

Document Downloaded: Monday November 09, 2015

COGR August 2015 Update

Author: COGR Staff

Published Date: 08/17/2015

COUNCIL ON GOVERNMENTAL RELATIONS 1200 New York Ave., NW, Suite 750, Washington DC 20005 (202) 289-6655; (202) 289-6698 (FAX)

August 17, 2015

TO: COGR Membership

FROM: COGR Staff

SUBJECT: August 2015 Update

TABLE OF CONTENTS

Uniform Guidance Procurement and Conflict of Interest Grace Period Extension Uniform Guidance Recommended 4-Step Approach for Responding to Agency Deviations Uniform Guidance F&A and Related Issues Uniform Guidance and Conflict of Interest NIH Subaccounting: 120-day Grant Closeout and the Payment Management System **COGR** Guide to Compensation and Documentation NSF OIG Report on Payroll Certification at George Mason University **Cloud Computing and MTDC Treatment** 2015 A-133 Compliance Supplement Finalized **COGR Signs on to Community Letter Opposing Reduction to HHS/NIH Salary Level** Affordable Care Act Compliance and Research Assistants **DOL Publishes Proposed New Floor for Exempt Overtime Pay** New Labor Law Violations Reporting Requirements Proposed for Federal Contracts **COGR/AAU Submit Comments on Proposed NARA BUI Rule COGR/AAU/APLU Comment on Proposed Harmonized Definitions for Export Controls Patent Troll Legislation Delayed USPTO Updates Patent Subject Matter Eligibility Guidance Research Terms and Conditions Applicable to NIH, NSF and Others** NSF Proposal and Award Policies and Procedures Guide **Revised Research Performance Progress Report Format** NIH Request for Information on Simplification of its Grant Application Instructions National Academies Federal Research Regulations and Reporting Requirements GAO Study Regulations and Reporting Requirements Imposed on Research Universities **National Science Board Meeting** NIH Scientific Management Review Board Report **DATA Act Implementation and Pilot** Notice of MOU Between NIH and NSF Concerning Laboratory Animal Welfare **USDA Petitions NSF IRB Approval**

Uniform Guidance: Procurement and Conflict of Interest Grace Period Extension

In a COGR letter to OMB, dated June 30, 2015, we requested that 2 CFR 200.112 (Conflict of interest) and 2 CFR 200.317-326 (Procurement Standards) be suspended immediately and subject to an extended grace period. The extended grace period would make these sections of the

1

Uniform Guidance effective for an institution's fiscal year FY2018. For most universities and research institutions, the effective date currently is July 1, 2017.

Research institutions, as well as other stakeholders, have deemed an extension to the grace period as a "must have". <u>Staff from OMB have been receptive to our request and have recommended to senior leaders at OMB that the request be approved.</u> Unfortunately, we have not received a final confirmation.

As we have shared with OMB and the COFAR, this one issue has the potential for undoing the many positives of the Uniform Guidance implementation. In the June 30 letter, we reiterated our message of past two years: IHEs and NROs should be granted the same opportunity as States to be exempt from these standards. Our current procurement systems are state-of-the-art systems that have resulted in significant cost savings and efficiencies for IHEs, NROs, and the Federal government. The track record of our systems with both the Single Audit and Federal Audit communities is stellar and there has been little evidence of our systems promulgating fraud, waste, or abuse. While our position remains that IHEs and NROs should be granted an exemption and allowed to use our current systems and processes, at a minimum, an extension of the grace period for all stakeholders will allow the grantee community and its Federal partners to address the full scope of issues and concerns.

We will provide an update to the Membership in as soon as we learn more.

Uniform Guidance: Recommended 4-Step Approach for Responding to Agency Deviations

In the June Meeting Report (dated June 19, 2015), we included a recommended approach for you to follow when your institution is presented with an agency deviation to 2 CFR Part 200 (or for that matter, deviations in general). Below is an example of the 4-step approach in response to an AHRQ funding announcement that did not require cost sharing, but encouraged cost sharing to be included. We expect the 4-step approach to be an email correspondence with the agency; initially, we recommend you work one-on-one with the agency and forward us the correspondence, as appropriate. COGR's engagement can be determined on case-by-case basis, which might include forwarding the situation to OMB.

Identify language in Funding Announcement - *This FOA does not require cost sharing. While there is no cost sharing requirement included in this FOA, AHRQ welcomes applicant institutions, including any collaborating institutions, to devote resources to this effort. An indication of institutional support from the applicant and its collaborators indicates a greater potential of success and sustainability of the project ...*

Provide UG Citation(s) - §200.306 Cost sharing or matching.

(a) Under Federal research proposals, voluntary committed cost sharing is not expected ...

Appendix I to Part 200—Full Text of Notice of Funding Opportunity

E. Application Review Information

... If cost sharing will not be considered in the evaluation, the announcement should say so, so that there is no ambiguity for potential applicants. Vague statements that cost sharing is encouraged, without clarification as to what that means, are unhelpful to applicants ...

Statement to Agency -

Per 1) and 2) above, "I have asked COGR, an association of 200 research institutions, to review this language in light of the newly implemented 2 CFR Part 200 that became effective on December 26, 2014. We are concerned that the vague request for cost sharing may inappropriately compel institutions to commit voluntary cost sharing in the budget proposal ..."

1) <u>Request to Agency:</u>

"At your convenience, please provide: a) the basis or justification for the language included in the FOA, and b) a Policy Official point of contact at the agency who is responsible for approving the language. We look forward to working with you and COGR to resolve any discrepancies with 2 CFR Part 200 ..."

While we do not expect the 4-step approach to rectify agency deviations, we believe it provides a systematic mechanism to notify the agency of a deviation and make the agency aware that we are paying attention. In addition, we are accumulating these situations and will document them in an anticipated year-end report on COGR's perspective on the implementation of the Uniform Guidance. Jackie Bendall at jbendall@cogr.edu and/or David Kennedy at dkennedy@cogr.edu are the points of contact for these situations, and will follow up, accordingly.

