



An Association of Research Institutions

OCTOBER 2020 MEETING REPORT

ANNOUNCEMENTS

Council on Governmental Relations February 2021 Meeting Will Be Virtual

CROSS CUTTING ISSUE: COVID-19'S IMPACT ON RESEARCH - GENERAL UPDATES

COGR's Resources and Continued Activities on COVID-19's Impact on Research (UPDATE)

Research Impact Under COVID-19: Financial Crisis and the "Pandemic Normal" (UPDATE)

Research Relief and the RISE Act (NEW)

COVID-19 Research Impact Survey (UPDATE)

COVID-Related Flexibilities (UPDATE)

COVID-19's Impact on Research from a People Perspective (NEW)

COVID-19's Impact to Research – Institutional and Federal Perspectives (NEW)

NIH Notice NOT-OD-21-006, Exceptions to Use of a Single IRB During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (NEW)

CROSS CUTTING ISSUE: OMB ISSUES FINAL GUIDANCE ON 2 CFR 200

Uniform Guidance Readiness Guide (UPDATE)

NSF Announces Update to Research Terms and Conditions (RTCs) (NEW)

CROSS CUTTING ISSUE: SCIENCE AND SECURITY

Department of Education Focus Continues on Foreign Gift and Contract

Reporting (UPDATE)

Confusion Over Section 889 Statutory Prohibitions on Telecommunications

Equipment (UPDATE)

DOE Orders Continue to Raise Concerns (UPDATE)

Interim DOD DFARS Cybersecurity Rule Poses Serious Challenges for

Universities (UPDATE)

Results and Analysis from COGR Survey on Institutional Disclosure Practices (UPDATE)

HHS OIG Survey for NIH Grantee Institutions on Actions Institutions are Taking to Address

Foreign Influence (NEW)

Anticipated NIH Guidance on Commitment Transparency (NEW)

Conflict of Commitment Principles Project (NEW)



RESEARCH SECURITY AND INTELLECTUAL PROPERTY

COGR Comments on Foundational Technologies ANPRM (NEW)

Bayh-Dole 40th Anniversary Celebrated (NEW)

COSTING AND FINANCIAL COMPLIANCE

Federal Audit and Single Audit Developments (NEW)

2020 Compliance Supplement (UPDATE)

Costing & Financial Compliance (CFC): Other Issues (NEW and ONGOING)

RESEARCH ETHICS AND COMPLIANCE

Follow-Up on NIH Guidance Regarding Change in Status, Including Absence of PD/PI and Other Key Personnel Named in the Notice of Award (UPDATE)

Meeting with Officials from the Office of Research Integrity (NEW)

Interview for NSF Sponsored Research Project Regarding RCR Education (NEW)

Animal Research

Submission of Comments in Response to the Requests for Information (RFI) (NEW)

Submission of Comments in Response to Notice of Proposed Rulemaking (NPRM)

Regarding Changes to Animal Welfare Act (AWA) Regulations (NEW)

<u>USDA Listening Sessions on Upcoming Regulation of Birds not Bred for Research under the</u> <u>AWA (NEW)</u>

CONTRACTS & GRANTS ADMINISTRATION

COGR Responds to DEA's Interim Final Rule (IFR) Implementing the 2018 Agricultural Improvement Act (UPDATE)

NIH Releases Final Data Management and Sharing Policy (UPDATE)

NIH Requirement to Upload FCOI Policy Annually in eRA Commons Institution Profile (IPF)
Module (NEW)



Announcements

Council on Governmental Relations February 2021 Meeting Will Be Virtual (NEW)

As communicated in our November 12 message on the COGR Listserv, our February 2021 meeting will be held virtually. We are targeting the week of February 22-26. Registration will open in late December or early January, and we will distribute a preliminary agenda shortly thereafter. Please send any questions to Toni Russo at trusso@cogr.edu.

Cross Cutting Issue: COVID-19's Impact on Research - General Updates

COGR's Resources and Continued Activities on COVID-19's Impact on Research

COGR's <u>Institutional and Agency Responses to COVID-19 and Additional Resources</u> page was initiated in March and continues to be publicly available and regularly updated. COGR remains focused on activities applicable to research operations under the pandemic, and applicable issues are addressed throughout this October COGR Meeting Report. If you have questions or concerns, please reach out to <u>COGR Staff</u>.

Research Impact Under COVID-19: Financial Crisis and the "Pandemic Normal" (UPDATE)

In August, COGR posted <u>Research Impact Under COVID-19</u>: <u>Financial Crisis and the "Pandemic Normal"</u> as a new COVID-19 resource. The paper presents a model for estimating research output loss and financial impact of COVID-19, describes the challenges of doing research under the new "Pandemic Normal," and advocates for renewed commitment and a substantial infusion of new research investment, calling on federal leaders, research institutions, and all stakeholders to rally around the longstanding Federal Government-Research Institution Partnership. The Research Impact Metric (RIM) Model presented in the paper is a tool institutions can use to estimate the research output loss and financial impact due to the COVID-19 pandemic. Case studies are shown, and other impact variables are described.

COGR is interested in additional case studies, so please contact David Kennedy at <u>dkennedy@cogr.edu</u> if your institution has developed analyses using the RIM Model or similar tools.

Research Relief and the RISE Act (NEW)

We recommend accessing the Association of Public and Land-grant University (APLU) webpage, under the section titled <u>Federal Emergency Funding</u>, as an excellent resource that documents the unfolding of COVID-19 legislative actions. As we know, after May and up to the election, pandemic (and research) relief grinded to halt. However, now that the Election Day is behind us, we expect new dialogue on Capitol Hill to address pandemic relief. Right now, it is an open question as to how pandemic



relief legislation would proceed—and depending on what dollar amount is realistic under a bipartisan approach, research relief may or may not be part of broad pandemic relief legislation. Still, with most of the pre-election politicking behind us, it is time to pay attention on next steps. COGR is in regular communication with our association partners—APLU, AAU, AAMC, ACE, AAAS, and COGR—participating in a "Research Relief Workgroup" and next steps are being strategized.

The Research Investment to Spark the Economy Act (RISE Act) is a potential vehicle for advancing research relief. Prior to the election, the RISE Act received bipartisan support in both the House and the Senate. The current version of the RISE Act would authorize approximately \$26 billion to address research relief for the federal science agencies (and ultimately, our institutions). Diverse entities and interest groups have come out in support of the RISE Act. A June 24 Press Release from Congresswoman Diana DeGette (D-CO) provides background. A July 23 Press Release from Senator Ed Markey (D-MA) articulates the bipartisan support for the RISE Act. And a September 15 Letter of Support from the U.S. Chamber of Commerce demonstrates the diversity of support.

