COUNCIL ON GOVERNMENTAL RELATIONS

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August 24, 2009

TO: COGR Membership

FROM: COGR Staff

SUBJECT: August 2009 Update

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ARRA Update; FederalReporting.gov Registration

The American Recovery and Reinvestment Act of 2009 (ARRA) was signed into law on February 17, 2009. Now, more than six months later, Universities and Research Institutions are receiving awards and getting prepared to report for the first time. Agencies issuing research awards clearly face a significant challenge to expedite the award process even though the dollar volume and number of awards to be issued is overwhelming. Using NIH, NSF, and DOE as examples, ARRA obligations as a percentage of "normal" annual research appropriations computes to dollar volume increases of roughly 33%, 50%, and 100%, respectively. Agency Inspector General (IG) offices are very attentive to the protocols the agencies are using to award

funds, and consequently, the agencies must be attentive to both quickly disbursing funds and exercising their stewardship responsibilities.

And of course, the October 10th reporting deadline looms. While this is another source of stress for the awarding agencies, it is equally stressful for the Universities and Research Institutions. To be in compliance with ARRA, the reporting requirements under Section 1512 of ARRA must be met. Many of your institutions have already registered for www.FederalReporting.gov. If your initiation has not registered, it is important to do as OMB has encouraged early registration. Also, if you will be delegating any reporting responsibilities to your subrecipients, they will need to register on FederalReporting.gov. Furthermore, prime recipients (and subrecipients who will be given rights by the prime to access FederalReporting.gov) must complete registration with the Central Contractor Registration (CCR) and Dun & Bradstreet (DUNS). Once again, time is of the essence as CCR and DUNS registration could require a week or more to confirm registration. CCR and DUNS information is available at:

CCR: http://www.ccr.gov/FAQ.aspx DUNS: http://fedgov.dnb.com/webform

If you have any questions regarding registration, the FederalReporting.gov Service Desk can be reached by phone at 1-877-508-7386 or by email at support@federalreporting.gov. According to the Messages posted on FederalReporting.gov, the Service Desk will be available for user support from 7 a.m. through 9 p.m. (ET) Monday through Friday to support registration. The FederalReporting.gov system opens for reporting on Thursday, October 1, 2009 and the Service Desk will be available 24 hours, 7 days a week during the reporting period. **ALSO NOTE, please do not contact the funding agencies (e.g., NIH, NSF, DOE, etc.) with questions related to registration; OMB has primary responsibility for managing this process and the funding agencies are not able to provide technical support.**

Staying Current with ARRA and the COGR-FDP FAQs

COGR has made the commitment to utilize a diverse set of resources to keep the membership up-to-date on developments related to ARRA. This includes use of the COGR ListServe, access to Comment Letters and other information on www.cogr.edu, and a new effort: a COGR-FDP Frequently Asked Questions (FAQs) interface. The FAQs are the initiative of a joint COGR-FDP Working Group and are driven by questions being gathered on an ongoing basis from the COGR and FDP memberships. Questions are answered to the best of our knowledge based on reviews of all available ARRA information, as well as discussions with Federal representatives. The FAQs include links to specific Federal guidance and they will be regularly updated to provide the most current information.

The first three FAQs under the COGR-FDP FAQs were designed to provide the COGR and FDP memberships with broad guidance and orientation to the most immediate and important information on ARRA. The third question, "*Where can I find the most up-to-date Federal Guidance on ARRA?*", provides the link to the OMB-Recipient Reporting Information (http://www.recovery.gov/?q=content/recipient-reporting). The OMB-Recipient Reporting Information provides access to the June 22nd OMB Implementing Guidance, OMB FAQs on the June 22nd Guidance, Technical Reporting documents (i.e., Data dictionary, Excel templates, XML schema, etc.) applicable to FederalReporting.gov, and the Registration guides for FederalReporting.gov.

In addition, the main body of the COGR-FDP FAQs addresses these topics:

A. INTRODUCTORY INFORMATION AND ARRA SPECIAL TERMS
B. INSTITUTION PREPARATION
C. REPORTING
    C1. Reporting Submission Basics - FederalReporting.gov
    C2. Reporting Dates, Timelines, and Data Correction
    C3. Subrecipient Reporting
    C4. PI Reporting
    C5. Vendor Reporting
    C6. Jobs Reporting
    C7. Letter of Credit (LOC) Draw and Reporting
D. AUDIT & ACCOUNTABILITY
E. F&A RATE PROPOSALS AND NEGOTIATIONS

Sections A, B, C1, and C2 have been posted. The remaining sections are being developed. We expect the next update to the FAQs to take place by August 28, followed by additional updates on a regular basis. The www.cogr.edu home page, under Recent COGR News, will always show the date of the most recent update to the FAQs.

