COGR
Council On Governmental Relations
An Association of Research Institutions

November 19, 2018

October 25-26, 2018 COGR Meeting Report

CONTRACTS AND INTELLECTUAL PROPERTY

COSTING POLICIES

Committee: Cindy Hope, University of Alabama (Chair) , Joseph Gindhart, Washington University-St. Louis, Lynn McGinley, University of Maryland-Baltimore, Jeffrey Silber, Cornell University, Cathy Snyder, Vanderbilt University, Michael Daniels, Northwestern University, Michael Legrand, University of California-Davis, James Fortner, Georgia Institute of Technology, Sarah Axelrod, Harvard University, Nate Martinez-Wayman, Duke University, Marcia Smith, University of California – Los Angeles, Michael Moody, Massachusetts Institute of Technology, Vivian Holmes, Boston University

F&A Update and the COGR White Paper

The Thursday morning session, "The COGR F&A Paper," was led by Cindy Hope (University of Alabama), Sarah Axelrod (Harvard), Mike Daniels (Northwestern), Joe Gindhart (Washington University), Jeff Silber (Cornell), and Cathy Snyder (Vanderbilt).

The panel presented an overview of the paper, ***which is scheduled for release in January 2019.***

The stated goal of the paper is to provide a basis for productive discussion so that research funding debates are no longer diverted by nonproductive disagreements over caps on F&A cost reimbursement and misunderstandings about what is covered in the F&A cost rate. The paper addresses equitable reimbursement of F&A costs, how the F&A cost rate works, misunderstandings and myths, and other related topics. The paper is clear about the importance of how a reliable F&A reimbursement policy is critical to the continued success of the research enterprise of the United States, while also providing a strong educational foundation for understanding how the current system works and exploring potential improvements.

The following chapters underpin the paper:

Chapter 1. BRIEF HISTORY
Chapter 2. F&A FOR "NON-ACCOUNTANTS"
Chapter 3. F&A "NUTS AND BOLTS"
Chapter 4. OVERSIGHT AND AUDIT
Chapter 5. POLICY & SPECIAL TOPICS
Chapter 6. FACTS AND MYTHS
Chapter 7. THE CAP AND BURDEN
Chapter 8. WHY THE SYSTEM WORKS
Chapter 9. ALTERNATIVE SYSTEMS
Chapter 10: IMPROVING THE SYSTEM

The paper will be a memorial to a wide variety of F&A issues; with the hope that it will be a longstanding resource to the research community, as well as an advocacy-piece that can be used when

F&A (inevitably) comes under scrutiny (again) in the future. We will keep the Membership updated as we get closer to the official release date.

Nonprofit Funders, Foundations, Research Institutions … and F&A

The second meeting of the Nonprofit Funder (Foundations) – Research Institution Partnership (the NFRI Partnership), sponsored by the Government-University-Industry Research Roundtable (GUIRR), was held on November 7 in Washington DC. Leaders from the COGR Costing Committee are taking an active role in the "Research Project Support Costs" working group (which means taking a closer look at all costs charged to foundation awards, including F&A). The goal of this working group (note, the other two NFRI working groups are Administrative Streamlining and IP-Tech Transfer), is to expand education, and ultimately, address practices related to the types of costs charged to foundation awards.

More specifically, the Research Project Support Costs (RPSC) working group aims to draw a sharper distinction on costs that are normally indirect on federal awards, but could in fact, be direct on foundation awards (e.g., IRB, hazardous waste removal, data and storage, etc.). As the NFRI Partnership has worked together over the past year, we have come to better appreciate that Foundations and Nonprofit Funders are a diverse community supporting cutting edge research, start-ups, and unique/niche funding, while also complementing other funding sources, including federal funding.

Historically, and today, F&A and infrastructure support has been understood, primarily, to be the role of the federal government. Whereas the federal government, as well as research supported by private industry, normally reimburse the full F&A rate, many foundations, nonprofit funders, and charitable organizations limit grantee F&A cost reimbursement according to their organization's internal policies. Many of these organizations recognize F&A costs as essential to research. However, these policies may be set by the organization's Board with the premise that donors desire their contributions to fund the direct costs of research only. Expanding the definition of direct costs to recognize RPSCs may result in an opportunity to provide more equity in those research costs paid for by foundations.