There could be other mechanisms to advocate for research relief, including the regular budget appropriation bills required for each federal agency. Further, whether pandemic relief is timed with the current administration or the new administration remains an unknown. In short, as wisely said by one of our association colleagues at our most recent meeting of the Research Relief Workgroup—"everything is clear as mud."

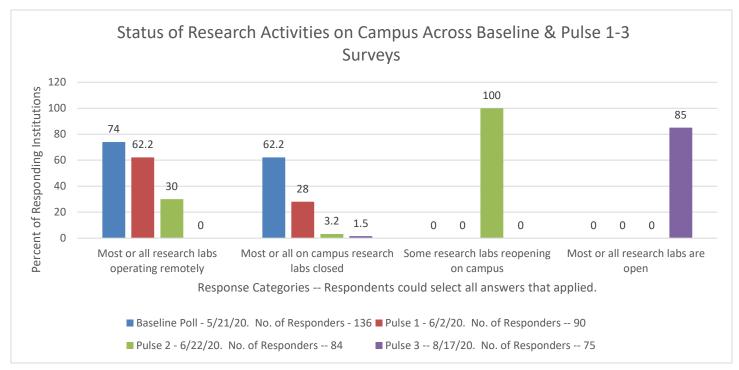
And finally, returning to research impact and case studies, it will be helpful to have the most up-to-date and comprehensive metrics available as it relates to research output loss and financial disinvestment. Based on the current case studies included in the *Research Impact Under COVID-19: Financial Crisis and the "Pandemic Normal"* paper, the Research Impact Metric (RIM) model has shown: 1) research output losses between **20 and 40 percent**, 2) financial disinvestment in the *hundreds of millions* of dollars at individual institutions, and 3) potential impact in the *tens of billions* of dollars across the entire U.S. research enterprise. The more data we have to support this analysis, the better! We encourage you to reach out to David Kennedy at dkennedy@cogr.edu to share the experience at your institution and to provide data that we can add to our case studies.

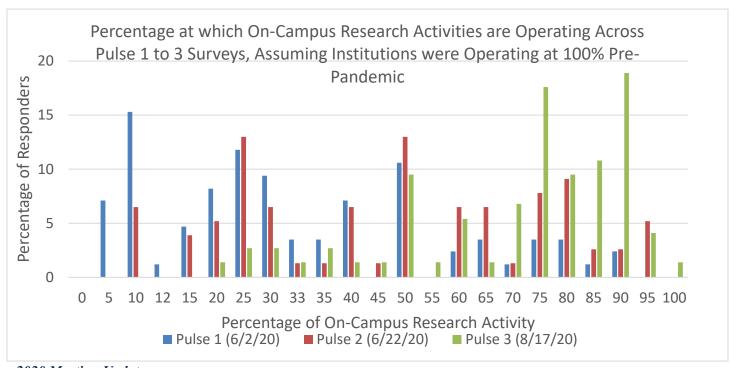
COVID-19 Research Impact Survey (UPDATE)

COGR's COVID-19 Research Impact Study is in its final phase. The penultimate pulse survey closed on August 28th, and the final pulse survey will be conducted in mid to late November. As was done with the first two pulse surveys, data from the last two pulses will be analyzed in one report and a final report encompassing all data will be released. The May 21 Baseline report and the July 2 Pulse 1 & 2 reports are available on the COGR website here.



In the interim, the two charts below show that on-campus research activities have bounced back after the rapid shutdown in March 2020, with 85% of responders reporting in the Pulse 3 survey that most or all on-campus research labs are open. Further, over half of responders (62.3%) reported that on-campus research activities were operating at 75% or more (assuming that they were operating at 100% prepandemic).







Note that due to the ongoing uncertainty of the pandemic and rapidly changing circumstances during the winter months, COGR may do a follow up pulse in early 2021, which would be included as an addendum to the final report.

COVID-Related Flexibilities (UPDATE)

As previously reported, the majority of the OMB COVID-related flexibilities were rescinded by the issuance of OMB Memorandum 20-26, and the restricted salary flexibility announced in that memorandum expired on September 30, 2020. Nevertheless, some funding agencies have announced that they will consider flexibility on a case-by-case basis or made general announcements that they will employ flexibility in administering awards. For example, on September 29, 2020, NASA issued Grant Notice 20-02, which stated that NASA would consider salary flexibility extensions on a case-by-case basis in accordance with 2 CFR 200.102, Exceptions. Similarly, on September 24, the Department of Energy's Office of Science released a statement regarding flexibilities that announced "it is committed to maximum flexibility in administering awards, recognizing potential delays in research caused by impacts of the COVID-19 pandemic." For latest agency developments, see COGR's Institutional and Agency Responses to COVID-19 website.

COVID-19's Impact on Research from a People Perspective (NEW)

At the October virtual membership meeting, COGR hosted a panel presentation that explored the pandemic's effects on research personnel. Dr. Kyle Myers from the Harvard Business School presented on his research examining the unequal impact of the pandemic on scientists. Research data shows that some researchers have been relatively unaffected by the pandemic, while bench researchers, female researchers and researchers with childcare responsibility have fared the worst. Dr. Brendan Cantwell from Michigan State University spoke about research findings and his observations on how the pandemic has impacted international trainees and students. The panel concluded with a presentation by Dr. Kay Lund, NIH's Director of the Division of Biomedical Research Workforce about steps that NIH is taking to measure and mitigate COVID's impact. Dr. Lund discussed NIH's launch of surveys to institutional research leaders and researchers to collect data on COVID's effects on research from an institutional and individual perspective. Slides for the presentation can be found on the COGR website at this link.

COVID-19's Impact to Research – Institutional and Federal Perspectives (NEW)

COGR held this virtual session on October 21 at the October COGR Meeting. The session piggybacked on a session from the June COGR Meeting and the <u>August 2020 COGR paper</u>, *Research Impact Under COVID-19: Financial Crisis and the "Pandemic Normal"* (see <u>previous section</u>). The panel included: Dr. Michael Lauer, Deputy Director for Extramural Research, NIH; Dr. Stephen Binkley, Principal Deputy Director in the Office of Science, Department of Energy; Dr. Tanju Karanfil, Vice President of Research at Clemson University; and Dr. Melur (Ram) Ramasubramanian, Vice President of Research at the



University of Virginia. The session was moderated by James Luther, Associate VP of Finance and the Research Costing Compliance Officer, Duke University. Each panelist provided a perspective on how their organization has been impacted during the COVID-19 pandemic, and further, how each panelist understands the more "macro" impact to research throughout the country. In a roundtable at the end, the panel focused on the impact on research going forward, new opportunities and challenges, and related issues. The PPT Slidedeck is available at www.cogr.edu.