Finally, you can visit the FDP ARRA web site at:
http://thefdp.org/ARRA%20Award%20Management%20and%20Reporting.html

In addition to having a link to the COGR-FDP FAQs, the FDP page provides links and information to other ARRA topics. Also on the FDP page is a "Send a message to the ARRA ListServe" link. The COGR-FDP collaboration has resulted in the FDP's invitation to COGR members that are not members of the FDP to participate in the FDP ListServe. We encourage all COGR members, those that are FDP members as well as those that are not FDP members, to participate in the FDP ListServe. The FDP ListServe should serve as an additional resource to address ARRA-related questions.

F&A Rate Negotiation Summaries

In the June Meeting Report (dated July 13, 2009), we indicated that the COGR Costing Committee would begin collecting information from the membership concerning recent F&A rate negotiations. While we have not finalized a template, we would like to begin gathering information. For example, some of the questions in which we are interested include:

- What were the results of your recent negotiation?
- What were the primary concerns by the Federal negotiators?
- Was ARRA and related research base growth an issue in the negotiation?
- Was ARRA discussed in other contexts?

Also, we want the COGR Survey of F&A Rates to be a real-time, up-to-date study, so it is important that we receive the most recent F&A rate negotiation information from your institution. **If you have completed a rate negotiation within the past 12 months, please contact David Kennedy at** dkennedy@cogr.edu**.** We can make sure the COGR Survey is updated, and also communicate on the questions listed above.

GAO Study of 35% DOD Cap

As we reported in the June Meeting Report (dated July 13, 2009), the GAO sent a 20-page survey on "F&A Costs and Cost Reimbursement" to 180 universities. By now, most of you who received the survey have completed it and returned it to the GAO.

The GAO Study on F&A costs and reimbursement was requested by Congress last year and the results of the survey could be used to determine how the 35 % DOD F&A cap will be addressed in future DOD appropriation bills. While COGR has had correspondence with the GAO team in charge of the survey and would like to be able to pre-review and comment on preliminary survey results, we are not sure how the GAO will proceed with analyzing the survey results. Our understanding is that they still expect to report to Congress by October 14.

The survey addressed issues such as the administrative cap and regulatory burden, and some of you took the opportunity to explain in narrative form the real financial impacts of caps and unfunded compliance mandates. We expect that the GAO will carefully review these comments.

On a related note, Congress also asked the GAO to look at Industry F&A rates and reimbursement. We are uncertain how the GAO has approached Industry, but since Congress requested Industry be included in the study, our hope is that the GAO has gathered this information. Our contacts at the GAO have indicted that they can be contacted if you have questions related to the study, and we encourage you to follow up with Janet McKelvey at 617-788-0528 or Scott Purdy at 617-788-0508 to address any questions you may have. We will keep the membership posted on additional developments as we learn more.

National Science Board (NSB) Report on Cost Sharing; Final Version

The NSB has finalized their report on cost sharing, "Investing in the Future: NSF Cost Sharing Policies for a Robust Federal Research Enterprise". Currently, it is only available in hard copy, though we expect it will be available on-line in the near future. Essentially, the same recommendations made in the Draft report and that COGR reported on in the Winter 2009 Update (dated February 6, 2009) are included in the final version. Some of the highlights of the final report are shown below.

- On pages vii and 3, the major emphasis of the report is stated: "In this report, the National Science Board (Board) prescribes a set of recommendations with two primary objectives: (1) to allow, but narrowly circumscribe, the application of mandatory cost sharing requirements in NSF programs in which such cost sharing is foundational to achieving programmatic goals, and (2) to prohibit voluntary committed cost sharing in NSF proposals and thus eliminate post-award tracking and reporting requirements associated with such cost sharing."

- In total, the NSB makes 8 recommendations. Recommendation 6 (page 11) addresses the prohibition of voluntary cost sharing on both solicited and unsolicited proposals.

