COGR
Council On Governmental Relations
An Association of Research Institutions

October 17, 2017

TO: COGR Membership

FROM: COGR Staff

SUBJECT: October 2017 Update

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The Administration's Efforts to Cut F&A: Into the Fall Season

The September 2017 COGR Update included an update, at of the end of the summer, on the Administration's efforts to cut F&A. That update still is timely, and our conclusion from that update still holds: Our community's combined efforts have had a significant impact and we are cautiously optimistic that we will be successful in turning back the Administration's effort to cut F&A. However, the work on this issue is not complete.

The Association F&A Working Group comprised of COGR, the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), the Association of Public Land-grant Universities (APLU), the Association of Independent Research Institutes (AIRI), the National Association of College and University Business Officers (NACUBO), and other partners, has been a galvanizing force to develop documents and other materials, which help to explain the role of F&A costs in the research enterprise. In addition, your institutions have been key in writing letters and engaging government leaders to explain the importance of F&A and other infrastructure costs, which contribute to the United States being the world leader in producing life-changing research outcomes.

As we enter into the Fall Season, the focus of the Association F&A Working Group is to stay diligent and attentive to all developments. While we have been successful stemming the tide, to-date, we expect more discussion, and at least one more Congressional Hearing, around this topic. We will address new issues during the October COGR Meeting, and will keep the Membership updated on all developments.

Alternatives to Effort Reporting: Thursday Afternoon Session at the COGR Meeting

This session will provide an update by the "National Cohort for Alternatives to Effort Reporting" organization on their recent activities and next steps. Paul Coleman, a former NSF fraud investigator, a representative from the SUNY System, and leaders of the National Cohort will engage in a panel discussion to share expertise, experience and perspective on alternatives to effort reporting. A new system implemented in early 2017 at SUNY Buffalo, which was reviewed by the institution's single auditors, will be used as a case study.

The "National Cohort" currently comprises 89 institutions and their leadership group is actively reaching out to the research community to present alternatives to effort reporting, with a focus on the internal control framework. In the backdrop of the National Cohort's work is the consistent message from OMB encouraging institutions to pursue alternatives. However, buy-in from the IG Community remains uncertain. A June 21st NSF OIG Memorandum from Mark Bell, Assistant IG, addressed to OMB, was noncommittal in the NSF IG's support of the FDP Pilot Payroll Certification Program. The NSF IG highlighted two observations in their memo: monthly/bi-monthly reconciliations and providing full allocations to PIs. COGR's position is that alternatives that comply with 2 CFR 200.430(i)(1), and equally important, that significantly can reduce burden, should be advanced. The Thursday afternoon session will include significant Q&A and opportunities to delve deep into this topic.

Uniform Guidance Update

COGR reported on the items covered below in the September 2017 COGR Update, as well as in previous COGR Updates over the past year. Several of the items below include comments made by federal officials at the National Conference on College Cost Accounting (NACCA), held in Bethesda, Maryland, October 2-5. While the comments made by federal officials are not available as official, written policy, they are informative and appear to represent federal policy intentions.

Procurement and the Micropurchase Threshold (MPT). The May 17, 2017 Federal Register Notice confirms a one-year grace period for implementation of 2 CFR 200.317-326 (Procurement Standards). For most COGR members, this means that 2 CFR 200.317-326 must be implemented on July 1, 2018.

The MPT you are using (e.g., $5,000, $10,000, $25,000, etc.) remains effective through the end of the one-year grace period. For those institutions that exceed $10,000, the one-year extension gives you cover to continue following your policies implemented under OMB Circular A-110. However, COGR recommends documenting your justification for exceeding $10,000 so that you are in compliance with the National Defense Authorization Act (NDAA; i.e., *(A) $10,000; or (B) such higher threshold as determined by the head of the relevant executive agency and consistent with clean audit findings under chapter 75 of title 31, internal institutional risk assessment, or State law*). As necessary, COGR recommends you consult with your Single Auditors and/or General Counsel for your institution.