We are hopeful that the NFRI Partnership will provide a long-term, productive forum where foundations and research institutions can work together to advance dialogue and work practices – ultimately, growing the quality of the partnership between our communities.

Blockchain Technology

COGR is listening to the growing buzz around "Blockchain Technology." The Federal Government is taking notice, as well. While COGR still is learning details about the practical application of this technology, in its simplest form it is described as the "next internet." The promise of blockchain technology is in its facilitating of financial transactions, plus the enhanced security behind these transactions, via a peer-to-peer paradigm that effectively eliminates the third party entity. In fact, practical applications already exist in fields such as the music industry, which introduces a stronger model of intellectual property protection.

At the invitation to COGR by at least one federal agency, COGR expects to start engaging with federal leaders and "getting smarter" in this area. Several interesting TED Talks are available on the Blockchain

Revolution website, sponsored by *Don Tapscott & Alex Tapscott, and we encourage you to contact COGR staff if you have experience in Blockchain Technology.*

Cloud Computing and F&A

In 2015, COGR for the first time reported that the treatment of cloud computing costs and application of F&A to these costs was of concern to select federal agencies, as well as to investigators at our institutions. At the time, it seemed an isolated discussion. Rather than opening the discussion to a broader discussion around the definition of Modified Total Direct Costs (MTDC) and the corresponding applicability of F&A, COGR leadership concluded the best strategy was to "pay attention." The issue recently was raised again, this time in the form of an NSF Program solicitation, NSF 19-510, which prohibits the application of F&A to cloud computing costs. As these costs normally are included in our MTDC research bases, prohibiting the application of F&A to these costs prompts the concern. We encourage the Membership to share any experience or concerns related to this topic, and as appropriate, COGR will engage further.

NIH Notice of Legislative Mandates for Fiscal Year 2019

The NIH has published its annual Notice of Legislative Mandates; NOT-OD-19-030. As described in the Notice, the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 (Public Law 115-245), signed into law on September 28, 2018, provides funding to NIH for the fiscal year ending September 30, 2019. The intent of this Notice is to provide current requirements outlined in the following statutory provisions [per the Notice] that limits or conditions the use of funds on NIH grant, cooperative agreement, and contract awards for FY 2019.

Included in the list of statutory provisions is implementation of the NIH Salary Limitation, which currently is set at $189,600, as benchmarked by the Executive Level II salary threshold. Note, the Executive Level II salary threshold will be subject to change on January 1, 2019, and we will keep the Membership posted. In addition to the Salary Limitation, implementation of other relevant, longstanding legislative mandates are described in the NIH Notice.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Pamela Webb, University of Minnesota (Chair); Michael Ludwig, University of Chicago; Jeffrey Friedland, University of Delaware, Walter Goldschmidts, Cold Spring Harbor Laboratory, David Norton, University of Florida, Jennifer Lassner, University of Iowa, Steven Martin, Indiana University – Bloomington, Lisa Mosley, Yale University, Allen DiPalma, University of Pittsburgh; Jeremy Forsberg, University of Texas-Arlington, Stephanie Endy, Case Western Reserve University, Twila Reighley, Michigan State University, Jennifer Rodis, University of Wisconsin - Madison

Sexual Harassment in Academia

For months now, we've been hearing about a new term and condition imposed by the National Science Foundation (NSF) in financial assistance agreements as a result of sexual harassment in science. The NSF term and condition now effective since October has Sponsored Programs offices, Title IX offices and General Counsel's working closely to map out a plan to meet the reporting requirements of the agencies term. Unquestionably the beginning of what will be more to come, Universities will likely be challenged with a plethora of compliance requirements as agencies across the spectrum roll out their own versions of a term and condition or new policies and guide notices.