NIH Notice NOT-OD-21-006, Exceptions to Use of a Single IRB During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (NEW)

On October 23, <u>NIH announced</u> institutions may seek an exception to the single IRB requirement for cooperative research that is ongoing, or has initial IRB review, during the COVID-19 public health emergency and for which:

- o Reliance on a single IRB is not practical; and
- Approval of the exception is granted by the HHS division that supports or conducts the research.

Cross Cutting Issues: OMB Issues Final Guidance on 2 CFR 200

Uniform Guidance Readiness Guide (UPDATE)

In COGR's <u>September Update</u> we mentioned the work group COGR formed to review key issues related to OMB's final guidance to 2 CFR Parts 25, 170, 183, and 200 effective November 12, 2020 (Uniform Guidance, or "UG"). During COGR's October virtual meeting, the work group referenced the draft "UG Readiness Guide" that addresses certain key provisions and points to consider as institutions implement the final revisions. The Readiness Guide is intended to be a resource to help institutions prepare for and implement the revisions to the UG. On November 17, COGR finalized the UG Readiness Guide and posted it to <u>our website here</u>. We continue to follow up with OMB regarding certain provisions and anticipated updates to the OMB Frequently Asked Questions (FAQs), and will update the membership as information becomes available. Please contact Jackie Bendall at <u>jbendall@cogr.edu</u> or Dave Kennedy at <u>dkennedy@cogr.edu</u> for additional information.

NSF Announces Update to Research Terms and Conditions (RTCs) (NEW)

On November 10, the National Science Foundation (steward of the RTCs), announced that participating agencies have released <u>implementation plans</u> and have revised RTCs and the following documents to align with the final revisions to OMB 2 CFR §200:

• RTC Overlay to 2 CFR §200



- RTC Appendix A: Prior Approval Matrix
- RTC Appendix B: Subaward Requirements
- RTC Appendix C: National Policy Requirements
- Agency Specific Requirements for the participating agencies

NSF notes that the OMB Frequently Asked Questions (FAQs) have not yet been updated and as such have been deleted from the RTC Overlay. COGR will be assessing agency RTCs along with the special terms and conditions. Contact Jackie Bendall at jbendall@cogr.edu for additional information.

Cross Cutting Issues: Science and Security

Department of Education Focus Continues on Foreign Gift and Contract Reporting (UPDATE)

We have extensively discussed in COGR meetings and updates the Department of Education (ED) activities with regard to the foreign gift and contract reporting required by Section 117 of the Higher Education Act. The <u>September Update</u> discussed the questions COGR sent to ED regarding issues and questions about the new reporting portal. To date we have not received a response from ED.

On October 9, the Department of Education and Department of State jointly sent a letter to university presidents on the "malign influence of the authoritarian government of the People's Republic of China (PRC) on our nation's campuses." The letter references an <u>earlier letter</u> sent to university governing boards by Department of State Under Secretary Keith Krach about foreign influence of the Chinese Communist Party. The letter goes on to say, "if you find that the PRC's presence, while meant to provide a Chinese language and culture opportunity for your students, also aims to constrain academic discourse about the PRC's actions, we urge you to take appropriate action."

On October 20, ED held an event to unveil the Office of General Counsel's Section 117 compliance Secretary **DeVos** suggested the report found "pervasive report. noncompliance" with institutions' Section 117 reporting obligations and evidence of "significant foreign entanglement with America's colleges and universities." The event featured comments from several government officials and others, including remarks from a student at the University of Washington who was sent to a Chinese retraining camp while doing coursework online in China. She said the University did not assist her family with her release because of a "multimillion dollar deal" the University was working on with China. The panel discussion featured comments from Bucky Methfessel, Senior Counsel for Information and Technology in the Office of General Counsel, and Charles Small, Executive Director for the Institute for the Study of Global Antisemitism and Policy. ED officials remarked that Section 117 requirements "are clear and straightforward" and suggested that statistics confirm the notion that institutions are underreporting. The panel also discussed the impact of foreign influence on curriculum, teaching, and departments. Small specifically labeled universities as "purveyors of anti-Semitism."



Additional conflation was made about the nexus of research dollars and the numerous DOJ cases which illuminate failures in faculty disclosure reporting. The inference was that it is somehow connected to Section 117 institutional reporting. Lacking from the event was any direction or discussion of guidance for institutions on how they can better report and/or maintain compliance.

The event was <u>covered in the press</u>. A number of higher ed. associations issued statements regarding the ED event and report. The AAU statement noted that institutions for decades have worked closely with our nation's national security agencies to properly identify and address threats and potential threats to our country and security. It went on to state that the Department of Education "purports to be concerned about threats but has consistently failed to respond to repeated requests for clarity, transparency, and guidelines in the reporting requirements for Section 117." The statement concluded that "This report is less a serious security assessment than it is a partisan and politically driven attack on America's leading research universities."

ED also announced that it would publish a <u>notice of interpretation</u> (NOI) in the Federal Register (FR) and update its <u>online portal</u> for data reported by institutions. The NOI is in addition to the true copies proposed rule which is still <u>pending</u> at OMB/OIRA. The Notice <u>was published</u> in the Federal Register on November 13. It addresses ED's enforcement authority for failure to adequately report under Section 117. The NOI claims that ED has authority to implement a range of corrective measures for an institution that violates its Program Participation Agreement under the HEA Title IV Student Financial Aid Program, including termination of the institution's Title IV participation. The NOI claims similar enforcement authority under Title VI. The NOI is effective immediately. Comments are due January 13. COGR will continue to work with the other associations on Section 117 reporting issues and will keep the membership informed.

Confusion Over Section 889 Statutory Prohibitions on Telecommunication Equipment (UPDATE)

Over the past two years we have extensively discussed the statutory prohibitions on the purchase and use of certain telecommunications equipment and services provided by Huawei and a number of other entities. (For a full discussion see the COGR <u>September 2020 Update</u>).