Gilbert Tran (Office of Federal Financial Management, Office of Management and Budget-OMB), spoke at NACCA and commented on the process for approval of an MPT that exceeds $10,000, after the one-year grace period concludes. According to Mr. Tran, OMB is the entity that will approve an MPT greater than $10,000, and this will be coordinated with the institution's Cognizant Agency for Indirect Cost (i.e., CAS-HHS, ONR-DOD). If your institution will need this approval, we encourage you to contact Mr. Tran at: hai_m._tran@omb.eop.gov. Note, this process for approval is not available as official, written policy, so please contact COGR if there are questions or concerns and we will attempt to facilitate, as appropriate.

Revisions to 2 CFR Part 200 (Uniform Guidance). According to Mr. Tran, revisions to the Uniform Guidance are necessary. In addition to official implementation guidance for the Procurement Standards and the MPT, provisions from the "Buy American Hire American" Executive Order (signed by the President earlier in the year), and other policy clarifications need to be incorporated as revisions to the Uniform Guidance. While there is no timetable for a Federal Register Notice announcing revisions to the Uniform Guidance, this is a development that COGR will follow closely for the remainder of the year and into 2018.

FAQs to the Uniform Guidance, Software Capitalization Threshold. OMB released updates to the Frequently Asked Questions for the Uniform Guidance (2 CFR Part 200). The FAQs are dated July 2017 and include 24 new FAQS and 4 revised FAQs. COGR did an initial assessment of those FAQs in the September Update. Since then, at the NACCA meeting, one update of note was made. A representative from Cost Allocation Services (CAS-HHS) clarified the intent of FAQ .33-1 Capitalization Level for Software to mean that the $5,000 software capitalization threshold is applicable only to situations where the software is attached to the hardware. The $5,000 software capitalization threshold is not applicable to internally developed software and is not applicable to stand-alone software. Therefore, institutions are not expected to change their software capitalization if they are in compliance with GAAP.

While it is not clear what opportunities will present themselves to influence additional updates to the Uniform Guidance, COGR will stay alert to all opportunities that can result in improvements.

Payment and Reimbursement under 2 CFR 200.305 and the Compliance Supplement

Recently, auditors have challenged COGR member institutions by suggesting that grants and cooperative agreements should be subject to a strict interpretation of what constitutes payment/disbursement to a vendor. Specifically, the auditor position is that prior to billing a federal sponsor for reimbursement, the institution must have evidence that the institution's payment to the vendor has been cleared. This is in conflict with existing policy per 2 CFR Part 200.305(b): … *payments methods must minimize the time elapsing between the transfer of funds from the United States Treasury or the pass-through entity and the disbursement by the non-Federal entity*. Predicating a request for reimbursement on when a payment to a vendor has cleared will make timely reimbursement inefficient, and in many cases, impossible. Furthermore, this discards longstanding, effective, and common-sense disbursement practices typically employed at research institutions where reimbursement is requested after an invoice from a vendor has been approved, identified for payment in the accounts payable system, and posted in the institution's official accounting records.

The source of this new audit approach has been generated by the IG community. COGR actively has pursued this issue with Federal government representatives, as well as representatives from KPMG, PwC, and the AIPCA. While many of these representatives are supportive of our position, single auditors are obligated to work under guidance from the IG community. Fortunately, Public Comments have been requested to address the 2017 Compliance Supplement, and COGR will provide a comment letter to OMB, Gilbert Tran.

Public Comments are due October 31, 2017. COGR will post a copy of its letter to OMB and Mr. Tran during the week of October 16 and will notify the Membership, via email, when that letter is posted. We encourage you to submit a letter if this issue is a concern at your institution.