The Thursday afternoon session, "Sexual Harassment in Science" led by four panelists briefed the audience on the findings and recommendations from the recent CWESM report, discussed legislative actions currently brewing on Capitol Hill and entertained questions from the audience surrounding NSF's new requirement. Dr. Frazier Benya, Senior Program Officer with the Committee on Women in Science , Engineering, and Medicine (CWSEM) and Study Director of the recent National Academies report, Peggy A. Hoyle, NSF Deputy General Counsel, Theresa J. Colecchia, Senior Associate General Counsel, Johns Hopkins University and Sarah Spreitzer, Director, Government and Public Affairs for the American Council on Education were panel presenters. Dr. Benya cited the six key recommendations from the report and indicated that a change in culture is needed rather than relying on reports of sexual harassment. The focus of the study was on Sexual Harassment of women in Science, Engineering, and Medicine only. In closing, the audience was asked to forward additional questions to COGR that will help NSF to expand its Frequently Asked Questions (FAQs) page.

COGR has been working closely with NSF to communicate questions of concern and clarity since before the term became effective. On November 13th, the NSF released a new version of Frequently Asked Questions (FAQ's), click here.

Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH, NOT-OD-19-020 ("Guide Notice")

COGR learned at its recent meeting that many of its members expressed concern about the October 17 Guide Notice (NOT-OD-19-020), Responsibilities of Recipient Institutions in Communicating Research

Misconduct to the NIH (the "Guide Notice"). The Guide Notice, requires reporting to NIH when the institution "suspects" research misconduct that "might impact the conduct of an NIH-supported project," or "suspects" that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research. Concerns were expressed in terms of putting respondents, researchers, and students, and institutions at risk of causing irreparable reputational damage. Other's expressed what the NIH planned to do with the information, how the term "suspicion" was being defined, and how it goes beyond the spirit of what the current PHS ORI regulation requires.

COGR is in the process of drafting a letter to NIH to express its concerns. For additional information, please contact Jackie Bendall at jbendall@cogr.edu.

Request for Information (RFI) on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research

On October 10, 2018, the National Institutes of Health (NIH) issued a Request for Information (RFI) in the *NIH Guide to Grants and Contracts* to solicit public input on proposed key provisions that could serve as the foundation for a future NIH policy for data management and sharing. The feedback received will be considered for use in the development of a new draft data sharing policy replacing the current NIH policy. On November 7, 2018 NIH hosted a webinar to address the key provisions, however had technical difficulties during the webinar. NIH is hosting its next webinar November 19, 2018 from 12:00 p.m. to 1:00 p.m. ET. The following information was pulled directly from their notification:

Instructions for Accessing Webinar:

1. To view the webinar presentation, please click here

2. To call-in to the webinar:

   - U.S. and Canadian participants can dial: **866-844-9416** and enter passcode: **9659769**
   - For international participants, please refer to the table of toll-free numbers found here. The passcode for international callers will also be **9659769**

PLEASE NOTE THAT WHILE YOU WILL ABLE TO VIEW THE WEBINAR THROUGH WEBEX, YOU MUST USE A SEPARATE PHONE LINE IN ORDER TO BE CONNECTED TO THE AUDIO. YOU WILL BE UNABLE TO CALL-IN VIA YOUR COMPUTER.

Participants may also send questions in advance of the webinar to SciencePolicy@od.nih.gov.

The slides from the first webinar held by NIH on November 7, 2018, are archived on the NIH Office of Science Policy website and can be accessed at: https://osp.od.nih.gov/scientific-sharing/nih-data-management-and-sharing-activities-related-to-public-access-and-open-science/.

Input on the RFI will be accepted through **December 10, 2018**, and can be made electronically by visiting here.

Comments on the RFI are accepted through **December 10, 2018**, and can be filed electronically by clicking here.

Please send any comments to jbendall@cogr.edu.

National Biodefense Strategy

Kavita Berger, Principal Scientist at Gryphon Scientific and her colleagues Corey Meyer, Scientist, and Venkat Rao, Program Director, Parsons joined the Research Compliance and Administration Committee (RCA) on Wednesday, October 24, 2018 to discuss their past year's work on a Systems-based analysis of biosecurity and biodefense policy that helped inform the National Biodefense Strategy.