Uniform Guidance: F&A and Related Issues

We expect to spend significant time in the near future, and beyond, to track F&A related issues within the context of the Uniform Guidance implementation. We are engaged actively and/or tracking the following:

- Employee Tuition Remission (200.431j). This section is problematic by potentially disallowing some forms of employee tuition remission. We believe this was an inadvertent error by OMB and the COFAR and we have advocated for a technical correction. We expect OMB to issue several technical corrections this summer, and this could be one of them.
- **DS-2 Approvals.** COGR will continue engaging with OMB for a clarification or FAQ that is crystal clear: "if allowable per the UG, a DS-2 approval is not required." While there are some schools of thought that this already is the OMB expectation, additional cover in the form of a clarification or FAQ would be helpful.
- UCA and 2.0 research weighting factor. COGR is developing an analysis, in partnership with a consulting firm, to address the flawed 2.0 factor. The goal is to present the analysis to OMB and the Cognizant Agencies later this Fall and to advocate for an adjustment.
- UCA up to 1.3%. We have shared in previous updates that implementation of the UCA has been favorably resolved: 1) For IHE's currently receiving the 1.3% UCA under OMB Circular A-21, for FY2014 and FY2015 F&A rate proposals, they will retain the 1.3% UCA. F&A rate proposals for FY2016 and forward must propose the UCA using the new

methodology, and 2) For IHE's not currently receiving the UCA, they may begin proposing the UCA for F&A rate proposals beginning with FY2014, and going forward.

- NIH Salary over the Cap and F&A Research Base. COGR expects to work with OMB and the Cognizant Agencies to review various methodologies that will allow for the fair treatment of NIH salaries over the cap and their treatment in the F&A research base. Prior to implementation of the Uniform Guidance, the treatment was never specified in any official OMB or federal policy, and consequently, this has been an unresolved issue. COGR's position is the Uniform Guidance is clear and that NIH salaries over the cap should be excluded from the F&A research base. We believe working with OMB and the Cognizant Agencies in partnership on this issue is the appropriate approach to achieve reasonable solutions.
- **Negotiation Experiences.** We want to hear about the results of your F&A rate negotiations. In addition to the results of the actual rate negotiation, this includes issues that were raised. If your institution has requested the 4-year rate extension, we also are interested in these results. This will allow COGR and the Membership to track issues and new practices that may be introduced by the Cognizant Agencies. This is of particular interest as we begin to observe the approaches of CAS/HHS and ONR to rate negotiations under 2 CFR Part 200.

Contact David Kennedy at <u>dkennedy@cogr.edu</u> on any of the items listed above. In addition, Cathy Snyder from Vanderbilt University and recently selected to the COGR Board also is a point of contact. Cathy can be contacted at <u>cathy.snyder@vanderbilt.edu</u>.

Uniform Guidance and Conflict of Interest

New agency policies (e.g., EPA, DOJ, Commerce, NEA) being released to address agency compliance with section 200.112 of 2 CFR Part 200 continue to create angst for COGR member institutions. COGR is engaging with agencies and OMB to advocate for either clarifying FAQs to section 200.112 and/or to request that new agency policies be "stayed" until more clarity and consistency is offered. We will provide an update to the Membership later this month. We ask that you continue to notify us if you see agency policies that go beyond the Uniform Guidance requirements.

NIH Subaccounting, 120-day Grant Closeout and the Payment Management System (PMS)

COGR continues to engage with Federal officials on these inter-related issues. The summaries from the June Meeting Report (dated June 19, 2015) are included below, with relevant updates included:

• NIH Subaccounting and Final Transition starts on October 1, 2015. The recent NIH Notice Number: NOT-OD-15-105 (May 28, 2015); Reminder of Timeline for Administrative Changes to NIH Domestic Awards to Transition to Payment Management System Subaccounts, reinforces the October 1 final transition date and addresses some of the operational procedures that will be in place. Note, the Notice is clear: Grantees with inadequate systems in place to appropriately manage this transition by October 1, 2015, may be unable to appropriately access PMS accounts and risk losing their ability to draw down funding.

<u>NOT-OD-15-105</u> further defines the role of the "Subaccount Transitional FFR" in facilitating the transition to establishing new subaccounts for each award, as well as clarifying the treatment of carryover balances. While <u>NOT-OD-15-105</u> does not specifically address carryover balances greater than 25%, <u>COGR's understanding is that these will be permitted without requiring a formal NIH approval process</u>. Finally, NIH is aware that the ability for an institution to maintain its internal institutional account/project codes will be important to some institutions, and consequently, the transition process has been designed where this should be possible. <u>NIH FAQs</u> are available, though we expect these will be updated as additional clarifications are necessary.

COGR leaders, who also are involved in the FDP, are tracking additional developments and will remain active in providing updates to the COGR membership and the broader community. Institutions should be focused on understanding what needs to be done to prepare for October 1st, and, as applicable, revamping systems and business processes to make for a smooth transition. Additionally, institutions should be considering how to support the additional work and financial risk associated with NIH subaccounting.

- Grant Closeout and 120-day Closeout Model. Under NIH subaccounting, award-byaward financial management and closeout is the new standard. In the 2015 NIH Grants Policy Statement, section 8.6 CLOSEOUT states: Recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 120 calendar days of the end of the period of performance (project period). The reports become overdue the day after the 120 calendar day period ends. While we are thankful for the new NIH 120-day closeout model, NIH-specific operational issues, as well as internal institutional management issues will provide unique challenges. Further note, the 120-day closeout model transcends NIH; as other funding agencies consider implementing similar models, institutions must be aware of those challenges created by potential inconsistencies across agencies.
- **PMS Consistency with the 120-day Closeout Model.** Consistency in the configuration and functionality of PMS with the NIH 120-day closeout model is integral to successful implementation. PMS is managed by the Division of Payment Management Services (DPM), which organizationally falls under the Program Support Center (PSC) and the Department of Health and Human Services (HHS).

In order for PMS to be consistent with the 120-day Closeout Model, the PMS "*Expired Grants Functionality*" needed to be modified from 90 days to 120 days. NIH issued a Guide Notice, dated August 4, announcing **that "the deadlines for submitting final financial reports and drawing funds from the PMS are now in synch**. Recipients may request payments from PMS up to 120 days past the period of performance end date for NIH awards with a project end date on or after October 1, 2014. PMS will no longer require NIH approval of each payment request submitted between 90 and 120 days after the period of performance end date."

The Guide Notice is available at: <u>http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-135.html</u>

COGR also has requested that NIH, in conjunction with PMS leaders, be available to provide additional and unanticipated operational support, as needed. Ongoing communications will educate PMS users on changes that have been made to PMS, as well as provide end-user assistance and troubleshooting to support PMS users with the new 120-day functionality. For example, potential reconciliation and timing issues between the FFR and the FCTR, most likely, will need to be addressed.