As specified in an August 14th Federal Register Notice, comments should be submitted to Gilbert Tran at hai_m._tran@omb.eop.gov. Include "2 CFR Part 200.305(b) and Subpart F-Audit Requirements, Appendix XI-Compliance Supplement-2017" in the subject line and the full body of your comments in the text of the email and as an attachment. Include your name, title, organization, postal address, telephone number, and email address in the text of the message. Comments may also be sent through regulations.gov.

This is an important issue to a number of institutions and comment letters from your institution, in addition to the COGR letter, will elevate the unease around this issue. Contact David Kennedy at dkennedy@cogr.edu if you have questions on how to best craft your concerns to OMB.

Costing Policies Committee: Other Issues

The Costing Policies Committee is working on a wide range of other issues. Some of these are ongoing and have been covered in past COGR updates. As appropriate, each one will remain on our list for the remainder or 2017, and into 2018.

GAO-17-721, National Science Foundation: Actions Needed to Improve Oversight of Indirect Costs for Research. The GAO report, GAO-17-721, reviewed the amount of NSF funding for indirect costs and NSF's negotiation of Indirect Cost Rates (ICRs). NSF has cognizance for about 110 organizations, mostly nonprofit and professional societies, museums, and operators of large shared-use facilities (such as

accelerators, telescopes, and research vessels. The GAO recommended NSF take three actions to improve its guidance for setting ICRs, including adding certain details and procedures. NSF concurred with GAO's recommendations and described plans to address them. While COGR's perspective is that the GAO report is neutral to our community, the fact that F&A rates are being closely scrutinized at the federal level suggests that we should pay attention to other perspectives and reactions to this report.

Single IRB and Direct Charging. The Research and Regulatory Reform (RRR) Committee continues to follow this topic, including developments related to the new January 25, 2018 implementation date. From a costing perspective, the primary focus has been on the costing FAQs. The most recent version of FAQs for the NIH Policy on the Use of a Single IRB for Multi-Site Research Costs is available at the NIH Office of Science website.

Equitable Treatment of Off-Campus Research Centers in NIH RFAs. This has been an ongoing "niche" issue to encourage NIH to devise a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. Off-campus research centers are at a competitive disadvantage; i.e., by being required to include lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. We hope to resolve this longstanding issue soon.

We will keep the Membership posted on all developments related to the above issues. We encourage you to raise issues not covered to the COGR staff or to members of the Costing Committee.

COGR/AAU Ask ED to Rescind Open Licensing Requirement

On September 19 COGR and AAU jointly submitted comments to the Department of Education (ED) in response to the Executive Order 13777 regulation review. We asked ED to substantially revise or rescind the open licensing requirement for grant funded copyrightable materials. The letter expressed our view that a "one size fits all" rule is inappropriate given the broad and diverse nature of ED-funded materials.

This is the third time we formally have asked ED to reconsider or rescind the rule. While discussions with ED indicate that the implementation of the rule may be tentative and the impact limited (see September Update), we still believe the rule is not well-considered and should be rescinded.

Discussions with DOD Continue on "Covered Defense Information"

The September Update discussed the comments submitted by COGR/AAU with regard to the DFARS 7000 clause and "covered defense information." The comments noted that the clause erroneously conflates the inputs of covered defense information with the conduct or output in fundamental research determinations. We asked that the DFARS be modified accordingly. (A copy of the comment letter is on the COGR website).

As noted in the June Meeting Report, we had invited DOD to meet with the COGR CIP Committee to discuss this issue. However, they were not able to participate due to transition of responsibilities within DOD/DPAP. Over the summer we continued to reach out with the assistance of the DOD Director for Basic Research. We now have confirmed the participation of an appropriate DOD representative to meet with CIP at the October meeting. We will report to the membership on the meeting discussion.