As we pointed out in the <u>September Update</u>, the discussion of the grants prohibition in the August 13 Uniform Guidance is inconsistent. This has led to confusion and inconsistent agency implementation. On September 24, we sent a letter to OMB pointing out the inconsistency and expressing concern about the potential confusion. We urged OMB to clarify the guidance. We also raised concerns about the unclear impact on institutions with subrecipients under federal grants, particularly in the case of international subrecipients in locations where the entire national infrastructure for telecommunications may be built using the now prohibited equipment. We also asked if a federal-wide waiver process would be available to agencies for allowing such use under these circumstances. If not, we noted that federally funded projects will be precluded from partnering with important entities in entire countries.



Other than acknowledge receipt, OMB has not responded to our letter. However, NSF, after issuing mass grant amendments with an erroneous interpretation of the prohibition, shortly afterwards corrected the interpretations with a subsequent mass amendment. Unfortunately, the revised DOD DODGARs also contain the erroneous interpretation. We have called this to DOD's attention. USAID recently updated a comprehensive set of FAQs which correctly state the grants prohibition and provide much related information both pertaining to grants and the separate contracts prohibitions, which the <u>FAQs</u> discuss in detail.

Among the important distinctions is that the "non-use" contract prohibition (FAR 52.204-25(b)(2)) extends only to prime contractors and does not flow down to subs. In contrast, the grant prohibition on use of funds to purchase the covered equipment extends to contractors at all tiers. Unlike the contract non-use prohibition, however, grant recipients are not prohibited from using the covered telecommunications equipment or services; the prohibition is on the use of grant funds for purchases of such equipment or services. Unfortunately, the Uniform Guidance confused these prohibitions, which led to the inconsistent agency interpretations.

DOE Orders Continue to Raise Concerns (UPDATE)

We have focused much attention in recent COGR reports and virtual meetings on Department of Energy (DOE) Order 142.3A requirement for DOE approval for foreign national access to DOE information, technologies or equipment. As discussed in the September Update, Steve Binkley, Principal Deputy Director of the DOE Office of Science, stated at the COGR August 18 webinar on Foreign Influence and Research Security that the Order specifically applies to visits to DOE sites and labs and was not intended to apply to financial assistance agreements. The removal of the exemption for university fundamental research from the 142.3A requirement in December 2019 was unintentional. A revision process has been initiated. It is expected to be completed by the end of the year.

COGR, AAU, and APLU have been in continued communication with DOE about this issue. Our member institutions have experienced increasing issues, with demands from DOE in some cases that foreign national PIs on existing awards be removed, even when the projects may have received long-term DOE funding. While the DOE Office of Science is sympathetic to our concerns, unfortunately most of the issues have involved the more applied components of DOE, particularly EERE and NETL. AAU plans to seek a meeting with senior leadership at DOE. However, there may not be good prospects for changes until there is a change in DOE leadership.

Another DOE Order of concern is 486.1, which prohibits participation by DOE employees and contractors in foreign talent recruitment programs with certain countries of risk. A recent revision (486.1A) restricts participation in a wide range of other activities with these countries, and imposes extensive disclosure requirements. This includes resource and/or financial support from all



foreign and domestic entities, including but not limited to, gifts, financial support for laboratory personnel, and participation of student and visiting researchers supported by other sources of funding. This further includes compensation, for example, and current or promises of future: grants, awards, funding, scholarship, appointment, sabbatical, travel, university directed funding, and honoraria. At the August 18 session, Dr. Binkley stated that the Order applies only to the DOE labs and contracts issued by them (as opposed to DOE financial assistance awards to universities). Flow downs to universities from the national labs also are excluded as are researchers conducting research under DOE facility user agreements. COGR subsequently was informed that a fact sheet was being developed that would clarify the scope of the order and confirm the exclusions. A FAQ was recently posted to the DOE website that addresses the issue. We will continue to pursue this matter with DOE.

Interim DOD DFARS Cybersecurity Rule Poses Serious Challenges for Universities (UPDATE)

On September 29, DOD issued an interim DFARS rule Assessing Contractor Implementation of Cybersecurity Requirements (RIN 0750-AJ81; DFARS Case 2019—DO41; 85 FR 61505). The rule includes changes to DFARS 212.301 and 217.207, and three new DFARS clauses: 252.204-7019, 20 and 21.

On September 1, COGR <u>had sent a letter</u> to DOD jointly with AAU, APLU, and EDUCAUSE expressing concerns about the implications of DOD's Cybersecurity Maturity Model Certification (CMMC) for fundamental research at our member institutions. We urged DOD to exclude fundamental research from the CMMC program. We also urged establishment of a dialogue with DOD on the issues associated with the implications of CMMC for institutions of higher education.

These concerns have been heightened by the interim rule. It requires companies included in the Defense Industrial Base (which includes our member institutions) to obtain at least a CMMC Level 1 certification. The Level 1 certification (Basic Cyber Hygiene) covers the Basic Safeguarding Requirements set forth in FAR 52.204-21. I. The rule also requires all DOD contractors to have current (not more than 3 years old) NIST SP 800-171 DOD Assessments on file with the DOD (DFARS 252.204-7019). This includes at least a Basic Level (CMMC Level 1) Self-Assessment. Without such an assessment, offerors cannot be considered for award. The rule is effective November 30.

The FAR Basic Safeguarding Requirements apply to federal contract information. Federal contract information (FCI) is defined in the FAR as "information not intended for public release." This does not include most fundamental research. While many of the FAR requirements in fact have been implemented by our member institutions, they include a number of requirements antithetical to fundamental research (e.g. restricting physical access to the research environment or the posting of public information).

The problem is further complicated by the fact that the focus of the NIST SP 800-171 security requirements that form the basis for the CMMC framework is the protection of Controlled Unclassified



Information (CUI) in nonfederal systems and organizations. The relevant DFARS clause that applies these requirements is DFARS 252.204-7012. That clause applies to the safeguarding of "covered defense information" (CDI) as described in the CUI Registry. But institutions that have received a fundamental research determination under DFARS clause 252.204-7000 by definition have no CDI. The clause thus is self-cancelling, as DOD acquisition officials have stated in the past.

The result is a conceptual problem with applying the interim rule to situations where the interim rule framework does not fit. The practical consequences are serious. In addition to threatening the openness of fundamental research, implementation of the CMMC/NIST requirements will result in unnecessary costs and burdens. The current assessment requirement may lead researchers and institutions, as well as some DOD contracting officers, to assume that such an assessment is required even though no CUI/CDI, and therefore no 171 controls, are involved. Similarly, the rule's application of the assessment requirements to subcontracts (252.204-7021) will likely also generate confusion about those requirements among industry prime contractors, which often carve out fundamental research activities for university sub-recipients. It is common for research universities to experience prime contractors flowing down inappropriate contract requirements for fundamental research activities, leading to inefficiency and expense as institutions have to work with prime contractors to resolve the issues. In fact, COGR has already been informed by a member institution of a recent situation where the 7019 assessment requirement has been flowed down from a DOD prime, even though the subcontract involves only fundamental research.