- Recommendation 6 also suggests that the Facilities, Equipment, and Other Resources (FER) section of NSF proposals be used to allow institutions to more fully describe resources available to the project. This would not include cost commitments, but rather

would allow for the opportunity to expand on the important elements of the institution's research infrastructure and the strategic vision related to its research enterprise.

- A notable "other recommendation" (page 14) includes: "The Board understands the fundamental intent of the administrative rate reimbursement cap – to ensure that the majority of research funding supports direct research effort, rather than administrative costs – but also concurs with the general view of the research community that the current 26 percent reimbursement cap requires re-evaluation."

The NSB report provides significant statements on a number of cost reimbursement and accounting issues that are important to the research community. As appropriate, we will make ourselves available to the National Science Board and NSF to explore how these recommendations could be further advanced on a more overall, Federal-wide basis. We will keep the membership updated on these efforts.

Furlough Programs and Implications for Financial Research Compliance

In the June Meeting Report (dated July 13, 2009) we informed the membership that COGR would be completing an analysis titled: "Furlough Programs and Implications for Financial Research Compliance". While we had planned to finalize the document earlier, the complexity of some of the issues resulted in the need for extra time. However, with that extra time, we have been able to establish an in-depth analysis of a number of important considerations. Included in the analysis are discussions covering:

- Rate of Pay and A-21 Compliance
- Application of furlough days based on funding source
- Effort Commitment implications
- Differential treatment of employee types
- Federal government perspective

The Federal government perspective discussion is centered on the theme of uncertainty. More specifically, there is no Federal requirement to have furlough plans approved – just the ongoing requirement to be in compliance with Circular A-21. While representatives from OMB, Funding agencies, or the Cognizant agencies (DCA-DHHS, ONR) could all provide feedback, it is unlikely that a single Federal official would be in a position to issue broad pronouncements. Therefore, institutions might have to accept some risk of implementing a plan without formal approval. However, any risk is minimized by showing compliance with the Federal costing principles, maintaining documentation that supports payroll charges and corresponding effort are in alignment, and demonstrating that the plan is being closely monitored by internal staff and audit personnel.

The Working Group that has contributed to the analysis has provided incredibly thoughtful and important insights. Finalizing the paper now rests with COGR, and you can contact David Kennedy at dkennedy@cogr.edu to receive an update. The paper should be completed this month, and as previously offered, the draft version can be obtained as a confidential copy. Upon completion of the final version, we will notify the membership via the COGR ListServe.

NASA Letter of Credit and Continuation Funding

Several COGR members have notified us of an issue involving NASA and a Letter of Credit "re-engineering project" that took place this past November 2008. This process involved the transition of awards between payment centers. As a result, there were a number of institutions whose opening balances were incorrect in the new payment center. In January 2009, NASA sent an e-mail where they acknowledged balance issues, and the recipient list was quite extensive.

Problems have included availability of funds for draw, and subsequently, problems with continuation funding for awards. Since the balances are incorrect, NASA has not been posting the draw activity. As a result, awards which should be receiving continuation funding are being viewed as having a spend rate issue and continuation funding is either being held or is at jeopardy for removal.

If your institution has experience and/or insight with this issue, please contact David Kennedy at dkennedy@cogr.edu. COGR is attempting to contact the appropriate individuals at NASA and will keep the membership posted on what we learn.

Administration Announces Support for Implementation of E-Verify

As noted in recent COGR Updates, implementation of the E-Verify employment eligibility requirement for federal contracts had been postponed to allow the Obama Administration additional time to review the rule. On July 8 the Department of Homeland Security (DHS) announced their intention to fully implement the requirement effective September 8, 2009. At the same time, the Administration will rescind the Social Security "No Match" rule, which has never been implemented.

The requirement will only affect federal contractors who are awarded a new contract after September 8, 2009 that includes the Federal Acquisition Regulation (FAR) E-Verify clause (73 FR 67704; FAR 52.222-54). Federal contractors may **NOT** use E-Verify to verify current employees until the rule becomes effective and they are awarded a contract that includes the FAR E-Verify clause. This new rule requires federal contractors to agree to use E-Verify to confirm the employment eligibility of all persons hired during a contract term, and to confirm the employment eligibility of federal contractors' current employees who perform contract services for the federal government within the United States. Basically it requires that Form I-9 information be entered into the E-Verify system, which checks the information against various government databases. For more information see www.uscis.gov/everify.