During the RCA discussion, Kavita and her colleagues described the framework developed for analyzing opportunity costs of new or changing regulations (the opportunity cost analysis framework), and a framework for evaluating the successful implementation of biosecurity and biodefense policies. These analyses enabled the development of a roadmap for implementing U.S. biosecurity and biodefense policy to maximally leverage science and technology advances while simultaneously, minimizing risks. We were told during this meeting that a new Congressional Biodefense Caucus had launched in March. The mission statement released on the new biodefense caucus can be found here.

COGR Working Group on Cannabis

Despite the turnover occurring in this Administration, COGR continues to advocate for cannabis research on all strains of the cannabis plant and to encourage the Drug Enforcement Agency (DEA) to act on a plethora of pending applications for our member institutions to grow cannabis for research purposes. With Jeff Sessions resignation, it is unclear whether pressure from members of Congress can move the pendulum forward and advance legislation for conducting research. While there have been some signs of progress including the recent federal register notice practically doubling the production quotas of cannabis from 2018, it remains to be seen where this issue falls in the line of priorities. Please click here for COGR's latest inquiry letter regarding the continued impediments of conducting legitimate research on industrial hemp. For additional information on this topic, please contact Jackie Bendall at jbendall@cogr.edu.

OMB Federal Register Notice: Draft Federal Grants Management Data Standards for Feedback

The OMB launched the President's Management Agenda (PMA) in March 2018. The President's Management Agenda was set forth to identify critical challenges where U.S. Government as a whole operates behind the times. The PMA identified fourteen (14) Cross-Agency Priority (CAP) goals throughout the Agenda. This federal register notice seeks comments on proposed grants management common data standards that have been created in support of CAP Goal 8, entitled, ''Results Oriented Accountability for Grants.'' COGR staff anticipates responding to this notice. Comments must be received on or before January 15, 2019. Please submit your comments to Jackie Bendall at jbendall@cogr.edu. Stay tuned for additional updates.

RESEARCH & REGULATORY REFORM

Committee: Lois Brako, University of Michigan (Chair), Kerry Peluso, Florida State University, Suzanne Rivera, Case Western Reserve University, Ara Tahmassian, Harvard University, Lynette Arias, University of Washington, Naomi Schrag, Columbia University, Marti Dunne, New York University, Martha Jones, Washington University – St. Louis, Mary Mitchell, Partners, J.R. Haywood, Michigan State University, Rodolfo Torres, University of Kansas, Debra Thurley, Pennsylvania State University, Michelle Christy, Massachusetts Institute of Technology

Research Involving Human Participants

NIH Notices and RFI on Basic Science Research Involving Human Participants

We previously reported that ongoing concerns from the research community about revised NIH clinical trial case studies led to language in the Consolidated Appropriations Act of 2018. The language directs NIH to "delay enforcement of the new policy published in the Federal Register on September 21, 2017 [2016], including NIH' s more expansive interpretation of 'interventions', in relation to fundamental research projects involving humans" and "consult with the basic research community to determine the reporting standards best suited to this kind of research."

NIH has, over the past several months, issued notices and a request for information regarding basic science research involving human participants. The July 20 notice, Delayed Enforcement and Short-Term Flexibilities for Some Requirements Affecting Prospective Basic Science Studies Involving Human Participants （NOT-OD-18-212）, indicated that "through September 24, 2019, NIH will continue to expect registration and reporting for prospective basic science studies involving human participants [those NIH considers both basic science and clinical trials], with additional flexibility to allow reporting on existing basic science portals, with the expectation that data will eventually be transported to ClinicalTrials.gov." The notice also provides a period of "leniency for applications submitted to the incorrect funding opportunity announcement (FOA) based on the study type designation" during which time NIH will not "administratively reject any application for submission to an incorrect FOA based on study-type designation." The October 26, 2018 Notice of Intent to Publish Parent Funding Opportunity Announcements for Basic Experimental Studies with Humans (NOT-OD-19-024), indicates NIH's intent to publish a series of new parent Funding Opportunity Announcements specific to prospective Basic Science Studies Involving Human Participants" in late November 2018 for due dates beginning on January 25, 2019.