COGR and the community appreciate the hard work and commitment that have been made by NIH, DPM, and HHS. All of this change creates a significant challenge at the institutional and the Federal levels. However, it represents a good example of productive partnership where the goals of reducing burden, while maintaining effective stewardship of Federal funds, are achieved. COGR will continue to work with the FDP and NIH to address potential issues associated with the final transition to subaccounting and we will engage actively with PMS administrators and NIH to confirm that open issues associated with PMS and the 120-day grant closeout model are being addressed. We will keep the Membership posted on all developments.

COGR Guide to Compensation and Documentation

Compensation and Documentation requirements from the Uniform Guidance (2 CFR 200.430) have been addressed in detail in recent COGR Updates and Meeting Reports. We expect this to be an ongoing discussion topic as institutions implement new approaches and systems in compliance with section 200.430 of the Uniform Guidance. COGR has developed the <u>COGR</u> <u>Guide to 2 CFR 200.430</u>, which is intended to serve as a resource to assist member institutions as they assess the alignment of their written policies and procedures and internal controls with this section of the OMB Uniform Guidance. The Guide should be viewed as a <u>first assessment</u>, which is based on our initial understanding of this section. As we learn more with regard to auditor perspective and interpretation from Federal and Higher Education leaders, this could inform updates. Version 1 of the Guide was distributed in a July 1, 2015 email to the COGR ListServe. If you have questions, contact Lisa Nichols at <u>Inichols@cogr.edu</u>.

A special "Thank You" to the Workgroup that worked on Version 1 of the Guide; the Workgroup included a combination of COGR Board members, Committee members, and other volunteers. COGR appreciates the significant contributions of the following individuals (presented alphabetically by institution):

Naomi Schrag (Columbia)	Sara Bible (Stanford),
Jim Luther (Duke)	Elizabeth Piga (Research Foundation of SUNY)
Kerry Peluso (Emory)	Ron Maples (Tennessee)
Jennifer Mitchell (Northwestern)	Joe Gindhart (Wash U in St. Louis)
Mike Daniels (Northwestern)	Kim Moreland (Wisconsin)

NSF OIG Report on Payroll Certification at George Mason University

The NSF OIG published a report on August 7, <u>Labor Effort Reporting Under the Federal</u> <u>Demonstration Project's Pilot Payroll Certification Program at George Mason University</u> (GMU). The OIG audited one year under the effort reporting process and over two years under the payroll certification pilot. The report indicates that a primary concern of the audit was to determine whether the fact that the pilot system does not require certifying 100% of each employee's "effort" increased the risk of improper allocations of payroll. Findings specific to the GMU pilot site **included late certification and issues surrounding IT controls**. The OIG report indicates that 11 sponsored project payroll expense reports were not certified in a timely manner and that charges were not removed per GMU policy. GMU responded that since the timing of report generation may vary based on several factors, the policy related to removing charges has been based on the time a PI has to certify a report once received (60 days from the distribution date). The report notes that GMU was able to explain the late certifications identified in the report (details are included in the GMU response), but that GMU's written policy specifies 120 days from the end of the award year to complete the certification. GMU indicated that it will update the policy.

Regarding IT controls, the report suggests that GMU did not use two-factor authentication to access its payroll system (Banner); did not adequately manage access controls; did not install security patches in a timely manner; and did not update its risk assessment for Banner and could therefore be vulnerable to access by unauthorized users who could modify information. GMU indicated that they do not believe that the data could be vulnerable to unauthorized users, but concurred that there were areas where IT controls needed to be strengthened and indicated that they were taking steps to do so. The report indicates that the issues identified, including late certification and IT controls, were not the result of inadequate design of pilot system controls and not attributable to the pilot system.

The report notes that the process for initiating salary charges is the same under the pilot and previous effort reporting process; but that the annual certification (previously triannual under effort reporting at GMU) includes individual salaries charged to awards for all applicable employees and that the PI is solely responsible for certifying that charges are reasonable. The **report notes that the certification meets the requirements of OMB Circular A-21 under which it was audited.** However, it also notes that this certification, which does not report charges to other awards the individual worked on and is a principal change from the effort reporting process, presents a risk. While noting that 78% of GMU employees charged salaries to a single NSF grant and that the full allocation remains recorded and available within GMU's systems, the OIG suggests that making full payroll allocations available to PIs would "be useful" and "is important" in assuring that charges to federal awards are accurate and that it could be an important control to help ensure that overcharges and inaccurate charges do not occur.

Additional controls under payroll certification are bimonthly reconciliations of award ledger and expense data where charges and credits to a fund or organization are reviewed and certified by department administration. Charges are also made available to the PI bimonthly for review but this is not documented. In its report, the OIG indicates that the reconciliations were not always reviewed and approved as required per GMU policy and suggests that the reconciliations are critical to assuring that the annual certifications are accurate.

This report is the second of four anticipated reports on individual pilot sites, and the first complete audit report. The previous report specific to UC Irvine notes that an audit was not conducted. The remaining reports are anticipated in early fall. A capstone report will provide overall results and summarize issues identified at the four pilot sites. COGR staff met with Brett Baker of the NSF OIG on August 10 to discuss OIG concerns about award-level review and the potential for inaccurate charging or overcharging under the pilot and we anticipate continuing this dialogue.

Cloud Computing and MTDC Treatment

This issue began percolating two years ago at a National Science Board retreat. The Federal Office of Science and Technology Policy (OSTP) became involved soon after and COGR was approached this past March. As this resource becomes a more feasible option for researchers, at issue is whether or not cloud computing vendor agreements should be included as part of Modified Total Direct Costs (MTDC), and the corresponding applicability of F&A.

As we reported in the June Meeting Report (dated June 19, 2015), Kelvin Droegemeier (VP for Research - University of Oklahoma) and Randy Bryant (Assistant Director for Information Technology R&D - OSTP) are developing a survey to be shared with Senior Research Officers. The survey will be designed to better understand the magnitude of cloud computing and related operational issues. COGR will stay connected to progress on the survey, the discussions that follow, and any applicable policy recommendations.

2015 A-133 Compliance Supplement Finalized

The <u>2015 A-133 Compliance Supplement</u> has been finalized and posted. Note, next year this document most likely will be referred to as the 2016 Single Audit Compliance Supplement as Subpart F, Audit Requirements, of the Uniform Guidance will supersede Circular A-133.