We extensively discussed the E-Verify requirement in the COGR October 2008 Meeting Report. As noted, the rule applies to prime contracts above $100,000 (the "simplified acquisition" threshold). The same clause will also be required in subcontracts over $3,000 for services or construction. Contracts for commercially available off-the-shelf items or whose performance terms are less than 120 days are exempt. Companies awarded a contract with the federal government will be required to enroll in E-Verify within 30 days of the contract award date**.** The rule implements Executive Order 12989, as amended by President Bush on June 6, 2008, directing federal agencies to require that federal contractors agree to electronically verify the employment eligibility of their employees. For institutions of higher education, the E-Verify requirement covers only those employees assigned to a Government contract (although we

understand that some institutions plan to include other employees not currently assigned to federal contracts).

COGR Again Discusses Foreign National Approval Requirements with DOD

Among the most contentious issues identified in our "Troublesome Clauses" surveys have been requirements for agencies to approve the participation of foreign nationals in funded awards. One of the most longstanding requirements of this nature is that of the Army Corps of Engineers, based on Corps regulation 380-1-18 (Sec. 4.14) (see http://140.194.76.129/publications/eng-regs/er380-1-18/toc.htm). The regulation is based on 8 USC 1324(a), which makes employment of unauthorized aliens (including by contract) unlawful. The regulation requires positive verification of the identity of foreign personnel working under contract. It is typically implemented through a provision in the Special Contract Requirements (Foreign National Clause) which requires approval of all foreign nationals working on the contract by the Corps Foreign Disclosure Officer.

Universities have objected to this requirement on the grounds that 8 USC 1324(a) requires employers to verify the legal eligibility of employees to work in the U.S. Enforcement responsibilities are assigned to Labor and/or INS. Federal and in some cases state laws preclude sharing of the documentation with other agencies. In addition, acceptance of these requirements from contracting agencies may threaten the universities' ability to claim the fundamental research exclusion from export controls. Universities have had varying success with Corps installations in negotiating the requirement. Over the years COGR also has had inconclusive discussions with both DOD and Army officials about the Corps foreign national approval requirement.

However, we have pointed out to DOD that with implementation of E-Verify for all federal contracts the Corps requirement now seems redundant and duplicative. We understand that the issue is under discussion within DOD, and are hopeful that the discussions will lead to withdrawal of the Corps regulation and clause. We believe any similar employment verification requirements of other federal agencies also should be withdrawn upon implementation of E-Verify.

Note: COGR members should be aware that the Special Contract Requirements section of Army Corps contracts may contain under "Foreign National Clause" both the ER 380-1-18 foreign national employment eligibility verification requirement and a separate requirement for screening of contractor employees who have access to government automated information systems through a required National Agency Check. This latter requirement is related to the Federal Information Security Management Act of 2002 and Homeland Presidential Security Directive 12 (see COGR Fall 2007 Update for more discussion of implementation of these requirements in federal contracts). It is not affected by E-Verify or relevant to issues of employment eligibility verification.

Administration Reviewing Export Controls; New Export Administration Act Planned

On August 13 the Administration announced that the National Economic Council and National Security Council will jointly oversee an interagency review of the existing system of export controls (see http://www.whitehouse.gov/the_press_office/Statement-of-the-Press-Secretary/). In a subsequent statement, House Foreign Affairs Chairman Howard Berman said that he has

launched a congressional review of dual-use exports. He plans to introduce a new Export Administration Act in early 2010. A number of industry groups have announced strong support for the review.

The export control system has been under somewhat continuous review in recent years, as discussed at many COGR meetings. Perhaps the most prominent recent review was that of the Deemed Export Advisory Committee (DEAC; see COGR February 2008 Update). The DEAC found that too many technologies currently are subject to deemed export controls. It recommended that the list of technologies subject to such controls be drastically reduced. It also found that that the deemed export regulations are overly complex and arcane, that the current Commerce Control List (CCL) for both actual and deemed exports is too all-encompassing, and that the licensing process should be simplified and streamlined. In response Commerce established the Emerging Technologies and Research Advisory Committee (ETRAC). As noted in our recent June Meeting Report, the ETRAC is focusing on developing a "zero-based" methodology for review of the Commerce Control List and clarifying certain definitions in the Export Administration Regulations (EAR).