DOD Issues Guidance on Implementation of Cybersecurity Requirements

The October 2016 Meeting Report includes an extensive discussion of the DFARS 252.204—7008 *Compliance* and 7012 *Safeguarding Covered Defense Information and Cyber Incident Reporting* clauses. While there appeared to be some confusion in the clauses as to the need for a variance from the requirements prior to December 31 of this year, the bottom line is that full implementation is required by December 31, 2017 (unless there is an approved variance). The costs of compliance with the security requirements (NIST SP 800-171) are high, particularly for institutions with a substantial number of DOD contracts.

On September 21 the Director of DOD/DPAP issued internal guidance on implementation. The guidance makes clear that any covered defense information (CDI) provided to a contractor must be marked by DOD. However, while there is a requirement for the contractor to also mark CDI developed in the performance of the contract, the guidance does not indicate specifically which information or how it is to be marked. If required by the contract to be developed, this should be specified by DOD in the contract with the specific marking requirements.

An additional security control was added by last year to NIST SP 800-171 that requires contractors to develop a System Security Plan (SSP). This requirement (3.12.4) requires the contractor to develop, document and periodically update system security plans that describe system boundaries, system environments of operation, how security requirements are implemented, and the relationships or connections to other systems. The DOD guidance indicates that contractors should have SSPs in place by December 31. They can be incorporated by reference in proposals (to avoid disclosing sensitive information). In addition, NIST security requirement 3.12.2 requires contractors to develop and implement Plans of Action (POAs) designed to correct deficiencies and reduce or eliminate system vulnerabilities. We understand that DOD has indicated that if a contractor has an SSP and POA in place by December 31 that accurately reflects its compliance status, that will be considered implementation of 800-171 for purposes of the 7012 clause (even if all 110 NIST security requirements are not met).

There is no specific format requirement for SSPs, and DOD will not monitor or require third party certificates of compliance. In addition to SP 800-171, the DOD guidance suggests that contractors consult NIST SP 800-53 (the FISMA requirements) for clarifying guidance on and examples of controls. The DOD guidance also discusses how compliance with the 7012 clause should be used in the source selection process and addressed in RFPs. DOD also plans to issue FAQs to respond to the most common questions and concerns.

Assuming CDI is involved, COGR members are reminded that by submitting contract offers and proposals to DOD, they are representing that the 800-171 security controls including SSPs and POAs will be implemented by December 31, according to the 7008 clause. Once incorporated in proposals they become a contractual obligation. The DOD guidance may be found here.

Revised Bayh-Dole Implementing Regulations Still on Hold

The September Update indicated that the revised Bayh-Dole regulations remain on hold. We recently confirmed with NIST that is the case. The February Meeting Report discussed the meeting of the CIP Committee with the NIST General Counsel.

We understand there is high level interest in the Administration in enhancing university tech transfer. What form this may take is not known at this time, but there are ongoing discussions. Clearly there could be some impact on Bayh-Dole and its implementing regulations.

We will notify the COGR membership of any change in the status or new initiatives.

Second Reminder: UIDP Contracting Forum

As mentioned in the September Update, on November 13 and 14 the UIDP is holding a university—industry contracting forum hosted by Arizona State University in Phoenix. COGR, AAU and the Council on Competiveness are partnering with the UIDP in the forum. For more information and the draft agenda see https://www.uidp.org/event/contracting-forum/.

Human Subjects Research and Related Policy

Proposed One-Year Delay to the Implementation of the Common Rule

On October 7 a proposed delay to the implementation of the Common Rule was posted to the White House Office of Information and Regulatory Affairs website. The proposed action pending review is entitled "Federal Policy for the Protection of Human Subjects: Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year." No additional information is available at this time. In a letter to Dr. Jerry Menikoff, Director of the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP), dated June 21, 2017, COGR, AAMC, AAU and APLU requested a one year delay in the compliance date with an effective date for most provisions [those other than cooperative research] remaining January 19, 2018. This would allow the regulated community to move forward with any or all provisions of the rule, including those that would reduce administrative burden for investigators (e.g., certain exclusions and exemptions, and elimination of the continuing review requirement for certain types of research and IRB review of grant applications) while allowing institutions more time to come into full compliance, given the uncertainty and lack of guidance and templates that has resulted from a regulatory freeze and review of the rule. Additional clarity on the proposed changes to implementation is anticipated when a notice of proposed rulemaking is issued in the coming weeks.