Draft joint association comments on the interim rule <u>are posted</u> on the COGR website. They make the above points and others. The comment deadline <u>has been extended</u> to January 4. However, we plan to submit the association comments this month.

We urge COGR member institutions to consider submitting their own comments. It is important that DOD receive a large volume of comments and concerns from the stakeholder community. Institutions, of course, are committed to cyber security. Many of our member research institutions have provided national and international leadership on information security for decades. However, the bottom line is that DOD should not subject fundamental research at our institutions to requirements that are intended to secure information that fundamental research does not entail and that run counter to the free exchange of knowledge that forms the very basis of fundamental research. Institutions may refuse to continue conducting DOD-funded fundamental research if it remains subject to these requirements. We will post the final comments as soon as available.

Results and Analysis from COGR Survey on Institutional Disclosure Practices (UPDATE)

A summary of results from COGR's Survey on Institutional Disclosure Practices <u>was presented</u> during the October membership meeting. This survey was conducted to collect information on institutional processes to address the government's emphasis on mitigating inappropriate foreign influence on research.



The presentation also included discussion by attorney Max Weber from the University of Texas M.D. Anderson Cancer Center and Dr. Allison Ratterman from the University of Louisville on policy/process changes their institutions put in place to address foreign influence concerns.

HHS OIG Survey for NIH Grantee Institutions on Actions Institutions are Taking to Address Foreign Influence (NEW)

HHS OIG recently issued a survey to institutions that receive research funding from NIH. The purpose of the survey is to collect information about institutions' practices for collecting and reviewing researchers' information concerning significant financial interests and other support. HHS OIG issued two versions of the survey: a longer version that was issued to 100 randomly selected institutions at the end of October, and a shorter version that was issued to all other NIH-funded research institutions in November. Surveys were issued based on DUNs numbers, and some institutions received more than one survey. COGR asked HHS OIG if it would consider extending the deadline for responses, and HHS OIG granted an extension until December 10, 2020.

COGR also discussed with HHS OIG the additional burden placed on institutions that received more than one copy of the survey. HHS OIG advised that institutions should contact HHS OIG to explain their circumstances, and in cases in which the same policies/processes apply enterprise-wide, institutions may be able to answer the survey once online and provide answers by email to specific count questions for each unit the received the survey. HHS OIG stated that the survey is designed to collect information that will be used to develop recommendations for NIH and that it is not for investigative purposes. The survey report will be public.

COGR is hosting a discussion forum call for institutions that received survey. Institutions should contact Kris West at kwest@cogr.edu if they would like to be included in this call.

Anticipated NIH Guidance on Commitment Transparency (NEW)

On October 27, NIH gave a presentation entitled "Commitment Transparency" at its <u>Virtual Seminar on Program Funding and Grants Administration</u>. During this presentation, NIH advised that it would issue a notice in November that provides "clarifications" to researcher disclosure obligations for Biosketches and Other Support. Among the anticipated new requirements is that institutions must provide NIH with copies of contracts that researchers have with foreign entities. If contracts are not in English, they must be translated. The new requirements are expected to take effect January 2021. The slides for this presentation can be found at this <u>link</u>.



Conflict of Commitment Principles Project (NEW)

COGR is launching a new project to develop a framework document for principles that institutions should consider in examining processes and procedures in area of conflict of commitment. The project also will consider the important differences between conflict of commitment and conflict of interest. For more information, contact Kris West at kwest@cogr.edu.

Research Security and Intellectual Property

COGR Comments on Foundational Technologies ANPRM (NEW)

As discussed in the <u>September COGR Update</u>, on August 27, the Commerce Bureau of Industry and Security (BIS) issued <u>an ANPRM</u> on Identification and Review of Controls for Certain Foundational Technologies. Identification of critical emerging and foundational technologies was called for in the Export Reform Act of 2018. BIS issued an ANPRM on emerging technologies in November 2018 (see COGR <u>December 2018 Update</u>). COGR <u>submitted comments</u> in January 2019 jointly with other higher education associations. To date, BIS has proposed or implemented case-by-case controls on a multilateral basis on a limited number of emerging technologies (e.g., see 85 FR 62583; 85 FR 71012).

On November 5, COGR <u>submitted comments</u> on the Foundational Technologies ANPRM jointly with AAU, APLU, AAMC and ACE. In our letter, we noted that since foundational technologies are essential to innovation, particular care was needed to assure that any controls were not imposed on items already in widespread use, such as "EAR 99." We expressed appreciation that the ANPRM explicitly recognized fundamental research as not subject to the EAR. In defining foundational technologies, BIS should assure that fundamental research remains unrestricted.

Foundational technologies (unlike emerging technologies) tend to have worldwide availability, including on U.S. campuses for research and teaching. Any new controls should not be unduly burdensome on fundamental research. They should follow the existing export controls framework and facilitate compliance by avoiding vague or open-ended language (e.g. "capable for use with"). We recommended that BIS focus on end use and end user controls to promote transparency and reduce burden. We also recommended that the Emerging Technology Technical Advisory Committee (or any comparable group established to advise on foundational technologies) include leading researchers as well as university export compliance officials.

We did not attempt to identify or define foundational technologies. We were concerned that this could be a slippery slope with high potential for unintended consequences for the academic research community. We expect that BIS will also hear from industry groups who may propose definitions. The bottom line is that foundational technologies underly U.S. competitiveness and economic security. Any attempt to regulate them needs to be carefully considered and do no harm to those interests, particularly



when the technologies have wide international availability. Our letter concluded that controls on a foundational technology should be the minimum necessary to address the specific national security concern posed by the technology. A copy of the comment letter is posted on the COGR website.

Bayh-Dole 40th Anniversary Celebrated (NEW)

A celebration of the 40th anniversary of the Bayh-Dole Act was held virtually on October 28. It featured many short segments with stories and anecdotes demonstrating the successes that the Act has brought over the years. Sen. Dole himself participated, as did one of Sen. Bayh's sons. Other participants discussed specific technologies developed under the auspices of the Act and the benefits. The relationship of the Act to the development and growth of the technology transfer profession was particularly emphasized. One of the featured speakers was Dr. Walter Copan, Undersecretary of Commerce for Standards and Technology and Director of NIST. He cited the significant contribution of the Act to U.S. innovation and economic growth. The program included a presentation to Nils Reimers, formerly director of the Stanford Technology Licensing Office and one of the few remaining "fathers" of Bayh-Dole.