As we reported previously, Part 3, Compliance Requirements, and Part 5, Clusters of Programs, Research & Development may be of special interest. Page 3-1 describes the implementation of the 2015 CS as a "Transition Supplement" and page 3-3 includes a cross-reference to the FAQs from the Uniform Guidance. Also, pages 5-2-1 through 5-2-6 (Part 5, Research and Development Programs) incorporate selected revisions proposed by COGR. For example, pages 5-2-2 and 5-2-3 describe the audit procedures applicable to reviewing Compensation and include provisions for institutions that have transitioned to 2 CFR part 200 and those that have not. This seems to confirm COGR's position that institutions should work with their auditors to determine an institution-defined transition date for implementing section 200.430, Compensation - personal services.

The 2016 Single Audit Compliance Supplement may require even closer review as Subpart F, Audit Requirements, of the Uniform Guidance become applicable for the first time. COGR expects to have the opportunity to review draft versions as early as January 2016 and we will solicit volunteers from the COGR Membership to help review these draft versions.

<u>COGR Signs-on to Community Letter Opposing Reduction to the HHS/NIH Salary Level</u>

Section 203 of the FY 2016 Labor-HHS appropriations bill, passed by the House Appropriations Committee on June 24, would reduce the salary limit on HHS/NIH extramural grants from Executive Level II to Executive Level III (\$168,700 in 2015), a cut of \$14,600 (8 percent). This cut follows a \$20,000 (10 percent) cut from Executive Level I to Executive Level II in the FY 2012 funding bill.

The Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), the Association of Independent Research Institutes (AIRI), and the Association of Public and Land-grant Universities (APLU) have taken the lead in drafting a community letter to Chairs and Ranking Members of the House and Senate Appropriations

8

Committees and the Labor-HHS Subcommittees to oppose any reduction to the HHS/NIH salary level. The community letter will be delivered in mid-August and COGR has signed on to the letter. We will keep you posted on all developments.

Affordable Care Act (ACA) Compliance and Research Assistants

COGR has been contacted by the American Council on Education (ACE) and the College and University Professional Association for Human Resources (CUPA-HR) to help them craft policy proposals concerning the management of graduate student employees consistent with the ACA's employer mandate. Specifically, ACE and CUPA-HR have inquired about Research Assistants (RAs) and sought COGR's help formulating a method – or "safe harbor" – schools could safely use to monitor the effort of RAs without specifically tracking their hours, which would give the IRS and the Department of Treasury assurance that universities are complying with the ACA's employer mandate.

According to Treasury, under the ACA, student employees including RA's working on campus, except under a government work study program, for 30 or more hours per week would be entitled to an offer of a university's employer health insurance coverage. Since the vast majority of RA appointments are less than 30 hours, ACA mandated coverage would not be required. However, at issue is the following: since RA hours are not tracked, <u>how does a university demonstrate that an RA has not worked 30 hours per week?</u>

This brings us to the potential "safe harbor" for RAs, which ACE and CUPA-HR have been discussing with COGR. In specific, we have suggested that language from 2 CFR 200.430(i)(x) could be helpful in developing the safe harbor: "*It is recognized that teaching, research, service, and administration are often inextricably intermingled in an academic setting.*" In effect, by confirming that an RA has completed his/her work, whether the confirmation is made through an effort report, a payroll report, or some other mechanism, the need to document hours is not applicable nor required under the 2 CFR 200.430. The "*inextricably intermingled*" principle is real and unique to the academic setting and to rely on hours as a tracking mechanism is not feasible. Instead, the idea is to propose a "safe harbor" to Treasury/IRS that universities can rely on the appointment of the RA (e.g., 19 hours) in combination with the effort report, payroll report, or other mechanism to demonstrate that the 30 hour threshold mandating ACA coverage has not been triggered. Hence, there is no need for any type of hours tracking or reporting. Of course, if the RA appointment is 30 hours or more, then ACA mandated coverage is applicable.

Note, Treasury accepted other safe harbors proposed by ACE and CUPA-HR for other groups of employees; including, Adjunct Professors and Work-study Students. We are hopeful that a similar safe harbor would be approved for Research Assistants.

On another note, we have been made aware of a separate ACA issue, also being monitored by ACE, which would detrimentally affect a number of graduate students. For a number of years preceding the ACA, many colleges and universities, particularly Tier 1 research universities, have provided graduate students with student health insurance plan (SHIP) coverage at greatly reduced or no cost as part of their graduate package. Apparently, the IRS recently provided informal guidance that this practice may not be permitted under the ACA's employer mandate and that institutions could face annual fines of \$36,500 per impacted individual (\$100 per day). Unfortunately, this interpretation is causing great concern and uncertainty at a number of institutions, causing some schools to consider ending graduate student SHIP subsidies.

Apparently, the IRS is basing this opinion on regulatory guidance issued in 2013, which was intended to prevent employers from eluding the employer mandate by providing funds to employees through such tax preferred mechanisms as Health Reimbursement Arrangements to cover the cost of individual health insurance coverage purchased on the individual market. ACE is seeking a clarification from Treasury that would permit schools to continue providing SHIP subsidies to graduate students, or, at a minimum, provide schools with permission to continue this practice during the 2015-16 academic year while Treasury further examines the issue.

January 2016 is an important marker for universities to demonstrate full compliance with the ACA's employer mandate, so we expect there to be significant activity around these issues throughout the remainder of the year. We will keep you posted on all developments.

DOL Publishes Proposed New Floor for Exempt Overtime Pay

The Fair Labor Standards Act (FLSA) sets minimum wage, overtime pay, equal pay, record keeping and child labor standards for employees (who are covered by the Act) in the private sector as well as those employed in federal, state and local government. In an attempt to modernize existing regulations and to provide clarity to exempt and nonexempt classes of workers eligible (non-exempt) or ineligible (exempt) from receiving overtime pay, the DOL is proposing to more than double the current threshold for the minimum salary requirement for overtime pay exemptions exempt from \$445/week (\$23,660 annually) to \$970/week (\$50,440) in 2016, when the final rule would potentially come into effect. There are a few caveats to being exempt in addition to just the salary cap. The primary duties must also be consistent with the standard duties test, defined in the regulations as managerial, professional, or administrative in Although the duties test hasn't changed, DOL is seeking comments on whether the nature. current standard duties test works as intended to screen out employees who are not bona fide white-collar exempt employees. Nondiscretionary bonuses such as performance bonuses are also being considered as to whether they will satisfy a portion of the standard salary test requirement. You might ask what this means to your institutions? A recent article in Nature gives a glimpse into what some Post Docs are saving. http://www.nature.com/news/us-postdocs-hope-forovertime-pay-1.17933?WT.mc id=TWT NatureNews.