Upcoming SACHRP Meeting

The Secretary's Advisory Committee on Human Research Protections will hold its next meeting on October 17-18. OHRP has posted an agenda and webcast URL.

HHS Draft Strategic Plan for 2018-2022 Posted for Comment

HHS released its draft strategic plan for 2018-2022 on September 26. Strategic Goal 4 centers on fostering "Sound, Sustained Advances in Science." Of potential impact to research is language on promoting ethical and responsible research, including improving "human subjects protection, and enforcement of human subjects protection regulations and other laws governing research, especially with respect to research involving human embryos or embryonic stem cells/tissue, fetal tissue, genetic engineering and manipulation of the germ cell, and the creation of chimeras." Comments on the plan are due by October 26, 2017.

OHRP and FDA Issue Joint Guidance on Minutes of IRB Meetings

On September 25, 2017, OHRP and the Food and Drug Administration (FDA) announced the availability of guidance entitled "Minutes of Institutional Review Board Meetings; Guidance for Institutions and Institutional Review Boards." The guidance is intended to assist IRBs in meeting HHS and FDA regulatory requirements for meeting minutes, including the type and amount of information to include. The notice indicates that this joint guidance is an effort to harmonize the agencies regulatory requirements and guidance, and is consistent with the goals of section 3023 of the 21st Century Cures Act which calls for harmonization of human subjects regulations. The guidance finalizes draft guidance that was issued for comment in November 2015. The notice indicates that the guidance represents "current thinking" and "does not establish any rights for any person and is not binding on OHRP, FDA, or the public." Per the notice, institutions "can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations."

New NIH Review Criteria for Research Project Applications Involving Clinical Trials

In a notice issued on September 21, 2017, the National Institutes of Health (NIH) announced "new and more rigorous" review criteria that NIH will apply to clinical trial applications submitted on or after January 25, 2018. The additional review criteria relate to the significance of the proposed work; the expertise and experience of the personnel; whether the research plan includes innovative elements; the approach in terms of study design and data management and statistical analysis; whether the environment is appropriate for conducting the proposed research; and the study timeline. Detailed questions are included in the notice.

NIH Clinical Trial Case Studies

COGR, AAMC, AAU and APLU sent a letter to Dr. Michael Lauer, NIH Deputy Director for Extramural Research, on September 17, 2017 expressing concern that NIH's definition of "clinical trial" has been significantly expanded through the set of case studies published by NIH in late spring/early summer. As noted in the joint letter, the three primary concerns of the research community are 1) that the case studies have themselves modified the definition so it now includes fundamental and basic health-related research, 2) that inconsistencies and insufficient clarity in the analysis may lead to different conclusions from institution to institution about which research will now constitute a clinical trial, and 3) that the impact on an investigator and research study of designating research as a clinical trial is more significant than has been acknowledged. The latter includes required registration and results reporting in ClinicalTrials.gov; Good Clinical Practice training for investigators and staff; limitations on the ability to apply for grants other than through clinical trial-specific FOAs; additional review criteria; training awards that cannot be used for clinical trials; and required use of a

single IRB for multi-site research. An expansion of the definition of clinical trials through published case studies may relate, in part, to assertions that all NIH-funded human subjects research should be reported, however, the research community has suggested that this can be achieved without the significant complications that result from designating basic health research as clinical trials. COGR will keep members informed of any updates on this topic.