The program was recorded and may be found at https://bayhdole40.org/bayh-dole-40th-anniversary-celebration/.

Costing and Financial Compliance (CFC)

Committee activities related to COVID are reported under the Cross Cutting Issue: COVID-19's Impact on Research General Updates section of this report. Several other items related to COVID are covered below, in addition to non-COVID related items.

Federal Audit and Single Audit Developments (NEW)

COGR held back-to-back virtual sessions on October 23 at the October COGR Meeting. The first session, "Update from the National Science Foundation, Office of the Inspector General (NSF OIG)," covered a comprehensive update on current activities by the NSF OIG. Mark Bell, Assistant Inspector General, Office of Audits, and Ken Lish, Director, Contract Grant Audits, Office of Audits, led the session. A wide range of topics were covered, though most notable were comments specific to the most current audit initiative—*NSF* Recipient COVID-19 Audits. The PPT Slidedeck is Award available at www.cogr.edu and Slide 11 shows key elements of this audit program. Ten institutions have been selected (note, these audits are now underway) and the focus will be on how the OMB COVID-19 flexibilities under M-20-11, M-20-17, M-20-20, and M-20-26 were implemented at the institutions. Note, the NSF OIG position is that the focus will not be on cost disallowances, but rather on fact-finding to determine how the flexibilities were implemented and related compliance analysis. The final output of these ten audits will be a "Capstone Report," which can then be used a resource for the entire community.



The second session, "Federal and Single Audit Update," covered audit issues and concerns from both the federal and single audit perspective. Jeff Silber, Senior Director Sponsored Financial Services, Cornell University, and Mike Vernick, Education Industry Section Leader, Hogan Lovells USA, led the session. The PPT Slidedeck is available at www.cogr.edu.

Jeff Silber covered the single audit perspective and one point in particular was of note—*Promise of a Compliance Supplement Addendum in the fall with "additional audit guidance for new COVID-19 related programs and existing programs with compliance requirement changes.*" As of the writing of this COGR Meeting Report, OMB has not yet released the Compliance Supplement Addendum. COGR's concern (based on discussion with experts in the audit community) is that when the Addendum is released, some of the audit guidance may not be clear, which could create uncertainty and inconsistency in how COVID-19 programs and activities are audited.

Mike Vernick covered the federal perspective, which included both OIG activity and Department of Justice (DOJ) Enforcement activity. Mike Vernick's presentation included:

- Summary of the recent DOJ settlement concerning investigators charging non-sponsored time (e.g., grant-writing) to awards;
- NSF OIG, Office of Investigations issuance of subpoenas related to Section 117 reporting (this appears to be an effort to crosswalk Section 117 reporting with Other Support reporting); and
- Status report on ongoing Foreign Influence enforcement.

As COVID-19 and Foreign Influence remain the two most pressing issues for the research community, it is not surprising that we will see ongoing audit and enforcement activity around both. COGR will stay at the forefront and provide regular updates to the membership. We also encourage you to contact <u>COGR</u> Staff when relevant audit and enforcement issues affect your institution.

2020 Compliance Supplement (UPDATE)

The 2020 Compliance Supplement was released in September. The 1,559 page document also can be accessed from the OFFM website. Key highlights, identified by OMB, include the reduction of the number of compliance areas for auditor review (see Part 2) from twelve to six (first implemented in the 2019 version) and guidance related to Coronavirus administrative relief (included in Part 8, Appendix VII, page 1542). As mentioned in the previous section, a Compliance Supplement Addendum to address how COVID-19 programs and activities are to be audited should be available soon. OMB accepted public comments to the 2020 Compliance Supplement and COGR submitted a Comment Letter. Feel free to contact David Kennedy at dkennedy@cogr.edu if you have questions, comments, or observations that you would like to share.



Costing & Financial Compliance (CFC): Other Issues (NEW and ONGOING)

The issues below include both new and ongoing issues that the CFC Committee is following:

NSF Higher Education Research & **Development** (HERD) Survey. COGR recently was notified of a new data collection element related to FTEs and Research Assistants, applicable to the FY2020 NSF HERD Survey. COGR members contacted COGR and shared concerns. out **NSF HERD** and our understanding is reached to proactively addressing this issue and that providing this data element may now be considered "optional." If your concerns have not been addressed, please contact COGR.

GAO Study on Grants Management under the OMB COVID-19 Flexibilities. COGR has been involved in two calls (June 16 and October 19) with the U.S. Government Accountability Office (GAO) related to this study by the GAO. The GAO is looking at how both federal agencies and research institutions responded to OMB COVID-19 flexibilities provided under M-20-11, M-20-17, M-20-20, and M-20-26. The report is expected to be completed in the Spring of 2021.

FY2021 F&A Cost Rate Proposals. Both Cost Allocation Services (HHS-CAS) and the Office of Naval Research (ONR), in recognition of the various challenges associated with doing an F&A cost rate proposal during a pandemic, have provided flexibilities around submitting a proposal. In the case of CAS, this includes use of provisional rates, if submitting an FY2021 proposal is unrealistic.

ONR and the DS-2. Several COGR members have shared a letter to their institution from Brian Bradley, ONR Director of IDC, requesting that the "University submit a current, accurate and complete copy of its Disclosure Statement no later than January 4, 2021." Included in the letter are several onerous expectations (e.g., "Any changes made or anticipated to be made to the disclosed practices within the past six years from certification date up to the beginning of your next accounting period should be identified using red font and include an effective date."). COGR reached out to Mr. Bradley and learned that DCAA and ONR are trying to address the issue of DS-2s and proposed revisions (going back to the mid-1990s) that never were reviewed or approved. COGR expressed concern that the requests in the letter are unreasonable and that all stakeholders need to be engaged before any new reporting requirement is finalized. ONR expressed the willingness to be flexible, and recently we have learned ONR is working with institutions on a case-by-case basis to facilitate the process.

Property/Equipment Biennial Inventory. If your institution has been unable to complete the biennial property/equipment inventory requirement as specified in 2 CFR 200.313(d)(2),



we encourage you to reach out to HHS Grants Policy to request relief. Address your request to Jimmie Curtis, Director, Division of Grants Policy and use "Urgent Inventory Exception" as your subject header. Send the request to: <u>GrantPolicyREQ@hhs.gov</u>. For those institutions that are ONR Cognizant, Wade Wargo has shared that ONR will treat this issue on a case-by-case basis and that Brian Bradley, ONR Director of IDC, is the point-of-contact.

