

COUNCIL ON GOVERNMENTAL RELATIONS

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Research Administration and Compliance Under Federal Government Shutdown

At the writing of this Update, an end to the Federal Government Shutdown remains unresolved. Many of your institutions are now experiencing the effects of the shutdown through selected interruptions or stoppages in research activities, financial and cash management repercussions, and other consequences related to the shutdown. Some recent challenges that your institutions have shared with COGR include:

- Denied reimbursement by the Payment Management System (PMS), even though NIH indicated in their guidance that PMS would be available except in situations that required manual intervention by agency staff.
- Treatment of university faculty and employees working under an Intergovernmental Personnel Act (IPA) Agreement as furloughed federal employees.
- Management of subrecipient agreements as the shutdown continues.

This list is growing. The “*Agency Contingency Plans*” posted on the OMB website (see below), while helpful, do not anticipate every challenge or issue.

<http://www.whitehouse.gov/omb/contingency-plans>

The analysis below is a resource to help navigate research administration and compliance activities during the shutdown – but again, as the shutdown continues, unanticipated challenges will develop.

The principal Federal agencies supporting research have issued notices outlining policy and system issues during the Federal government shutdown.

The National Institutes of Health notice (NOT-OD-13-126) is available at the still accessible but not updated website at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-126.html>.

As you know the National Science Foundation's website is not available but NSF's guidance to grantees appears at: www.nsf.gov.

Applications: Both agencies, NIH and NSF, will announce new deadline or target dates for programs with deadlines during the shutdown as soon as government operations resume. Submission through Grants.gov, which is available during the shutdown, seems unwise as the agencies will not be downloading applications to Fastlane or the eRA systems until the resumption of operations. The checks for compliance or confirmation of receipt will not occur and the potential back-log could create its own set of problems.

Reviews: Panels and study sections have been canceled and will be rescheduled as the agencies open for business.

Awards: All new awards or new increments have been halted. NIH notes that "for any awards processed before the funding lapse that have an issue date during the funding lapse, the awards will not be sent to the grantee on the issue date. Once operations resume, all pending NoAs will be sent. This will not affect the start date nor the issue date of these awards; it just affects the date the award document is actually sent to the grantee and available for access in the eRA Commons. In the absence of actually receiving the NoA, institutions may use pre-award costs authority at their own risk."

Performance: If an institution has a current award, all work and activities performed under currently active awards can continue to the extent that funds are available (e.g., within the currently approved budget).

Reporting: Because the electronic systems used for reporting, eRA Commons and Fastlane, are not available, various reports – progress, project, etc. – cannot be submitted. Nor will requests be acknowledged or responded to, e.g., no-cost extension, close-outs, etc.

Regulatory Compliance: In general, the institution's responsibilities for meeting its compliance obligations – protection of human subjects, care and use of animals, review and determination of financial conflicts of interest, inquiries and investigations of research misconduct, training in the responsible conduct of research, etc. (it's a long list) – remain the same. There is no shutdown or lapse in an institution's responsibilities; those responsibilities and requirements are on-going. Compliance and oversight staff will not be available for consultation and the systems used for reporting are not available. Emergencies related to human subjects protections under NIH awards should be reported to NIH Deputy Director Sally Rockey, (see NIH notice for contact information).

Other Agencies: The impact of the shutdown on operations across agencies is not consistent. For example, those agencies and offices with sources of revenue outside the Federal appropriations process – the collection of fees for services – remain open and operating, e.g., the Patent and Trademark office. The length of the shutdown has resulted in changes in operation during the shutdown itself. The Centers for Disease Control and Prevention

brought some workers back to address a recent salmonella outbreak, and the Department of Defense will bring back most of its civilian work force based on the reading of the law that allows the DOD to eliminate furloughs for employees whose responsibilities contribute to the morale, well-being, capabilities and readiness of service members.

This change in DOD staffing can have a direct impact on the research enterprise. The Congressionally Directed Medical Research Program (CDMRP) program deadlines have not been changed and its eReceipt system including the help desk remains available for submissions. The website site acknowledges “actions related to existing funded grants are likely to experience some delay.”

Other agencies will have implemented different policies for management during the shutdown. It is wise to check whether the agency you NEED to reach is available.

Finally, note that in a Thursday morning session at the October 24th COGR meeting, we have scheduled a session to discuss recent developments related to NIH Subaccounting/Closeout Policies. ***If we still are amidst a Federal Government Shutdown, we will plan to adjust this session to address practical coping strategies and institutional management responses to the shutdown.*** We will continue to monitor the debate and discussions concerning the Federal budget and any changes in program activity at the agencies.

