discussion of the background of prior user rights and a comparative analysis).

A hearing was held on the PTO report on February 1 by the House Judiciary Subcommittee on Intellectual Property, Competition and the Internet. Witnesses included PTO Director David Kappos, representatives of Eli Lilly and Cisco, and a law professor. The university community was represented by AAU. Three concerns were raised about the AIA prior user rights provision: the required one-year "lookback," the fact the defense applies only to actual commercial use and not substantial preparation for use, and inconsistencies in the AIA with regard to the subject matter covered. Director Kappos indicated that while PTO felt the AIA achieved the right balance, he agreed the three concerns were legitimate. While most other countries have prior user rights, in most cases these extend to substantial preparation for commercial use and do not require that the use take place at least a year before the patent filing. However, the AIA had made good progress, and he recommended that changes of this type be considered as part of the 2015 reevaluation, when more data on impacts will be available. He also pointed out that the university exemption was not found elsewhere and not part of the "harmonization"

objective of patent reform. However, he felt that U.S. university technology transfer is a “21st century best practice,” and that this should not be part of harmonization. The company witnesses also supported the university exemption.

There was further discussion in the hearing of the tension between trade secret and patent protection, which prior user rights help address; the risks associated with commercializing early stage university inventions and the possible adverse effects of prior user rights; and the effects of prior user rights on U.S. job creation (which devolved into a discussion of company practices with regard to outsourcing jobs abroad). There was some encouragement from the Congressional representatives to seek a further compromise, such as through further defining substantial preparation. However, there was not a strong signal from the Subcommittee that changes in the AIA should be made at this time. (A record of the hearing may be found at http://judiciary.house.gov/hearings/Hearings%202012/hear_02012012.html).

PTO Issues Proposed AIA Implementing Rules - We noted in the COGR Fall 2011 Update that the PTO website contains a useful chart of the effective dates and other information on the planned AIA implementation at http://www.uspto.gov/patents/init_events/aia_implementation.jsp. PTO now has issued a number of proposed rules, covering the Inventor’s Oath or Declaration (77FedReg982; 1/6/12); Third Party Submission of Prior Art in a Patent Application (77FedReg448; 1/5/12); Citation of prior art in a patent file (77FedReg442; 1/5/12); Statute of Limitations Proceedings for Office Disciplinary Actions (77FedReg457; 1/5/12); Supplemental Examination (77FedReg3666; 1/25/12); and a Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing (77FedReg3748; 1/25/12).

Members of COGR’s CIP Committee are participating in an AAU Patent Reform Implementation Task Force which is analyzing the proposed rules and considering whether to submit comments. It is not clear at this time whether we will comment on any of the proposed rules. The Task Force also is discussing concerns that have been raised about the grace period for publications in the AIA. The AIA is unclear as to whether the one year grace period covers only disclosures of subject matter identical to the original disclosure, or also covers subsequent disclosures of obvious variants. If the grace period is limited only to disclosures of identical subject matter, it will not establish a priority filing date protecting the inventor against intervening patent applications that claim obvious variants. On the other hand, if the subject matter covered by the grace period is too broad, the inventor making the initial public disclosure could unfairly gain the benefit of technologies that were disclosed by others between the date of the initial public disclosure and the date that the patent application is filed, claiming they constitute an enablement of the original invention. The task force is considering possible solutions to this problem through a technical amendment to the AIA.

White House Announces New Initiative on Innovation for Global Development Including New NIH License Terms for Global Health Technologies

A White House event on “Innovation for Global Development” was held on February 8. A number of new initiatives were announced, including a new USAID university partnership program to strengthen the understanding of potential problems and the range of solutions, support multidisciplinary approaches to development and encourage innovation to improve the

efficacy of development interventions and to reduce costs to U.S. taxpayers. USAID will fund awards for single university centers and consortia centers and will request that applying universities provide matching funding to leverage USAID's investment. (For a copy of the White House Fact Sheet see www.whitehouse.gov/the-press-office/2012/02/08/fact-sheet-harnessing-innovation-global-development).

As part of this initiative, NIH will expedite licenses to not-for-profit institutions such as Product Development Partnerships (PDPs) with a demonstrated commitment to diligence in providing broad global access to technologies. It has developed a set of terms for license agreements with such non-governmental organizations (NGOs) to provide global access to NIH technologies (e.g. drugs, therapeutics, diagnostics) for prevention, diagnosis or treatment of neglected tropical diseases, HIV, TB and malaria in humans or animals. The term sheet was rolled out in conjunction with the White House event. The terms require PDPs and NGOs to submit developmental plans detailing the time and financial commitments to bring final products to application, distribution or sale. Non-exclusive licenses are favored, but limited exclusivity also may be granted. The terms provide for sharing of patent expenses between NIH and licensees and for royalties to be paid to NIH (1.5% (exclusive) or 0.75% (nonexclusive) of net direct sales). The terms are intended to apply only to government-owned patents or inventions managed by the NIH Office of Technology Transfer (i.e. inventions made by intramural NIH or FDA scientists or unpatented biological materials developed by such scientists). According to the White House Fact Sheet, DOE also will offer a license to not-for-profit organizations with a demonstrated commitment to providing global access to clean technologies and services. Licensees will pay a reduced fee and a nominal royalty. These organizations will have access to the unlicensed patents held at DOE Headquarters for clean energy technologies. (We have not yet seen a copy of the DOE terms).