It is not clear how these new reviews will relate to the DEAC/ETRAC activities. However, the EAR has been kept in force by a series of continuations of Executive Order 13222 under the International Emergency Economic Powers Act. The Administration extended the authority for the EAR for another year on August 13 (74 FR 41325). Thus Congressional reauthorization is more than timely. Also, most of the recent review activities have focused on the Commerce dual use regulations. The interagency review also will consider the International Traffic in Arms Regulations (ITAR) for defense items overseen by the State Department. Hopefully the new reviews will lead to badly overdue simplification and clarification of both sets of regulations.

GAO Issues Report on March-In Rights

We have reported a number of times on the pending Government Accountability Office (GAO) report on "march-in" rights under the Bayh-Dole Act. The Report (*Information on the Government's Right to Assert Ownership Control over Federally-Funded Inventions*) was issued on July 27, 2009 (GAO-09-742). It is available at http://www.gao.gov/cgi-bin/getrpt?GAO-09-742

The report is reasonably balanced, and contains no recommendations. It is based mostly on discussions with federal officials at NIH, NASA, DOD and DOE. COGR is not specifically listed among the stakeholder groups contacted, although we had two lengthy meetings with GAO representatives, in person and by phone.

The Report discusses reasons why the agencies have not exercised march-in authority under Bayh-Dole, nor issued agency-specific guidance. These mostly involve the lack of any demonstrated need. Of the four agencies, only NIH has been petitioned to march-in under Bayh-Dole, and has denied all three requests. However, all of the agencies except DOE believe the authority is valuable because it provides leverage to promote commercialization of federally-funded inventions. All agencies rely on the public to identify potential candidates for march-in (the legislative history of Bayh-Dole indicates that this was the expectation). The report also discusses the government's license right, licensing guidance issued by NIH, and the "other transactions" authority as ways other than march-in to assure commercialization and use of federally-funded inventions.

The report identified four disincentives to the use of the Bayh-Dole march-in authority. These are: 1) the potential "chilling" effect such an action might have on the willingness to invest in commercialization of the technology; 2) its unworkability in a time-critical situation; 3) the fact that commercial products based on federal inventions may employ multiple patents, some of which are not federally funded, which poses difficult if not intractable issues for exercise of march-in; and 4) the loss of specialized knowledge of licensees that might jeopardize commercialization.

The Report clarifies the concern we had with the initial draft about seeming confusion between agency march-in and license terminations. It does, however continue to note a possibly chilling effect of march-in on researchers' participation in federally-funded research. It acknowledges that none of the officials contacted was aware of any such specific instances. We had told GAO that we doubted there was much of a chilling effect on researchers.

The only real surprise in the Report is the statement (pp. 2—3) that the legislative requirement for a 5-year recurring GAO review of Bayh-Dole implementation was eliminated last March, in the '09 Omnibus Appropriations Act. We had not previously been aware of that development. There appear to be pluses and negatives. Some of the previous GAO findings were of concern (e.g. failure of federal awardees to properly disclose inventions). On the other hand, the periodic reviews did provide visibility and a forum for discussion of Bayh-Dole implementation issues.

The Report is directed to the House and Senate Judiciary Committees. Those Committees remain quite interested in Bayh-Dole, but we currently are unaware of any planned follow-up activities.

NIH Issues BRDG-SPAN Pilot Program Announcement

On June 3 NIH announced an ARRA-funded pilot program (RFA-OD-09-008) to address the funding gap between promising research and transitioning to the market (the so-called "Valley of Death"). The full program name is *Biomedical Research, Development and Growth to Spur the Acceleration of New Technologies.* Under this program applicants can request funding to carry out later stage research activities necessary to move a technology along a pathway to commercialization. NIH expects to commit $35M and make 10 awards under this program, limited to $1M/year for a three year maximum. Applications are due by September 1, '09.

The program is aimed at for-profit U.S. companies. However, individuals with university appointments may serve as project directors/principal investigators, provided they commit a minimum of 10% effort and have an "official relationship" with the applicant organization. Small business applicants are given priority.

The program is similar in concept but larger in scope than related programs such as SBIR/STTR and NSF's Partnerships for Innovation (PFI). It also is explicitly aimed at providing later stage "gap funding," which is not fully addressed by SBIR/STTR (NSF's SBIR/STTR "Phase IIB" option does provide gap funding which with the required third party match can provide a maximum of $1M for up to two years).