Grants Reform Update

We provided an update on this topic in the August 2013 Update (published on August 29th). Included in the August 2013 Update was a summary of the outreach COGR made to other stakeholders in the grants recipient community. In addition to our longstanding allies at other higher education and research associations, we connected with associations and organizations representing State, Local, and Tribal Governments, and Nonprofit organizations.

As a result of that outreach, we worked with the other stakeholders to assemble a “Coalition in Support of Innovative Grants Reform” (i.e., CSI Grants Reform) and crafted a letter to OMB and the COFAR requesting a meeting to address our perspectives on the status of the grants reform and developments with the OMB guidance (i.e., the Omni-Circular). Primarily, the CSI Grants Reform letter raised the concern that we have with an outlying perspective (i.e., the Council of Inspectors General for Integrity and Efficiency, or CIGIE) that could jeopardize those reform opportunities that provide the most potential for regulatory relief. The CSI Grants Reform letter is available at www.cogr.edu (see Latest News, September 3, 2013).

On September 11th, our Coalition met with representatives from OMB and the COFAR. Some of the observations from that meeting include:

- 1) OMB and the COFAR appear to be interested in active engagement after the Omni-Circular roll-out.
- 2) If there are egregious issues/oversights, we should address them with OMB and the COFAR – though they have no interest in significant rewrites.
- 3) FAQs are a “must have” and OMB and the COFAR seem interested in developing them.
- 4) It is fair for us to push back on gray areas and ask OMB and the COFAR for more clarification in these situations.

- 5) Training/Webinars/etc. provided by OMB and the COFAR will be helpful – however, there still is a need for an “arbiter” in situations of agency/grantee disagreement. We should continue to encourage OMB and the COFAR to have a process to arbitrate disagreements with agency interpretations.

We believe that OMB and the COFAR have an aggressive timeline for publishing the Omni-Circular and have indicated that their goal to release the final version is December – of course, the duration of the Federal Government Shutdown could have an impact on their schedule. We are hopeful that a coalition of diverse stakeholders can prove to be an effective voice to encourage OMB and the COFAR to stay true to the President’s mandate for grants reform. We will keep the membership posted on all developments.

Thursday Afternoon Session at October 24th COGR Meeting - OMB Grants Reform and Perspectives from Other Stakeholders

Several of the organizations that we engaged with on the CSI Grants Reform outreach (see previous section) will join us in a panel discussion to provide their perspectives on the OMB grants reform initiative and other issues related to managing federal grants. Invited guests include representatives from State Governments, Tribal Governments, and Nonprofits.

COGR and FDP Influence the NIH Policy Revision - Subaccounting and Grants Closeout

We provided an update on this topic in the August 2013 Update (published on August 29th), which covered the initial announcement of these NIH policies (NIH Notice: NOT-OD-13-079, July 3, 2013) and subsequent COGR actions to engage and share concerns with NIH and the Department of Health and Human Services (HHS) Office of Grants and Acquisitions Policy.

Throughout September, we provided updates to the membership on steps that COGR was taking to advocate for a revision to the July 3rd NIH policy change. Many of you provided feedback to COGR that helped to formulate talking points to NIH and HHS. At the core of our unease with the NIH policy change was that a hasty implementation of NIH subaccounting will create a major disruption in the payment management process at research institutions, and potentially at HHS and NIH, as well.

In collaboration with the Federal Demonstration Project (FDP), we conveyed specific concerns to NIH and HHS – i.e., our concern with the implementation timeline and technical/practical concerns related to administrative burden and the functionality of the Payment Management System (PMS). Organizationally, the Division of Payment Management (DPM) is a support center under HHS and is responsible for operating PMS. The fact that a thoughtful pilot had not been undertaken by DPM highlighted the risks associated with the hasty implementation.

While our primary appeal to NIH and HHS was for a 100% delay in implementation of the transition to subaccounts, there were political pressures on NIH and HHS to initiate the policy change on October 1st (see a recent GAO report on “*Action Needed to Improve the Timeliness of Grant Closeouts by Federal Agencies*”; <http://www.gao.gov/products/GAO-12-360>). However, COGR and the FDP were successful in addressing certain issues of concern – the NIH Notice does specify that the October 1, 2013 transition will be limited to awards with new document numbers (Types 1, 2, 4, 6, 7, and 9). Continuation awards (Types 5 and 8) will be transitioned beginning on October 1, 2014.