NIH Certificates of Confidentiality

On September 7, 2017, NIH issued its Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality which became effective October 1, 2017. The agency's policy on Certificates of Confidentiality (CoCs) was updated to comply with Section 2012 of the 21st Century Cures Act, Privacy Protection for Human Research Subjects. Although CoCs are intended to prohibit disclosure of sensitive, identifiable information in response to legal demands, applicability of the revised policy centers on identifiability and has been broadened to include biospecimens and "any other research that involves information about an individual" for which "there is at least a very small risk" that some combination of the biospecimen/information, a request for the biospecimen/information, "and other available data sources could be used to deduce the identity of an individual." In addition, the revised policy applies to "research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data" regardless of identifiability.

Effective October 1, 2017, certificates of confidentiality will issue automatically for applicable NIH awards as part of the award terms and conditions. NIH will not determine applicability, that is now the responsibility of the awardee institution and investigators. NIH will also no longer provide a paper certificate. The award itself may be used as confirmation that CoC protections are in place. The policy applies to research commenced or ongoing on or after December 13, 2016. The NIH CoC website has now been updated and includes updated consent language and FAQs. Additional questions can be directed to mailto:NIH-CoC-Coordinator@mail.nih.gov.

NIH Genomic Data Sharing (GDS) Policy: Access Model for Genomic Summary Results

NIH has published a request for comment on proposed updates to its GDS Access Model for Genomic Summary Results, or aggregate genomic data, that the agency suggests would provide access that is proportional to risks and benefits posed. Per the notice, "access to this information is currently only available through controlled access. NIH is proposing to allow broader access to genomic summary results from most studies subject to the NIH GDS Policy." The notice indicates that public data resources to share genomic summary results have not resulted in "individuals being matched to participation in a research study." NIH is proposing to "promote broad sharing of genomic summary results from most research studies with data held in an NIH-designated data repository through a new 'rapid access' tier" that requires that users "affirm agreement with a statement regarding responsible use of the information." With respect to "potentially stigmatizing traits" and "increased privacy risk or heightened risk of group harm", the notice suggests that institutions submitting summary results can indicate, as applicable, that the results should be provided only through controlled access as part of their Genomic Data Sharing Plan. Comments on the proposed changes will be accepted through October 20, 2017. COGR anticipates submitting comments in support of the proposed updates.

Regulatory Reform

FDA Seeks Comments on Regulatory and Information Collection Requirements

The Food and Drug Administration published a Federal Register notice on October 8 on Review of Existing Center for Biologics Evaluation and Research (CBER) Regulatory and Information Collection Requirements.

Per the notice, CBER "regulates a wide range of biological products and related products including: Allergenics, blood and blood products, certain medical devices for blood and tissues, gene therapies, human cells, tissues, and cellular and tissue-based products, vaccines, and xenotransplantation products." The agency is seeking comments "solely on regulations and approved information collections related to these product areas" to identify "requirements that could be modified, repealed, or replaced…to achieve meaningful burden reduction." The request is part of the agencies implementation of Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs" and Executive Order 13777, "Enforcing the Regulatory Reform Agenda." Comments are due December 7.

Audit

NSF Office of Inspector General (OIG) Reports

The NSF OIG posted several recent reports on audits of incurred costs, including two performed at research universities. In the first report, auditors questioned $639,479 in costs related to expenses near award expiration ($304,290), indirect costs on subawards ($217,387), charges related to participant support, travel costs, and other expenses. With respect to expenses near award expiration, the report suggests that the university "did not properly plan the purchase of items or equipment within the allotted period awarded to be operational for regular research." The university disagreed with all but one of the questioned costs. With respect to subawards, the auditors suggest that the $25,000 indirect cost limitation requirement was not properly followed. The report suggests that "rather than treating each university as a stand-alone subaward" the university "applied the IDC threshold requirement to each subaward purchase order, instead of the aggregate level, thus causing subaward universities to exceed the $25,000 threshold requirement." The university disagreed with the finding, suggesting that "there is no requirement that [the university] aggregate all subawards made to a single institution and treat them as a single subaward for purposes of applying [the universities] F&A rate to the first $25,000 of direct charges."