While universities can participate in a subcontract capacity, they are not eligible for direct awards under any of these programs. Recently there has been intense interest in mechanisms to encourage and expand the university role in regional economic innovation. The university

associations have been deeply engaged in discussions of this subject (see e.g. APLU Commission on Innovation, Competitiveness, and Economic Prosperity, http://www.aplu.org/NetCommunity/Page.aspx?pid=265). A program such as BRDG-SPAN focused on universities could be one such mechanism. We expect to continue discussions with the other associations about possible initiatives in this area.

UIDP Holds Ninth Meeting

The University—Industry Demonstration Partnership held its 9th meeting on August 3—5 at Monsanto Company headquarters in St. Louis. The meeting was very productive, with presentations from Monsanto as well as other local companies including start-ups on their strategies and experiences with technology commercialization. Other sessions included a presentation on conflict of interest and its impact on U-I Partnerships, NSF's partnership programs, and a presentation on security risks by a local FBI representative.

There also was a plenary session and a very well-attending working group session on export controls. The plan is to try to develop a contract accord on export controls, which if successful could be a big help to universities in negotiating contracts and subcontracts with industry involving export controlled technologies. One possible focus might be agreement on the scope of the fundamental research exclusion.

The next full UIDP meeting will be in March 2010 in Atlanta.

New PCAST Holds First Meeting

The newly-formed President's Council of Advisers on Science and Technology (PCAST) held its first meeting on August 6—7. The co-chairs are Harold Varmus, former Director of the National Institutes of Health, and Eric Lander, Director of the Broad Institute of MIT and Harvard.

The first day included presentations and discussions on healthcare and energy. The American Recovery and Reinvestment Act (ARRA) includes $20B for integrating health information systems, where the level of technology is "appalling," according to the meeting discussion. The PCAST also met with Department of Energy Secretary Steve Chu. He echoed some of the themes mentioned by Energy Undersecretary Steve Koonin at the June COGR meeting, including concerns about STEM education and development of energy technologies. He recommended that PCAST look into DOE's funding methods, especially in the applied areas. Chu expressed the view that the DOE Office of Science is "as good overall as NSF," but indicated that he had questions about some of DOE's applied areas, where PCAST advice might be helpful.

The second day featured reports from the various PCAST subcommittees. The STEM Education Subcommittee is considering studies on how best to increase the number of STEM teachers, curriculum goals, national standards, IT-based classrooms, and the role of community colleges. The Innovation and Technology Subcommittee will focus on advanced manufacturing and advanced computing and communication for their potential economic gains. The Economic Development Subcommittee may review where the government can make more effective infrastructure investments, and the best type of government standardization activities for networks. The International Security Subcommittee is interested in the potential hazards of space debris, issues related to the Comprehensive Nuclear-Test-Ban Treaty and related issues for

weapons labs, and the national portfolio of S&T activities in support of Homeland Security. Finally, the Energy and Environment Subcommittee's list of possible areas of research include carbon offsets, climate observations, energy R&D, and climate adaptation.

Presidential Science Adviser John Holdren noted that President Obama is "overwhelmingly supportive" of science, and that the scientific community must step forward to work with policy makers in areas of national interest. A webcast of the meeting can be found at http://www.tvworldwide.com/events/pcast/.

Follow-on Biologics Provisions Stir Controversy

Among the controversial items in pending Congressional health care reform legislation are provisions dealing with "follow-on biologics" or biosimilars. These are biological treatments based on biotechnology inventions, often stemming from university research.

The current debate centers on the appropriate period of data exclusivity for such biologic treatments. **COGR has taken no position on this issue or on any pending legislation that addresses it.** However, in June AAU endorsed H.R. 1548, the "Pathway for Biosimilars Act." This would provide 12 years of data exclusivity for innovator companies. A competing bill (H.R. 1427) would limit the data exclusivity period to five years. The Administration supports a seven-year period.

A number of consumer groups are strongly opposed to the 12-year period of exclusivity. In a July 14 letter the Universities Allied for Essential Medicines (UAEM) and other student groups demanded that AAU rescind its support of the legislation (see http://www.essentialmedicine.org/).

On July 13 the Senate Health, Education, Labor and Pension Committee approved an amendment to health care reform legislation that provides for 12 years of exclusivity for biologic drug manufacturers, rejecting an amendment that would have limited protection from generic competition to seven years. A hearing on the legislation by the House Judiciary Committee was held on July 14.