No doubt there will be many questions raised, just as there was when the regulations were last revised in 2004. Ultimately, many will want to know who will absorb the increase, and many institutions may be forced to re-classify certain positions. The College and University Professional Association for Human Resources (CUPA-HR) is closely monitoring this one and COGR will be responding as well. Comments are due September 4th, however an extension has been requested for sixty (60) days by CUPA-HR and many others in the employer community. For additional information, see: http://www.dol.gov/whd/overtime/NPRM2015/. Please send your comments to jbendall@cogr.edu.

New Labor Law Violations Reporting Requirements Proposed for Federal Contracts

On May 28 a proposed new Federal Acquisition Regulation (FAR) requirement was proposed (RIN 9000-AM81--<u>https://www.federalregister.gov/articles/2015/05/28/2015-12560/federal-acquisition-regulation-fair-pay-and-safe-workplaces</u>) that would require increased reporting of labor law violations by federal contractors and subcontractors. A companion rule (<u>https://www.federalregister.gov/articles/2015/05/28/2015-12562/guidance-for-executive-order-</u>

<u>13673-fair-pay-and-safe-workplaces</u>) was issued by the Labor Department (DOL) that provides guidance on these requirements.

The proposed FAR rule builds on existing FAR requirements for responsibility determinations. Prospective contractors must have "a satisfactory record of integrity and business ethics" to be responsible, including compliance with applicable laws. It implements Executive Order 13673, Fair Pay and Safe Workplaces (7/31/14; 79FR45309). It would add a FAR Subpart 22.20, requiring contractor disclosure of any violations during the previous three years of 14 listed federal labor laws as well as equivalent state laws to be further defined by DOL (only OSHAapproved state plans currently are included). Offerors would be required for solicitations in excess of \$500k (excluding COTS items) to disclose violations, defined as any administrative merits determinations, arbitral awards or decisions, or civil judgments (the DOL rule provides further guidance). Contracting officers would evaluate this information as part of their responsibility determinations, and enter the information into the government-wide System for Award Management (SAM <u>www.sam.gov</u>). Contractors would have to make similar determinations for subcontractors at any tier, although they have flexibility in the approach. DOL will provide consultation and assistance. Alternatively, the FAR Secretariat is considering having subcontractors disclose violations directly to DOL and report back to prime contractors DOL's response, or giving primes the discretion to select either approach.

In addition, contractors and subcontractors must disclose violations semi-annually in SAM during contract performance, which contracting officers must continue to evaluate. Remedies for violations include imposition of labor compliance agreements with DOL, terminations, or suspension and debarment in the case of repeated or willful violations which demonstrate a lack of integrity and business ethics. Additional supplemental language may be added to the FAR requiring contracting officers to consider meeting terms of labor compliance agreements as part of contractor past performance evaluations. Finally, the proposed FAR rule implements another provision of the EO requiring contractors to provide wage statements in each pay period stating hours worked with overtime and any additions or deductions ("paycheck transparency").

Public comments were sought on the scope of the public disclosure requirements, the alternative language, and recordkeeping requirements. Comments were due July 27. The proposed FAR rule closely tracks the EO, and the prospect for substantial changes appears small. In addition, while it adds much greater specificity with regard to reporting of labor law violations, the responsibility determination requirements are not new. However we recognize the proposed rule will add burden. In a comment letter dated July 27 we suggested that the alternative approach discussed in the proposed FAR rule of having DOL evaluate subcontractor labor compliance be adopted. The comment letter is posed on the COGR website.

COGR/AAU Submit Comments on Proposed NARA CUI Rule

The June <u>Meeting Report</u> summarized a number of issues with this proposed rule. We had previously commented twice to NIST on the related security standards in the draft NIST Special Publication 800-171, which was published in final form in June (<u>http://www.nist.gov/manuscript-publication-search.cfm?pub_id=918804</u>).

On July 7 we submitted comments to the National Archives and Records Administration (NARA) on the proposed rule. We expressed support for the goals of establishing uniform federal policies and practices for controlled unclassified information (CUI), but we urged NARA

to clarify how the proposed rule would apply to universities and other contractors, and to more fully consider the associated regulatory burden. We also asked NARA to delay implementation of the rule to assure coordination with the pending FAR rule (expected in 2016). A copy of the comment letter is posted on the COGR website.

<u>COGR/AAU/APLU Comment on Proposed Harmonized Definitions for Export Controls</u></u>

The June <u>Meeting Report</u> summarized the proposed "harmonized" definitions for the Export Administration Regulations (EAR) and International Traffic in Arm Regulations (ITAR) issued on June 3. We noted that the definitions will directly impact university research.

On August 3 COGR submitted joint comments with AAU and APLU on the proposed definitions. In our comments we were generally supportive of the proposed EAR changes. However, we expressed concerns about the proposed restatement of the education exemption from export controls and attempts to distinguish technology resulting from fundamental research from software used to conduct fundamental research. We also commented on a number of issues where public comment was sought, including definitions of "fundamental research" and "applied research," end-to-end encryption, and the proposed effective date.

In the comments on the proposed ITAR changes, we were sharply critical of a proposed provision that research agreements with provisions for sponsor proprietary information before publication would not be considered fundamental research. We expressed the view that this would have a chilling effect on university—industry research collaborations, which is a high priority for the Administration. We also noted that it is inconsistent with the objective to harmonize definitions between the ITAR and EAR (which explicitly allows such review) as well as with government policy as reflected in National Security Decision Directive 189. We also made comments similar to the EAR comments on the education exemption, attempts to distinguish software from information resulting from fundamental research, end-to-end encryption, and the proposed effective date.

A proposed provision that controlled technical data or software would not be in the public domain if it has been made available to the public without authorization from the government has attracted tremendous controversy and Congressional inquiries. Thousands of objections have been submitted from groups such as the NRA on constitutional grounds involving prior restraint. We did not highlight this issue in our comments, but did note that the result appeared to be contradictory and confusing provisions in the ITAR on public domain. We also expressed concerns about the revised definition of ITAR "defense services" (after several earlier attempts by the State Department to revise the definition).

Copies of the comment letters are posted on the COGR website. We encouraged member institutions to submit comments directly, and many did so.