The NIH revised policy Notice (and FAQs); “*NIH Domestic Awards to Transition to PMS Subaccounts in FY2014 and FY2015*” can be accessed at the first two links below. In addition, the third link addresses FAQs applicable to PMS procedures to process expired grants:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-120.html>

<http://grants.nih.gov/grants/payment/faqs.htm#3781>

http://www.dpm.psc.gov/awarding_agency/pms_grant_expiration_faq/pms_grant_expiration_faq.aspx?explorer.event=true

There are additional issues to be addressed, such as: 1) NIH implementation of a more strictly enforced 90-day close-out period, 2) the future relevance of the quarterly FFR, 3) better guidance on implementation procedures from the other HHS Operating Divisions (e.g., HRSA, SAMHSA, etc.), and 4) uploading/batch processing capabilities of PMS. We expect to address these issues during a COGR session on Thursday, October 24th, and through other forums over the next several months.

On a final note, we appreciate all of the feedback you provided to COGR and the FDP over the past month. It has been extremely helpful in making our case to NIH and HHS. The strong voice from the membership has had a huge influence on the NIH and HHS decision to issue revised guidance ... thank you!

Two GAO Studies on Indirect Costs

As we have reported throughout the year, the U.S. Government Accountability Office (GAO) – an independent, nonpartisan agency that works for Congress to investigate how the federal government spends taxpayer dollars – has been working on a study that addresses indirect costs for National Institutes of Health (NIH) funded extramural research. The study is in response to a request from Senator Jeff Sessions (R-AL) on the Senate Committee on the Budget. In April, COGR met with the GAO team conducting the study, and we know of the six universities that also met with the GAO staff. We believe this study may be completed and released soon.

A second GAO study was requested by Congress in June. The House Energy and Commerce Committee’s Subcommittee on Oversight and Investigations, chaired by Rep. Tim Murphy (R-PA), sent a letter to the GAO asking the agency to review indirect costs on grants issued by NIH. A copy of the letter is available at:

<http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/letters/20130624GAO.pdf>

We will pay particular attention to this new study as the Subcommittee on Oversight and Investigations would be more likely to initiate further action. If contacted to provide input, COGR will be available to the GAO as they engage in this study. If your institution is contacted and you are comfortable sharing this with COGR, please contact us.

COGR Discusses Revised DFARS 7000 Clause with DOD

The COGR August Update discussed the revised final version of the DOD/DFARS 252.204-7000 clause, which requires DOD contracting officer approval of release of any unclassified information pertaining to the contract. As noted in the Update, this clause has been of longstanding concern to COGR members.

The revised clause specifically cites the two previous DOD memoranda on contracted fundamental research stating that such research should not be managed in a way that it becomes subject to restrictions on the involvement of foreign researchers or publication restrictions, including subcontracted fundamental research. While this is an improvement over previous DOD DFARS policy, we noted concerns that the exception in the revised clause to contracting officer approval applies only when the project has been scoped and negotiated at the proposal stage by the DOD contracting officer with the contractor and research performer (assuming some portion of the project will be subcontracted) and determined to be fundamental research. As we noted, there is no upfront carveout for university fundamental research nor is it clear when and how universities will be able to participate in the proposal stage to obtain the required determination.

COGR and AAU representatives discussed these concerns with DOD representatives. We expressed the need for flexibility in application of the revised clause so that later determinations can be made in cases where the determination is not made in advance. One possibility might be to include additional guidance in the DOD Procedures, Guidance and Information (PGI) that accompanies the DFARS.

The CIP Committee plans to meet with Robin Staffin, Director for Basic Sciences in the Office of the Assistant Secretary of Defense for Research and Engineering, during the October COGR meeting to further discuss this issue.

(Note: as discussed in the August Update, the DFARS 7000 clause has been separated from the proposed DOD rule on Safeguarding Unclassified DOD Information that was previously proposed. The September 23 Federal Register indicated that a revised Safeguarding clause has been submitted to OMB for approval, and asks for comments by October 23 (78FR58292). However, no content is provided. We checked with DOD, and were informed that the revised Safeguarding clause is still in the DOD/DFARS approval process. We will continue to monitor the situation).

Export Controls - COGR Comments on Proposed Rules

The August Update mentioned that Commerce/Bureau of Industry and Security (BIS) published a proposed rule for the transfer of military electronics from the U.S. Munitions List (USML) to the Commerce Control List (CCL). A companion rule also was published by the Department of State on July 25 (78FR45023) to amend the ITAR to revise Category XI (Military Electronics) of the USML.