We understand AAU continues to believe that the 12-year period balances the need for incentives to encourage investment in development of biologic treatments with the need to encourage competition and assure patient access. UAEM and other groups strongly disagree. The COGR CIP Committee does not believe we have sufficient information to take any position on this matter, or to support any particular period of exclusivity. Given the ongoing debate we wanted COGR members to be aware of our views.

NSF Implements RCR

In the August 20, 2009 Federal Register, the National Science Foundation (NSF) announced the implementation of the America COMPETES Act provisions for the "training and oversight in responsible and ethical conduct of research" (RCR) for students and postdoctoral research fellows.

Effective for applications submitted on or after January 4, 2010, NSF will require the proposing institution's authorized organizational representative (AOR) to certify that the institution has a

plan to provide appropriate training and oversight for students (undergraduate and graduate) and post-doctoral fellows who will be supported by NSF to conduct research. Plans are not to be submitted with the proposals. However, NSF reminds the applicants that the plans are subject to review on request. Institutions will be required to verify that the students and fellows have received the required training.

The approach taken by NSF – certification by the AOR and maximum flexibility for the institution to design a training program and oversight system tailored to the institution's students, fellows and disciplines – mirrors the position COGR advocated in its comments in February 2009. We are pleased that NSF will continue to support research in effective training practices and will build a resource of information and tools to assist institutions in meeting this requirement.

Under this policy approach, Institutions will be able to design and deliver training programs that reflect the institution's NSF-supported disciplines and deliver that training at a level appropriate to the student's and fellow's academic position. The content and mode for delivery – seminars, web-based programs, etc – will be determined by the institution. The institution is required to train and track only those students and fellows supported by NSF funding. However an institution can choose to provide training to a greater number of students at its discretion.

There are a range of materials available to institutions to assist in implementing a program. Those institutions that have National Institutes of Health (NIH) trainees will have a program in place that might be adaptable to meet the NSF requirement. NSF will be building a "library" of materials to assist institutions in meeting the requirements as well.

NSF has not defined a role for the principal investigator(s) (PIs) in the training process. Institutions will want to work with their PIs in delivering training programs that compliment their research activities and incorporate institutional policies and procedures. However, institutions will want to caution PIs to be thoughtful about describing unique, individual training activities within the proposal itself. Because the activities appear in the proposal, auditors or inspectors may expect those training activities to be tracked as a part of the institution's plan.

NIH Stem Cell Guidelines Extended to All Agencies

In a July 30, 2009 memorandum to all federal departments and agencies, President Obama directed all agencies that conduct human embryonic stem cell research to adopt the NIH Guidelines issued on July 9, 2009 (and reported on in the COGR June Meeting Report). The agencies are directed to report to the Office of Management and Budget (OMB) by October 30 on any proposed additions or revisions to the agency's current guidance, policies or procedures to bring its policies in line with the NIH Guidelines. OMB, in consultation with NIH, will review the proposed revisions to ensure consistent implementation of the NIH Guidelines across the agencies. COGR will monitor any proposed changes to agency guidelines for consistency as well. The President's Memorandum is available at http://www.whitehouse.gov/ in the Briefing Room under Presidential Actions or in the August 5, 2009 Federal Register (74FR38885).

NIH issued a notice on July 15, 2009 describing the *Status of Applications and Awards under the New NIH Guidelines for Human Stem Cell Research* (NOT-OD-09-123). The notice makes clear that NIH will continue to accept new and competing applications proposing human embryonic stem cell (hESC) research but, until the NIH Registry of eligible cell lines is available, applicants

should not include a specific cell line in their applications. On-going investigations can complete work begun in the currently approved competitive segment of the award but no new uses of hESC should be initiated by the investigators. Pending applications that have been approved for funding will be awarded but the hESC research must be delayed until the NIH Registry is available. Investigators and their institutions should review the NIH notice for complete details.

OMB Updates Guidance on Lobbyists and ARRA

On July 24, 2009, Peter Orszag, Director of OMB, updated OMB's April Guidance Regarding Communications with Registered Lobbyists About Recovery Act Funds. This Guidance has been developed to implement President Obama's March 20, 2009 Memorandum focused on "Ensuring Responsible Spending of Recovery Act Funds." The President's goal in issuing the memorandum was to ensure or enhance merit-based decision-making in the distribution of Recovery Act funds. To that end, the President prohibited oral communication between federal agency officials and registered lobbyists concerning specific Recovery Act projects.