Patent Troll Legislation Delayed

Both the House and Senate adjourned for summer recess without taking further action on the patent troll legislation (Innovation Act, H.R. 9; PATENT Act, S. 1137; see COGR June <u>Meeting</u> <u>Report</u>).

In addition to universities, broad opposition to the legislation has been expressed from inventors, small companies, venture capitalists and the life science industry. A bipartisan group of Senators and Representatives also held a press conference to highlight their opposition (see http://democrats.judiciary.house.gov/press-release/bipartisan-bicameral-group-highlights-broad-opposition-sweeping-anti-patent). In addition, a number of conservative groups have ratcheted up their opposition (see http://www.ipwatchdog.com/2015/08/02/conservative-groups-upping-patent-bill-opposition/id=60170/). Reportedly a number of members of Congress who previously supported the legislation now have expressed concerns to Congressional leadership. Association staff have continued to discuss the Senate PATENT Act legislation with Senate staffers. As previously noted we believe the Senate bill is a substantial improvement over the House bill. It is possible that with some further clarifications we would not oppose the Senate bill. However, prospects for either the House or Senate bill are uncertain. We understand the position of the House bill proponents (mainly high tech companies) has hardened.

USPTO Updates Patent Subject Matter Eligibility Guidance

On July 30 the U.S. Patent and Trademark Office (USPTO) issued updated guidance on subject matter eligibility <u>http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0</u>. We discussed the *Interim Guidance on Patent Subject Matter Eligibility* published by USPTO last December in the March <u>Update and Meeting Report.</u> COGR testified on behalf of the higher ed. associations on the *Interim Guidance* at a public forum held by USPTO on January 21, and on March 13 we submitted joint comments to USPTO (see COGR website).

The updated July *Guidance* (80FR45429) includes a new set of examples and discusses various issues raised by the public comments. It identifies six major themes from those comments: need for additional examples of eligibility, further explanation of the markedly different characteristics analysis, further information on identifying abstract ideas, requirements for *prima facie* eligibility rejections, need for more patent examiner training, and the role of preemption and the streamlined eligibility analysis set forth in the *Interim Guidance*. Our comments had focused on the latter, and we had urged USPTO give more emphasis to the concept of preemption in determining patent eligibility, citing a number of Supreme Court and Federal Circuit decisions. A claim may not totally tie up or preempt for other uses the particular law of nature or abstract idea claimed, but still not be sufficient to pass the two-step analysis in the *Interim Guidance*.

The additional examples given in Appendix 1 (Examples 21—27) are mostly in the area of abstract ideas. The updated *Guidance* notes that "Because the courts have declined to define abstract ideas, other than by example, the (*Interim Guidance*) instructed examiners to refer to the body of case law precedent in order to identify abstract ideas by way of comparison to concepts already found to be abstract." It identifies four particular concepts that courts have found abstract: "fundamental economic practices," "certain methods of organizing human activity," "an idea {of itself})", and "mathematical relationships/formulas."

In our comments we had expressed concerns about the subjectivity inherent in these types of analyses. While we respect USPTO's attempts to provide more guidance and greater clarity, the updated *Guidance* does not solve the basic problem. In the discussion of identifying abstract ideas, the update cites a statement from the 1978 Supreme Court *Parker v. Flook* case (cited in

the 2012 *Mayo v. Prometheus* decision) that "basic tools of scientific and technological work" lie beyond the domain of patent protection. This is along the lines of what we tried to suggest in our previous comments.

Undoubtedly there will be a great deal of commentary on the updated *Guidance*, as there was on the *Interim Guidance*. We will further analyze and consider submitting comments on the update. Comments are due October 28.

Research Terms and Conditions, Applicable to NIH, NSF, and Others

These may be published in the Federal Register, <u>for public comment</u>, this Summer. The exact timing remains uncertain.

DoD Terms and Conditions. DoD has released a draft of their Research and Development (R&D) terms and conditions. These terms are under final review at DOD; they will be sent to OMB for clearance next and then published in the Federal Register, <u>for public comment</u>. COGR will be responding to the notice. If you have questions on the terms, please direct all inquiries to <u>jbendall@cogr.edu</u>.

National Science Foundation Proposal and Award Policies and Procedures Guide (PAPPG)

The NSF released for comment a draft of the PAPPG incorporating NSF's new Public Access Policy and other policy-related changes. <u>COGR's letter dated July 20, 2015</u> addressed a number of concerns, including the request to extend submission rights to Sponsored Research Office (SRO) personnel, a request to submit current and pending support only for those proposals receiving favorable reviews, and the timing called for Dual Use Research of Concern (DURC) notifications to align with the existing OSTP policy.

Revised Research Performance Progress Report (RPPR) Format

The National Science Foundation, lead agency sponsor of the Federal-wide performance progress reporting format initiative, has release for public comment an updated standardized RPPR format. The revised draft format was developed to incorporate lessons learned by agencies during the initial implementation of the RPPR. *The approach also has been changed from using the format for interim performance progress reports only to using the format for both interim and final performance progress reports.* Comments are due September 21, 2015. COGR will be responding to this notice based on feedback from its membership. Please send all comments to jbendall@cogr.edu

Resources: <u>http://www.gpo.gov/fdsys/pkg/FR-2015-07-23/pdf/2015-18007.pdf</u> <u>http://www.nsf.gov/bfa/dias/policy/rppr/index.jsp</u>

<u>NIH Request for Information (RFI) - Strategies for Simplifying NIH's Grant Application</u> <u>Instructions</u>

For the purposes of reducing administrative burden, clarifying and simplifying existing approaches and updating current information, the NIH is seeking your input on the restructuring of the NIH grant application instructions; more specifically on new strategies to present materials in a more concise, helpful manner. Comments are being sought from multiple

stakeholders, including: PD/PIs, Administrative Offices, Offices of Sponsored Programs, Systems Administrators, and any other parties that rely on our application submission information. A number of improvements are being considered including, a single, consolidated guide in PDF and in HTML, with more interactive web-based content in the HTML version; an HTML version that can filter instructions based on the funding mechanism or specific funding opportunity announcement (FOA), and other areas, and an "instructions wizard".