HHS/PMS Closeout of G-Accounts. Pre-COVID-19, the message from Alice Bettencourt, Deputy Assistant Secretary for Grants, HHS, was that HHS and Payment Management Services (PMS) would soon initiate the closeout of G-accounts. In the spring, after the beginning of the COVID-19 pandemic, Ms. Bettencourt indicated that G-account closeouts would not be prioritized. However, if your institution has provided HHS/PMS with data and has not heard back, you should reach out to Dan Long at PMS and/or Jimmie Curtis at HHS to remind them that you are waiting for HHS/PMS to respond. If needed, we can provide direct email contacts to Mr. Long and Mr. Curtis.

HHS/NIH Federal Financial Report (FFR) and Federal Cash **Transactions** Report (FCTR). As reported in the June Meeting Report, submission of the FFR for HHS Operating Divisions (which includes NIH) will change for the 10/1-12/31 quarter (i.e., reports due Jan. 31, 2021). This is considered phase one of two phases, specific to changes in HHS/NIH financial reporting. The FFR will be submitted via a newly designed portal in the HHS Payment Management System (PMS). Later, in 2021 or 2022, phase two will be implemented (please note, per HHS/NIH, all dates are subject to change). This will entail the quarterly SF-272 (FCTR) being eliminated and replaced with a new "Certification of Cash Drawn" process. By eliminating the FCTR, this will also eliminate the difficult and confusing reconciliation process between the FFR and the FCTR. COGR will continue to engage with HHS/NIH and we also understand that the FDP-ERA subcommittee will be actively involved in this process.

Please contact David Kennedy at <u>dkennedy@cogr.edu</u> to further discuss any of these issues.

Research Ethics and Compliance

Committee activities related to COVID are reported under the **Cross Cutting Issue: COVID-19's Impact** on **Research General Updates** section of this report, and activities related to inappropriate foreign influence are reported under the **Cross Cutting Issue: Science and Security** section of this report.

<u>Follow-Up on NIH Guidance Regarding Change in Status, Including Absence of PD/PI and Other</u> Key Personnel Named in the Notice of Award (UPDATE)

The July 11 NIH Notice NOT-OD-20-124 describes the information NIH expects to receive from October 2020 Meeting Update



institutions in connection with requests submitted for a change in PI/PD or key personnel; or a change in the institution receiving an award, each of which actions require prior approval from NIH. Members from COGR's REC and Contracts and Grants Administration (CGA) committees met with Dr. Carrie Wolinetz, Associate Director for Policy at NIH, to ask questions regarding interpretation of this notice. These questions included inquiries about how the guidance aligns with institutional responsibilities under Title IX of the Education Amendments of 1972.

The meeting attendees agreed that they all shared the common goal of ensuring a safe research workplace that is free from sexual harassment and bullying. The group asked Dr. Wolinetz if institutions have flexibility under the Notice to accommodate the local laws and policies under which institutions must operate. Dr. Wolinetz advised that institutions do have this flexibility, and she confirmed that although institutional policies should reasonably address the Notice's goals, each organization's policies and processes will differ to reflect institutional circumstances.

In response to questions about possible conflict between the Notice and Title IX regulations, Dr. Wolinetz stated that the Notice does not address Title IX because NIH does not have jurisdiction under this law, but does have jurisdiction to ensure safety in the research workplace. Dr. Wolinetz also clarified that institutions do not need to certify the negative, i.e., that a change in PI/PD or transfer of an award is *not* related to a reportable item. Dr. Wolinetz advised that NIH may be open to publishing a FAQ to make clear that such negative reporting is not required. COGR prepared such a FAQ for Dr. Wolinetz' consideration, along with an additional FAQ regarding her statement that institutions have some flexibility in implementing the Notice. NIH has not yet responded to the proposed FAQs.

Meeting with Officials from the Office of Research Integrity (NEW)

REC members met with the following officials from the Office of Research Integrity (ORI): Director Elisabeth (Lis) Handley, Deputy Director Wanda Jones, Director of the Division of Investigative Oversight (DIO) Alex Runko, and Director of the Division of Education and Integrity Karen Wehner. Dr. Handley explained that ORI has a new initiative regarding the impact of retractions. This initiative includes detailed analysis of all retractions that ORI requested in research misconduct cases that were settled or adjudicated. Dr. Runko described the following DIO initiatives: (a) modernizing database systems for the receipt of documents and reports (e.g., possible use of Box or similar applications); (b) adoption of a web-based system to receive allegations; (c) use of artificial intelligence software to assist in image analysis; and (d) analysis of information received from ORI's Request for Information (RFI) on evidence sequestration (on which COGR submitted comments). Dr. Wehner discussed a new RFI to collect information on responsible conduct of research (RCR) educational practices. This RFI is entitled Request for Information and Comments on Fostering Research Integrity and the Responsible Conduct of Research are due on December 18, 2020. REC will develop comments for submission.



Interview for NSF Sponsored Research Project Regarding RCR Education (NEW)

The Chair and Director of REC were interviewed by one of the investigators conducting a research project designed to assist the National Science Foundation (NSF) in developing a webpage of resources for the RCR requirements under the America Competes Act. Interview discussion centered around current resources on the NSF webpage, as well as ways in which NSF could assist institutions in promoting RCR education.

Animal Research

Submission of Comments in Response to the Requests for Information (RFI) (NEW)

COGR submitted the following comment letters in response to the following Requests for Information regarding research that uses laboratory animals:

- Office of Laboratory Animal Welfare (OLAW) RFI Seeking Comments on Flexibilities for Conducting Semiannual Animal Facility Inspections (<u>NOT-OD-20-145</u>) Read COGR's October 20, 2020, <u>response here</u>.
- OLAW RFI on Clarification of Institutional Responsibilities Regarding Grant to Protocol Congruency (NOT-OD-20-153) Read COGR's October 30, 2020, <u>response here.</u>

Comments advocated further reduction of administrative burden in each of the areas.