OMB Director Orszag's recent memo to agencies clarifies how this restriction is to be applied. OMB has applied the restriction on oral communication during the period after the submission of formal applications for and up through awards of competitive grants or other competitive forms of federal financial assistance under the Recovery Act. The restriction on initiating oral communications concerning pending competitive Recovery Act applications applies to all individuals outside the federal government – not just federally registered lobbyists.

COGR has received a number of inquiries from members concerning this restriction. We urge you to consult with your institution's general counsel and/or federal relations staff concerning how this restriction applies to administrative and scientific staff members, including principal investigators. Some oral communications (initiated by the applicant) with federal officials may be restricted but not all communications falls under these provisions. Consultation with the institutional experts – counsel or federal relations staff – will ensure that the initiation of communication with federal officials is appropriate.

OBA Self-Assessment Tool for IBCs

The NIH Office of Biotechnology Activities has developed a self-assessment tool that institutions can use to evaluate their own Institutional Biosafety Committees (IBC) and programs of oversight of recombinant DNA research. The tool is available on the NIH OBA website (under recombinant DNA, Educational Materials) at http://oba.od.nih.gov/rdna_ibc/ibc_training.html . Based on the requirements in the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), the tool offers a series of questions linked to specific requirements or "expectations". As with any self-assessment tool, the institution's responses can help determine if changes in the institution's operating procedures might be appropriate. It is important to remember that, for some institutions, the responses to the questions may become a part of the public record that can be requested and reviewed by an interested public.

Each year, OBA identifies several institutions to visit and conduct reviews of the biosafety program including the operation of the IBC. OBA has been conducting these visits regularly for the past several years as a part of its oversight responsibilities. If an institution is contacted by

OBA to arrange a visit, a review of the biosafety program using the OBA self-assessment tool can be a useful preparation for that visit.

Compliance with NIH Public Access Policy

As we described in the COGR June Meeting Report, NIH is concerned that institutions (and investigators) are not in full compliance with the NIH Public Access Policy. One way to indicate compliance with the Public Access Policy requirement is to include the PubMed Central reference number in papers cited in the application (as references and within the biographical sketch). Another way is to include the NIH Manuscript Submission Reference Number (MIHMSID) in lieu of the PubMed Central number. NIH believes the NIHMSID is a temporary number only to be used for very recently accepted articles while the author completed the manuscript submission process.

In a notice posted on August 12, 2009, NIH has *Clarifi(ed) the Use of an NIHMSID To Indicate Compliance with the NIH Public Access Policy* (NOT-OD-09-136). Effective August 21, 2009, an NIHMSID may be used for up to three months after a paper is published. After that period, a PubMed Central number is required. Institutions will want to remind investigator-authors to complete the multi-tiered PubMed Central manuscript submission process in a timely manner. As NIH notes, compliance with the Public Access Policy is a condition of the award making the applicant – the institution – responsible for compliance.

COGR Comments on AAHRPP Standards

COGR submitted comments to the Association for the Accreditation of Human Research Protection Programs (AAHRPP) on its proposed revision of the standards it uses for the accreditation of human subjects protection programs. A copy of the comment (in the AAHRPP format) is posted to the COGR website (www.cogr.edu) along with a cover letter and comment on the time period for accreditation.

We focused our comments on several key issues, most notably, the broaden of AAHRPP's review of financial conflicts of interest to include institutional financial conflicts of interest, investigator "other interests," and the reference to "financial interests" as opposed to a focus on financial conflicts of interest throughout the document. The standards included a review of the organization's general business ethics which we took issue with in our comment as well. We urged the elimination of the standard/element that called for the inclusion of community members in the design, conduct and reporting of community-based research. We argued it was inappropriate to shift the responsibilities for the determination of exempt research and the need for management of that research from the organization/institution to the institutional review board (IRB).

With regard to the length of the accreditation period, we proposed extending the time from three years to five years to allow institution's to design and implement changes or enhancements to their protection programs and avoid a virtually endless process of accreditation – self assessment, application preparation and submission, site visit, response to concerns, etc. Institutions reported frustrations with the short time period, arguing that they needed to begin to prepare the next application within 12 to 18 months of the prior approval.

Finally, in the cover letter we expressed our concern with an apparent shift from performance-based standards – one of the strengths of the AAHRPP process – to more process-oriented evaluation depending on policies and procedures.