On November 12, 2018, COGR responded to an August 10 request for information on Registration and Results Reporting Standards for Prospective Basic Science Studies Involving Human Participants. As indicated in the response, COGR and other associations, organizations, and societies representing research institutions, medical centers, and scientists (as well as scientists and institutions individually),

have previously expressed concern that NIH had, practically speaking, broadened its definition of a "clinical trial" through revisions to its case studies, expanding the scope of the clinical trial definition to include a number of areas of basic science research involving human participants. New and revised case studies published in late summer 2017 vary substantially from previous cases published at the time of, and subsequent to (April 2015 and September 2016), the October 2014 publication of NIH's revised definition of "clinical trial," greatly expanding the interpretation of an "intervention" and retroactively subjecting these studies to agency policies specific to clinical trials as well as any future policies and requirements. NIH has asserted at widely-attended meetings that nothing has changed, that the community was simply not paying attention at the time that the revised definition was published, and that the community is only now waking up to this, as new policies specific to clinical trials are put in place.

A letter submitted jointly to NIH with a number of other associations and societies calls for maintaining the distinction between basic science and clinical trials while increasing transparency and reporting for basic science studies involving human participants and fostering the development of efficient and effective processes and frameworks for the treatment and reporting of basic science research. The following overarching recommendations were made:

- That NIH not adopt the proposed designation of "prospective basic science studies involving human participants," and simply require reporting of all NIH-funded basic science research involving human participants in a manner that both: (a) avoids subjecting these studies to clinical trial requirements and (b) is developed in consultation with stakeholders.
- That NIH appoint a working group of the Advisory Committee to the Director and identify other means for working collectively with the community to establish appropriate standards and frameworks for reporting all basic science studies involving human participants and to determine where that information should be stored.

FDA Proposed Rule on IRB Waiver or Alteration of Informed Consent for Minimal Risk Studies

The FDA issued a proposed rule on November 15, 2018, that would allow IRBs to "waive or alter certain informed consent elements or to waive the requirement to obtain informed consent…for certain FDA-regulated minimal risk clinical investigations" consistent with the Common Rule. Waiver or alteration would be permitted provided that the IRB finds and documents that:

- "The clinical investigation involves no more than minimal risk to the subjects;
- the waiver or alteration of informed consent will not adversely affect the rights and welfare of the subjects;
- the clinical investigation could not practicably be carried out without the waiver or alteration of informed consent; and

- whenever appropriate, the subjects will be provided with additional pertinent information after participation."

Comments are due January 14, 2019. COGR will submit comments.

NIH Genomic Summary Results Access

NIH released the notice Update to NIH Management of Genomic Summary Results Access (NOT-OD-19-023) on November 1, 2018. The notice notes the 2016 National Human Genome Research Institute workshop entitled "Sharing Aggregate Genomic Data" that considered the risks and benefits associated with access to and use of genomic summary results (GSR) and the agency's 2017 Request for Information. In follow-up, NIH is "updating its data management procedures under the GDS Policy to allow unrestricted access to GSR from most NIH-supported studies for health or research purposes" which the agency anticipates "will be appropriate for the majority of genomic datasets available through NIH-designated data repositories." The update it effective immediately.

The notice indicates that investigators will be expected to note in their genomic data sharing plan whether a study should be designated as "sensitive" for the purposes of access to GSR, and that this should be confirmed in the Institutional Certification. Per the notice, "For studies for which an Institutional Certification form has been submitted to NIH before the effective date of this update, November 1, 2018, submitting institutions will have six months to indicate if GSR from any of these studies should be maintained in controlled-access due to concerns about the sensitivity of study information." Please see the notice for additional details.

Research Regulatory Reform

October 24 Meeting with HHS and NIH Staff

The Research and Regulatory Reform, Research Compliance and Administration, and Costing committees met with Andrea Brandon, Deputy Assistant Secretary, Office of Grants and Acquisitions Policy and Accountability, Office of the Assistant Secretary for Financial Resources, HHS, and Michelle Bulls, Director, Office of Policy for Extramural Research Administration, NIH, on October 24 to discuss agency efforts to reform research regulations under the 21st Century Cures Act (Cures Act) and reform efforts under the Research Business Models Working Group.