Voluntary responses are due electronically on the <u>submission website</u> by September 25, 2015. <u>http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-134.html</u>

<u>The National Academies Committee on Federal Research Regulations and Reporting</u> <u>Requirements Fifth Meeting</u>

The National Academies Committee on Federal Research regulations and Reporting Requirements held its fifth meeting in Washington, DC on July 21 and 22. Brett Sweet of Vanderbilt University and Tejus Kothari of the Boston Consulting Group presented data from their evaluation of the cost of federal regulatory compliance. This data was included in a <u>report</u> issued in February by the Task Force on Federal Regulation of Higher Education, a complimentary effort to the current Academies effort that focused on higher education regulations. They noted that of \$148 million dollars in annual estimated compliance costs, \$117 million was specific to research compliance. Committee members suggested that for some institutions this might represent a significant underestimate.

Sally Rockey, Deputy Director of Extramural Research at NIH, presented on NIH reform efforts. Report language in FY14 and FY15 appropriations bills directed NIH to charter a workgroup to develop a plan to reduce administrative burden on NIH grantees. NIH has chosen instead to contract with the National Academies Committee to include a review and recommendations specific to NIH. Sally suggested that the Public Health Service (PHS) conflict of interest (COI) regulations were an area for possible reform, potentially in the form of technical corrections to the regulations. In particular, disclosures for travel reporting and just-in-time submission of financial disclosures. AAMC, COGR and AAU data indicate that travel disclosures do not identify COI to manage. COGR and AAU staff met with the Deputy Secretary of the Department of Health and Human Services (HHS), Mary Wakefield, on July 20 to discuss the PHS FCOI regulations and other areas under HHS in need of reform. COGR and AAU also recently spoke with a Nature reporter on the revised PHS FCOI regulations. Nature is preparing an article on the topic and it is expected to be published soon.

Gil Tran and Danny Werfel presented on behalf of OMB. There was a lot of discussion with Committee members on how OMB and other agencies can solicit input from research universities and other stakeholders. Danny Werfel suggested that interactions with stakeholders during the recovery act process allowed for greater transparency and resulted in a better product. He suggested that stakeholders need to organize themselves. Gil Tran presented on aspects of the Uniform Guidance that affect research universities most, including the potential for fixed awards and outcome based measures and the Utility Cost Factor. There were also presentations by the human and animal research accrediting agencies, AAALAC and AAHRPP; the HHS OIG on OIG audits; the U.S. Department of Commerce on export controls; and a patient research advocacy group.

Senator Lamar Alexander spoke before the committee. He requested that the Committee submit an interim report to Congress in September with 10-12 specific recommendations

that should be put into law (via legislation or changes to HHS or OMB regulations) that would simplify requirements and reduce costs for institutions conducting federally funded research. The Chair of the Academies committee indicated that he thinks they will be in a position to submit an interim report in the timeframe Senator Alexander suggested. <u>Presentations</u> can be found on the National Academies website.

Government Accountability Office Study on Regulations and Reporting Requirements Imposed on Research Universities

In October 2012, Representative Mo Brooks, former Chairman of the House Science, Space and Technology Committee's Subcommittee on Research Education, sent a <u>letter</u> to the GAO comptroller requesting GAO review the current regulations and reporting requirements imposed on research universities; in particular effort reporting, subrecipient monitoring and the paper record maintenance required for contractors under FAR. COGR met with GAO in April. As we understand it, the GAO study is likely to focus on finances, personnel, effort reporting, subawards, data sharing, and conflict of interest.

National Science Board August Meeting

The National Science Board met August 12 and 13. <u>Archived webcasts</u> can be found on the NSB website. The Audit and Oversight committee met largely in closed session. During open session, NSF CFO Marty Rubenstein mentioned that as part of the DATA Act implementation there has been a big push on agencies from OMB and Treasury, but did not provide details. She noted that BFA leadership is changing. They are in the process of filling four vacancies. Dale Bell has been reassigned to Mary Santonastasso's former position as Director of the Division of Institution and Award Support.

The NSB Working Group on Administrative Burdens met on August 13. The Chair, Artie Bienenstock, indicated that the working group had sent a letter to NIH in support of the draft single IRB policy, but with a few word of caution on liability and implementation. NIH is working to address comments before releasing a revision and implementation policy, noting very divergent opinions within the community.

Dr. Bienenstock indicated that the National Academies Committee on Federal Regulations and Reporting Requirements met with Senator Lamar Alexander and Congressman Lamar Smith recently and, at Senator Alexander's request, will issue an initial report in September with appendices to be released in spring. In addition to identifying priority areas for harmonization or elimination of existing regulations, the committee is expected to specify a design for a high-level standing committee for ongoing harmonization as recommended by the NSB in their report released last May. He noted that GAO is also expected to release a report on this topic early next spring.

On the subject of the recently released NSF OIG report on the FDP payroll certification pilot at George Mason University, Artie noted that pilot sites have indicated that there are significant reductions in PI burden with payroll certification and suggested that the report findings offer significant hope. On the topic of PIs reviewing effort for all employees across all grants, he indicated that COGR met with the OIG this week to discuss this, noting the importance of these discussions. He expressed appreciation for the OIG's engagement with the community as a means to develop systems and controls that are less burdensome while protecting federal funds.

NSF Acting Deputy Director Richard Buckius and Policy Head Jean Feldman were present to discuss how NSF is implementing recommendations from the NSB report. They noted a number of pilot efforts among NSF directorates, including mechanisms to increase success rates among applicants; eliminating budgets at the time of proposal or only requesting a justification (where budgets are not requested by federal agencies, institutions are encouraged to follow-suit); reducing reporting requirements; and streamlining reports for the first year of a grant. NSF also noted that presently 2.8% of proposals are returned without review for a number of reasons. They are working to improve their automated compliance checking system to ensure that once proposals are successfully submitted they cannot be returned without review. They are also working to standardize proposal formats. NSF noted that beginning October 1, NIH OLAW will oversee all vertebrate research conducted with NSF funding and suggested that OLAW and USDA are seeking to reduce burden associated with animal research. An NSB member suggested that NSF gain feedback on their efforts from institutions. Dr. Buckius noted that NSF has sought feedback from institutions, PIs and reviewers in relation to some pilot efforts and will continue to do so.

NIH Scientific Management Review Board Report

The NIH Scientific Management Review Board released a <u>draft report</u> on Streamlining the NIH Grant Review, Award and Management Process. The draft report was the topic of a teleconference on July 6. Among the recommendation, that NIH pilot test an expanded preapplication process in which potential applicants submit brief summaries of proposed projects; pilot testing an expanded continuous submission policy; fast-tracking awards for high priority, top scoring applications; and evaluating just-in-time procedures to identify potential mechanisms to enhance efficiencies.