<u>Submission of Comments in Response to Notice of Proposed Rulemaking (NPRM) Regarding Changes to Animal Welfare Act (AWA) Regulations (NEW)</u>

On November 13, 2020, COGR <u>submitted comments</u> to the USDA Animal and Plant Health Inspection Service regarding this <u>NRPM</u>. The proposed changes to the AWA include eliminating the requirement that research facilities renew their registration every three years. The changes also would eliminate the requirement that the IACUC conduct annual continuing review of research activities and replace it with a mandate to conduct a complete review of research activities every three years. COGR is supportive of these proposed changes. Comments were due November 16.

<u>USDA Listening Sessions on Upcoming Regulation of Birds not Bred for Research under the AWA (NEW)</u>

COGR participated in recently held <u>USDA listening sessions</u> designed to obtain input from the regulated community on regulations that the USDA is developing for birds that are not bred for research. One key



issue brought forth during these sessions is the difficulty of developing such regulations because of the tremendous diversity in this species of animal. Draft regulations have not yet been issued for comment.

Contracts and Grants Administration

Committee activities related to the Uniform Guidance are reported under the Cross Cutting Issue: OMB Issues Final Guidance on 2 CFR 200.

COGR Responds to DEA's Interim Final Rule (IFR) Implementing the 2018 Agricultural Improvement Act (UPDATE)

On August 21, the DEA issued an Interim Final Rule (IFR) to implement changes in controls over marijuana and marijuana-related compounds pursuant to the Agriculture Improvement Act of 2018 (otherwise known as the Farm Bill) with comments due October 20, 2020. See COGR's September Update for more information. COGR's October 20 comment letter noted that THC concentrations can likely exceed the 0.3% Δ9-THC limit during hemp extraction and thus expose researchers who seek to extract low THC derivatives (e.g., CBD) to criminal penalties for not acquiring a Schedule I license. This undermines the goal of reducing regulatory burden for individuals and entities engaged in hemp production and processing solely for the purpose of producing low-THC products like CBD, including for research purposes. COGR also recommended that DEA provide guidance on how a non-approved Schedule I registrant can comply with federal law during the processing of hemp. Contact Jackie Bendall at jbendall@cogr.edufor additional concerns or questions.

NIH Releases Final Data Management and Sharing Policy (NEW & ONGOING)

On January 10, 2020, COGR submitted a <u>comment letter</u> in response to the NIH Draft Policy and Supplemental Guidance posted to the Federal Register for public comment on November 8, 2019.

On October 29, NIH released NOT-OD-21-013 <u>Final Policy for Data Management and Sharing</u>, which is effective January 25, 2023, for grant applications and proposals for contracts submitted on or after that date, and for other funding agreements executed on or after that date. The final policy includes links to three additional guide notices containing supplemental information to address the following: 1) elements of a data management sharing plan (DMSP); 2) allowable costs for data management and sharing; and 3) information regarding repository selection for NIH supported research.

Due to the complexities of complying, monitoring, and enforcing the final policy once effective, COGR has created a cross-committee (REC, CGA, and CFC) Data Management and Sharing workgroup to address concerns. At a minimum, the work group will develop a list of issues and questions for discussion with NIH and may make suggestions for contributing to NIH's frequently asked questions. Immediate concerns noted in the policy include the following: 1) how to address and budget for allowable costs of



data sharing and management, including those that may be incurred after the period of performance of an award; 2) the potential for inconsistent implementation across NIH institutes, centers, and offices (ICOs); 3) uncertainty with respect to how data management and sharing plans will undergo programmatic assessment in the ICOs; and 4) the burden of submitting plans at time of application rather than Just-In-Time. Contact Jackie Bendall at jbendall@cogr.edu for additional questions or concerns.

NIH Requirement to Upload FCOI Policy Annually in eRA Commons Institution Profile (IPF) Module (NEW)

Effective November 12, 2020, NIH <u>now requires</u> institutions to upload Financial Conflict of Interest policies to the eRA Commons IPF module on an annual basis. Compliance checking will not go into effect until December 1 in the event institutions require additional time to make appropriate systems changes. Please contact Jackie Bendall at <u>jbendall@cogr.edu</u> for additional concerns or questions.



COGR would like to thank COGR Board Chair David Norton (University of Florida) and the COGR Committee members for their time, dedication, and expertise, without which the efforts and activities conveyed in these updates would not be possible.

Research Security and Intellectual Property (RSIP)

Elizabeth Peloso (Chair)	University of Pennsylvania
Alexandra Albinak	Johns Hopkins University
Allen DiPalma	University of Pittsburgh
Cindy Kiel	University of California, Davis
Michael Moore	Northwestern University
Dan Nordquist	Washington State University
Jennifer Ponting	University of Chicago
Kenneth Porter	University of Maryland
Fred Reinhart	University of Massachusetts
John Ritter	Princeton University
Janna Tom	University of California
Kevin Wozniak	Georgia Institute of Technology

Costing & Financial Compliance (CFC)

Joseph Gindhart (Chair)	Washington University St. Louis
Robert Andresen	University of Wisconsin-Madison
Sarah Axelrod	Harvard University
Michael Daniels	Northwestern University
Vivian Holmes	Boston University
Cynthia Hope	Georgia Institute of Technology
Michael Legrand	University of California, Davis
Nate Martinez-Wayman	Duke University
Gerald Mauck	University of Delaware
Lynn McGinley	University of Texas Medical Branch
Jeffrey Silber	Cornell University
Marcia Smith	University of California, Los Angeles
Cathy Snyder	Vanderbilt University
Renotta Young	Columbia University



Contracts & Grants Administration (CGA)

Walter Goldschmidts (Chair)	Cold Spring Harbor Laboratory
Stephanie Endy	Brown University
Jeffrey Friedland	University of Delaware
Jeremy Forsberg	University of Texas, Arlington
Charles Greer	University of California Riverside
Jennifer Lassner	University of Iowa
Steven Martin	Indiana University
Bruce Morgan	University of California, Irvine
Lisa Mosley	Yale University
Twila Reighley	Michigan State University
Craig Reynolds	University of Michigan
Jennifer Rodis	University of Wisconsin-Madison
Pamela Webb	University of Minnesota

Research Ethics & Compliance (REC)

Naomi Schrag (Chair)	Columbia University
Lynette Arias	University of Washington
Lois Brako	University of Michigan
Theresa Colecchia	Johns Hopkins University
Grace Fisher-Adams	California Institute of Technology
Keri Godin	Brown University
Karen Hartman	Mayo Clinic
J.R. Haywood	Michigan State University
Mary Mitchell	Mass General Brigham
Kerry Peluso	Florida State University
Brian Smith	University of California - San Francisco
Ara Tahmassian	Harvard University
Debra Thurley	Pennsylvania State University