In a second university audit of more than $176 million, auditors questioned $56,904 of costs claimed to NSF awards including $39,770 in subaward payments; $12,196 in compassionate leave; and $3,529 in travel. Per the report, a transaction classified as a subaward was not budgeted within the original or revised budgets. The university indicated that the subaward was made so that an investigator transferring to another university could complete their work. The auditors note that this requires NSF approval which the university did not obtain. With respect to compassionate leave, the universities own policy, not NSF policy, requires agency approval to charge a grant or contract for compassionate leave which was not obtained.

National Science Foundation

NSF Request for Information on Mid-Scale Research Infrastructure

The National Science Foundation has issued a request for information on mid-scale infrastructure in response to the American Innovation and Competitiveness Act which requires NSF to "evaluate the existing and future needs, across all disciplines supported by the Foundation, for mid-scale projects" and "develop a strategy to address the needs." The RFI is focused on "projects with an anticipated NSF contribution of between $20 million and $100 million towards construction and/or acquisition." NSF is looking for ideas for mid-scale infrastructure projects that include the potential for inter-agency or international partnerships and contributions, transformative science or scientific breakthroughs that would be enabled by the project, and evidence of research community support. The notice includes additional details on information that should be included in submissions. Submissions are due by December 8.

COGR Staff Attend Closed Workshop at the NIH on Data Sharing

COGR staff was invited to participate in a one-day workshop co-hosted by the NIH Office of Science Policy and the NSF Science of Science and Innovation Policy (SciSIP) program. The workshop entitled, "T**he Value of Data Sharing"** was held to identify approaches and frameworks in order to inform a future research agenda and policy directions.

Invited guests from universities, private industry, and federal agencies gave brief talks that addressed lessons learned from existing data systems and repositories. Other areas discussed included evaluating methods and metrics for analyzing the impact of data sharing, examined appropriate mechanisms for best practices in privacy, security, and ethics, and cost/benefits and the return of investment of data sharing.

Recommendations from this workshop will be used to develop a future agenda such as the potential development of a white paper, the creation of specialized focus groups by topic and the potential release of funding opportunity announcements to fund recipients' additional research in this area.

Stakeholder Engagement Meeting on Dual Use Research of Concern

In September's Update, we shared that The U.S. Government and the National Science Advisory Board for Biosecurity (NSABB) was co-hosting a workshop to engage with stakeholders and facilitate information sharing among research institutions regarding their approaches to, and experiences with, implementing the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC). COGR staff attended this day and a half workshop to listen to the attendees share their challenges, best practices and solutions regarding policy implementation and to deduct whether any future changes could be forthcoming to the existing USG policy.

A member of Office of Science and Technology Policy asked what would happen if the USG removed the 15 select agents from the policy instead limiting the policy only to the seven experiments of concern as documented in the Companion Guide. Several at the workshop suggested that this would increase burden by triggering formal risk mitigation plans. In addition several indicated that they had added an eighth question to

the list of experiments asking whether the investigator could envision a reasonable scenario where the research could be used as a weapon(s). Some require that all PIs respond to the seven questions listed on the IBC application while others have suggested that they support the seven questions being added to the USG Policy. Other topics during this workshop included concerns about publishing DURC research. COGR will continue to monitor updates in this area.

Ad Hoc Committee on Confidentiality in Research Misconduct

In the June Meeting Report COGR indicated that a new ad hoc committee on Confidentiality in Research Misconduct was being formed to address and seek solutions to issues related to confidentiality during and after the active assessment, inquiry, investigation, and determination process. The working group last met on October 13th and has discussed topics including whether the committee should review all other agency policies (non HHS) around confidentiality (see https://ori.hhs.gov/federal-policies) to determine if policies are different and unclear in addressing members concerns and formulate various scenarios that arise regarding confidentiality in misconduct cases. The committee is in the process of forming deliverable(s) and will communicate the results to the COGR membership. For more information, please contact jbendall@cogr.edu.