DATA Implementation and Pilot

The implementation of the Digital Accountability and Transparency Act is underway and the section 5 pilot was initiated in May. OMB is seeking to create standard definitions for data elements used across the federal government. A number of data elements and their proposed definitions are currently open for comment. *Institutions are encouraged to review the definitions and <u>comment</u> as appropriate before the pending deadlines (August 17, 21 and 28).*

OMB is also partnering with HHS in an effort to reduce administrative burden in the grants community. On August 3, representatives from AAU, COGR, APLU and FASEB met with OMB staff to discuss the <u>National Dialogue</u>. Section 5 of the DATA Act stipulates that the OMB Director, in consultation with relevant Federal agencies, recipients of Federal awards, including State and local governments, and institutions of higher education, review the information required to be reported by recipients to identify common reporting elements across the Federal Government; unnecessary duplication in financial reporting; and unnecessarily burdensome reporting requirements. It requires the OMB Director to establish a pilot program to meet these goals.

The Dialogue is a means to facilitate communication with recipients of federal grants and contracts to identify and reduce duplication and burden. Among the ideas we put forth during our meeting with OMB staff, in response to a broad question on reporting burden, were reducing the number of federal payment management systems; reducing the frequency of financial reporting;

piloting/implementing collaborative awards as an alternative to subrecipient monitoring; raising the micropurchase threshold from \$3,000 to \$10,000; and piloting aspects of the Uniform Guidance that have the potential to reduce administrative work associated with federal awards as part of the data collection activities included in the pilot. These include, awards of similar purpose or blended funding (200.430); fixed amount awards (200.45; 200.201); and outcome-based reporting (200.430).

In follow-up to our meeting OMB released a <u>blog post</u> by Howard Shelanski, Administrator of the Office of Information and Regulatory Affairs, OMB; David Mader, Acting Deputy Director for Management, OMB and Controller of the Office of Federal Financial Management; and, Anne Rung, Administrator, Office of Federal Procurement Policy, OMB. The blog post promotes the Federal Government's partnership with the Nation's colleges and universities in conducting federally funded research, noting that it is strong, but perhaps not as efficient and beneficial to taxpayers as it could be. It invites institutions to share their ideas on how to reduce unnecessary duplication and burdensome reporting requirements as part of the administration's ongoing efforts to reduce burden on federal contractors and grant recipients. Following our meeting with OMB, new questions have been added to the <u>Dialogue web page</u>.

OMB will seek comments over the next 4-6 weeks and review feedback in mid-October. AAU, COGR, APLU and FASEB will provide feedback via the National Dialogue and we will make additional information on this effort available to members over the next few days. Institutions, and their administrative staff and PIs, are encouraged to respond to some or all of the questions posed and to comment on existing ideas, including those submitted by the associations (AAU, COGR, APLU and FASEB) and other stakeholders.

The Government Accountability Office is conducting multiple audits on the federal government's implementation of the DATA Act. Gene Dodaro, Comptroller General of the United States, recently testified before the Subcommittees on Information Technology and Government Operations, House Committee on Oversight and Government Reform. GAO has published its <u>findings</u> to date on the status of the implementation as well as <u>highlights</u> of the findings.

Notice of MOU between NIH and NSF Concerning Laboratory Animal Welfare

NIH released <u>NOT-OD-15-139</u> on August 10 announcing an <u>MOU</u> between the NIH Office of Laboratory Animal Welfare (OLAW) and the NSF to ensure consistent and effective oversight of the welfare of animals used in activities funded by the NSF while harmonizing the agencies' efforts and reducing regulatory burden to institutions.

Effective October 1, 2015, institutions receiving NSF support must include NSF-supported activities with live vertebrate animals as covered activities in their OLAW Animal Welfare Assurance and report situations involving NSF-supported animal activities to OLAW as required by the Public Health Service Policy on Humane Care and Use of Laboratory Animals. For its part, OLAW will negotiate new Assurances for institutions with pending NSF awards; review and evaluate noncompliance reports and the actions taken involving NSF-supported activities; and report findings to NSF.

USDA Petitions

The USDA's Animal and Plant Health Inspection Service has published three petitions from animal welfare organizations over the last few months. COGR and AAU have submitted joint comments on the <u>Petition to Amend the Reporting Requirements for Research Facilities Under the Animal Welfare Act</u> and the <u>Petition to Develop Specific Ethologically Appropriate</u> <u>Standards for Non-human Primates in Research</u>.

We have strongly recommended that no action be taken in response to these petitions. There is no evidence to suggest that current regulations and reporting requirements should change. We believe the proposed changes would only serve to increase the administrative work and expense associated with the conduct and oversight of animal research. Comments were distributed to members via the COGR listserv and will be posted on the COGR website. Institutions are encouraged to send separate comments. Comments are due August 24 and August 31 respectively.

NSF IRB Approval

Several universities notified COGR that NSF has requested IRB approval in a week's time or less over the course of the summer. This presents a real challenge for investigators and institutions and potentially compromises the quality of review. The NSF policy office has indicated that NSF was nearing the end of the Foundation's fiscal year and funds must be obligated by a specific date. Institutions have suggested that the issue was more pronounced this year.

Another issue raised with the NSF policy office was that NSF does not allow for IRB approval "in concept" for research in which human subjects will not be included at the outset of the study and for which the study design/protocol cannot be completed/predicted at the time of award. This was reaffirmed in the most recent version of the PAPPG. We asked how NSF reconciles this with <u>45 CFR 690.118</u> which indicates that IRB approval for these types of studies is not required at the time of award. The policy office responded that NSF remains fully compliant with the Common Rule for Protection of Human Subjects, and, an IRB can make a determination that a project lacks definite plans for human subjects involvement pursuant to 45 CFR §690.118. It was noted that the language contained in Chapter II.D.8 of the PAPPG relating to the restrictions against "in concept" and conditional approval documents do not contravene this.

The NSF policy office suggested that an appropriate use of a 118 determination are situations where while it is likely human subjects will be involved in the project during the award, a reviewable protocol cannot be developed until more definite plans are established. This protocol development is normally only possible following an initial period of research in which human subjects are not being engaged. The determination would also specify that the human subjects cannot be involved until the revised protocol has been reviewed and approved by the IRB, and would bind the researcher to a timeline and process for returning to the IRB with a reviewable protocol. In terms of binding researchers to a timeline, institutions might consider addressing this through shortened continuing renewal times.