COGR and AAU commented on both proposed rules on September 9. In our comments on the proposed Commerce rule, we reiterated our concern about the definition of “use” in the new proposed 600 series Export Control Classification Numbers (ECCNs) for the transferred military

electronic items. They include in the list of items technology required for the “development,” “production,” “operation,” “installation,” “maintenance,” “repair,” “overhaul,” **or** (emphasis added) “refurbishing” of the commodities or software controlled by the ECCN. Our letter noted the controversy that arose when a similar change with regard to use technology (i.e. “or” instead of “and”) was proposed by the Commerce Inspector General in 2004. We pointed out the inconsistency with Part 772.1 of the Export Administration Regulations (EAR) governing other ECCN series. We expressed concern that access for any category of use raises the potential of a greatly increased need for deemed export licenses at universities. Many fundamental research projects at universities involving items controlled under this series will require determinations of the need for deemed export licenses in order for foreign students, faculty, visitors, technicians and other research staff to work on such projects, including merely operating equipment where no information is conveyed. Security will have to be implemented to ensure against unauthorized access by foreign nationals in such cases. We had expressed similar concerns in July with regard to the proposed transfer of spacecraft and satellites to the CCL.

Commenters on a previous version of the military electronics rule also had raised this issue. In response, BIS stated: “Nearly all of the software and technology in existing and proposed 600 series ECCNs comes from USML categories. One goal of the U.S. government in the Export Control Reform Initiative is not to decontrol completely and inadvertently items the President determines no longer warrant control on the USML.” BIS believes the “or” formulation achieves this objective. We noted in the comment letter that we found this response unpersuasive. It contradicts the objectives of the Export Control Reform Initiative to reduce unnecessary controls and to create bright lines between the control lists, so as to focus on transactions that raise the greatest concerns.

COGR/AAU also submitted comments to the State Department supporting comments submitted by the Association of University Export Control Officers (AUECO) on the proposed ITAR rule. AUECO expressed concerns that the proposed Category XI(a)(7) would subject all electronic devices, systems or equipment funded by DOD to control as defense articles unless they have been declared subject to the EAR. We expressed concern that this revision might have a chilling effect on the ability of our member institutions to conduct DOD funded fundamental research in these areas. We also questioned whether DOD contracting officers are the appropriate entities to make such determinations.

Copies of both comment letters are posted on the COGR website.

Fixing the AIA Grace Period

We have previously discussed our concerns about the narrow grace period for scientific publications under the America Invents Act (AIA) (see COGR October 2012 Update and February 2013 Meeting Report). Under the dysfunctional AIA grace period, early disclosure risks loss of ability to patent, discouraging publication of research results that contain potentially patentable inventions before submitting a patent application. The AIA grace period as interpreted by the Patent and Trademark Office (PTO) will protect for one year a disclosure of an invention against a subsequent disclosure only of the same *subject matter*; disclosure of an *obvious variant* - an invention close enough to the grace period disclosure to be considered patent-defeating prior art, but different enough that it would not be blocked by the AIA grace period - would nullify the patentability of the initially disclosed invention.

This leaves the grace period disclosure vulnerable to publication of an obvious variant. The publisher of the obvious variant also would be unable to get a patent, since the grace period disclosure would be prior art to the obvious variant; the two disclosures would cancel each other out. But if, for example, an existing business encountered the description of an invention in a journal article written by a university researcher and regarded that invention as a potential competitive threat to its operations, it would need only publish an obvious variant to the invention to block the ability of that researcher obtain a patent. (The AIA does provide a derivation procedure for an initial inventor to prove that the subsequent inventor derived the invention from him/her. However this procedure is likely to prove costly and time consuming, with uncertain outcomes). Moreover, if after his or her initial disclosure, the inventor himself or herself subsequently published or otherwise disclosed a further development of the invention or other variation on the initial disclosure, that disclosure by the inventor also could constitute a patent-defeating obvious variant.

In the course of the long negotiations that led to the AIA, one university objective was to assure a grace period that would operate essentially as a “first-to-publish” system, substituting the first person to publish an invention for the first person to conceive of an invention under prior-AIA patent law. In this concept, the grace period would protect the first inventor to disclose an invention from having that disclosure serve as prior art, and the inventor would have up to a year to file a patent application on that invention. But that initial disclosure would also serve as prior art for any subsequent inventor of that invention. These provisions would enable an inventor to disclose an invention without risking someone else appropriating that disclosure and beating that discloser to the patent office. Language thought to accomplish this objective was carefully and openly negotiated early in the patent reform process, involving universities, industry, and House and Senate Judiciary members and staff. Only after AIA passed did universities – and Congress – come to understand that the AIA grace period language as interpreted by PTO does not accomplish the objective.