The Administration is anxious to promote these types of initiatives and asked AAU and APLU for similar commitments from universities. AAU and APLU have posted a statement on their websites on "Ensuring Global Access to Medical Advances" (www.aau.edu ; www.aplu.org).

Many universities and university associations including COGR, AAU and APLU have endorsed Point 9 of *In The Public Interest: Nine Points to Consider in Licensing University Technology* document (available at www.autm.net/Nine-Points_to_Consider.htm): "Consider including provisions that address unmet needs, such as those of neglected patient populations and geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world" including "Universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of these medical innovations." The AAU/APLU statement includes these quotations. However, previous efforts to develop model license terms and agreements in this area have raised concerns in the tech transfer community. Such terms have been viewed as too prescriptive, putting too much emphasis on academic licensing as the critical factor in inhibiting access, and ignoring other important policy goals of university licensing. While we support the intent, given these concerns, we urged caution to AAU and APLU in proceeding with regard to this initiative. It also should be pointed out that the NIH terms were developed specifically for NIH technologies, although the White House Fact Sheet indicates that the University of California at Berkeley will adopt the NIH model term sheet for licensing technologies that can diagnose, prevent or treat neglected tropical diseases, malaria, tuberculosis and AIDS.

Export Controls: DTAG Discusses Changes in Definitions of “Fundamental Research” and “Defense Service”

The Plenary Minutes of the November Meeting of the Defense Trade Advisory Group (DTAG) (http://www.pmddtc.state.gov/dtag/documents/plenary_minutes_11_11.pdf) include the following excerpt:

“Finally, the Working Group proposed a modified definition of fundamental research in a new section of Part 120 of the ITAR (rather than defining it within the definition of public domain). The new definition would clarify that fundamental research could occur anywhere (and is not limited to educational institutions) and that the inputs into fundamental research may require licensing prior to release to foreign students, even if the results of the research are considered “fundamental research.”

We had understood that a new definition of fundamental research was under development as a part of the “harmonization” objective of the President’s Export Control Reform Initiative (see COGR February 2011 Meeting Report). It is unclear how the proposed DTAG definition relates to this effort. It also is unclear whether the proposed definition merely restates the existing understanding that use of controlled or proprietary information takes research out of the fundamental research exemption from export controls, or is intended to apply more broadly.

The DTAG minutes also contain the statement “To enable the U.S. Government to control the use of information that was not lawfully placed in the public domain, the Working Group recommended a modification to the proposed new definition of “defense service” that was published ... on April 13, 2011 to clarify that notwithstanding ...(the definition of public domain), furnishing assistance to foreign persons using information that a person knows or has reason to know has not been approved or authorized for public release by the cognizant U.S. Government department or agency constitutes a defense service.”

We supported the change in definition of defense service last year that excludes furnishing assistance including training using data solely in the public domain from being considered to be a defense service (see COGR May 2011 Update). The proposed clarification appears to introduce a subjective element that may be a step backward.

Neither of the proposed modified DTAG definitions has been formally proposed. We already have informally communicated our concerns to a government representative about the proposed changes. Should they be formally proposed, we will respond appropriately.

Final FAR Rule on Public Access to FAPIIS Adopted

The January 3 *Federal Register* (77*FedReg*182) contained a series of changes to the Federal Acquisition Regulations (FAR). None appear to have a major impact. The most significant change for COGR member institutions is Item V (77*FedReg*197; FAR Case 2010-016), which adopts as final the interim rule on public access to the Federal Awardee Performance and Integrity Information System (FAPIIS; see COGR February 2011 Update). The final rule allows an automatic 14-calendar-day delay before data is posted to the public segment of FAPIIS. In response to concerns about proprietary data or data that otherwise may be protected under Freedom of Information Act exemptions, contractors have 7 calendar days within those 14 days to assert a FOIA disclosure exemption. In such cases the information will be removed subject to

normal FOIA processes. Also there is now more space in the FAPIIS system for contractor comments regarding information that is posted.

COGR members are reminded that all information posted in FAPIIS on or after April 15, 2011 now will be posted (after the 14-day delay) in the segment accessible to the public, except past performance reviews (or information that is withdrawn because of FOIA issues). Contractors must update FAPIIS information semi-annually throughout the life of the contract. Contractors will receive notice of all new information posted in the system. Fortunately the \$500k statutory threshold for solicitations and contracts triggering FAPIIS reports has not been lowered.