The obvious solution is to amend the AIA to define the grace period so as to operate as intended. COGR has worked with the other higher ed. associations that have been active in patent reform to craft a legislative proposal that would accomplish this. The proposed legislation would clarify that: (1) the grace period protects an inventor against disclosures by anyone after the inventor has made a public disclosure of the claimed invention; (2) the grace period applies to any and all of an inventor’s patent-defeating acts that are public disclosures; and 3) the grace period removes prior art from consideration under both sections 102 (novelty) and 103 (non-obvious) of the Patent Act (35 U.S.C.). All inventors must still satisfy the (written description and enablement) disclosure requirements of 35 U.S.C. 112(a). However, the proposed new section also clarifies that if an inventor has made more than one public disclosure, he or she should be able to use all of these public disclosures to establish the extent of his or her grace period protection.

This language could be introduced either as a stand-alone bill or as an amendment to other legislation (see below). The higher ed. associations currently are discussing an appropriate legislative strategy. We understand that some institutions currently are discouraging their inventive faculty from publishing and that some companies have expressed unwillingness to engage in collaborations with universities unless the universities agree to file provisional patent applications on all disclosures by participating faculty. **It would be helpful for COGR and the other associations to receive more information about these developments.** Please let Bob Hardy of the COGR staff know if you have specific information along these lines or if you would like to receive a copy of the legislative package.

Discussions Continue on Anti-Patent Troll Legislation

Recent COGR Updates and Meeting Reports have discussed legislative initiatives to address the patent “troll” problem. The June Meeting Report discussed a 38-page “Discussion Draft” being circulated by Rep. Goodlatte (R—VA), House Judiciary Committee Chair.

Rep. Goodlatte recently circulated a revised 47-page Discussion Draft. The draft includes a stronger “loser pays” provision under which the loser in a patent infringement lawsuit would be required to pay the winner’s attorney fees and costs, unless the court finds the position of the loser “was substantially justified or that special circumstances make an award unjust.” The effect would be to raise the risk to a nonprofit or small business of bringing patent infringement suits. Another provision that might particularly impact research institutions is a joinder provision where defendants in infringement suits can require interested parties to join in the suit. “Interested parties” include assignees or others that have “a direct financial interest in the patent or patents at issue, including the right to any part of an award of damages or any part of licensing revenue.” This might, for example include university inventors or any 3rd party a university inventor has designated to receive some or all of his or her inventor share.

The draft also contains much more specific pleading requirements for patent infringement suits, limitations on discovery, disclosure requirements for the real party in interest, with a duty of ongoing disclosure to PTO (and harsh penalties for non-compliance), and procedural safeguards for customer suits where a customer is sued for infringement for using a product or process purchased from a manufacturer. While perhaps of less direct potential relevance to universities, some of these provisions have been the subject of harsh criticisms elsewhere (see <http://j.mp/On-Goodlatte-Bill>).

The draft also contains a number of technical amendments to the AIA. One would repeal the “reasonably could have raised” estoppel provision in the new AIA post-grant review. The university associations had supported this provision as a way of limiting challenges to issued patents. There also are provisions that address claim construction in post-grant and inter partes reviews. The draft also adds a section on prior art and double patenting and clarifies a number of AIA terms. Finally, it calls for PTO studies of the secondary market oversight for patent transactions and, somewhat curiously, of patents owned by the U.S. Government, and a study by GAO of ways to improve PTO patent examination and patent quality.

The university associations have not yet taken a position on the draft Goodlatte bill. However, AAU was asked to provide comments on a bill proposed by Sen. Hatch that would require plaintiffs in infringement suits to post bonds sufficient to ensure payment of the accused infringer’s fees and other expenses, including attorneys’ fees. After discussions with the other associations including COGR, AAU expressed concerns to Sen. Hatch’s staff that where a university or university start-up is seeking to enforce a patent in court against a clear case of infringement, they would be vulnerable to requests for bonding by the defendant, particularly by large, well-capitalized companies. The bill is designed to allow the court to reject the defendant’s request if it lacks sufficient merit, but the cost to get to that point could become debilitating, particularly for small start-ups. Such consequences would constitute a powerful disincentive for universities to defend their patents, creating an anti-competitive environment where universities and their start-ups, with limited financial resources, are unable to pursue legitimate assertion of their patent rights. AAU also suggested adding a number of factors to the

bill aimed at further protecting nonprofit research entities (and associated tech transfer entities). However, these are not necessarily failsafe in fully protecting universities or start-ups.

While the Goodlatte or other anti-troll bills might also provide a vehicle for the grace period legislation that the higher ed. associations have developed, to date stand-alone legislation appears preferable.