Section 2034 of the Cures Act, reducing administrative burden for researchers, directed the HHS Secretary to "lead a review by research funding agencies of all regulations and policies related to the disclosure of financial conflicts of interest (FCOI), including the minimum threshold for reporting" and "make revisions, as appropriate, to harmonize existing policies and reduce administrative burden" within two years of enactment (the bill was enacted in December 2016). An interagency review of financial conflict of interest regulations and policies has not been conducted. HHS and NIH are expected to begin work on an evaluation of the Public Health Services FCOI regulations to assess the extent to which the 2011 revisions to the regulations were effective or added unnecessary administrative burden. HHS/NIH

may begin an evaluation this month and will work collaboratively with the Research Business Models (RBM) working group which will be considering ways to harmonize FCOI requirements across agencies to reduce burden as indicated in its May 25, 2018 report.

The HHS Secretary was also directed to "evaluate financial expenditure reporting procedures and requirements for recipients of funding from the National Institutes of Health and take action, as appropriate, to avoid duplication between department and agency procedures and requirements and minimize burden to funding recipients." Regarding the Federal Cash Transaction Report, the agency is looking at the possibility of only certifying, not reporting. This would take place over the course of the next year. HHS, with Treasury, is piloting the use of block chain for grant payments.

The Cures Act directs NIH to reduce administrative burden associated with subrecipient monitoring, which may include exemption where the subrecipient is subject to Federal audit requirements. NIH and other agencies are working with the RBM on a potential government-wide solution. There were no updates on progress on animal research regulatory reform as directed by the Cures Act and in follow-up to NIH's request for comment earlier this year.

Strengthening Research Rigor and Reproducibility

Federal agencies and nonprofit organizations and societies continue to introduce resources to enhance research rigor and reproducibility and address concerns regarding both preclinical and clinical research results. In an October 25 panel discussion, Shai Silberberg, Director of Research Quality at the National Institute of Neurological Disorders and Stroke (NINDS), discussed NIH efforts to improve rigor, the outcomes of the October 22-23 NINDS workshop "A Visionary Resource for Instilling Fundamental Principles of Rigorous Neuroscience Research," and the role institutions can serve to facilitate rigor and reproducibility. Funding mechanisms such as the R35 allow for longer-term, flexible funding; and efforts have been made to improve rigor and transparency in grant applications, including addressing the rigor of prior research, providing a rigorous experimental design, consideration of relevant biological materials, and authentication of key biological or chemical resources.

Major recommendations from the October 22-23 NINDS meeting included that culture change is required at all levels, from undergraduates to senior faculty, and that failures should be embraced as part of the learning process; that resources should be targeted to all career stages; evaluations should assess behavioral change; that the community needs to champion efforts and share resources; and that institutions need to step up their engagement and consider a research improvement strategy. Slides from the presentation can be found here.

Brian Nosek, Co-founder and Executive Director of the Center for Open Science (COS) that operates the Open Science Framework also participated in the discussion. Dr. Nosek discussed the current focus on publishing as a means of measuring success and efforts to change the current research culture. The Open Science Framework, OSF Institutions, TOP Guidelines, and badges are some of the tools developed by COS to change culture. Badges have led to measurable increases in preregistration, open

data, and open reporting of materials. The use of registered reports allows for publication regardless of outcome and greater reporting of negative results. Slides from the presentation can be found here.

COGR Research and Regulatory Reform committee members Naomi Schrag, Vice President for Research Compliance, Training, and Policy, Columbia University, and JR Haywood, Assistant Vice President, Office of Regulatory Affairs and Professor, Michigan State University, presented results from the COGR survey on rigor and reproducibility. Sixty-four of COGR's 187-member institutions (34%) completed the survey. Slides from the presentation with survey results can be found here. A report is expected to be issued in early December 2018.

SciLine - Scientific Expertise and Content on Deadline

At a time when newsrooms are facing economic challenges and there are fewer and fewer science reporters, SciLine, a AAAS-hosted and philanthropically-supported initiative, provides journalists with quick, free, access to knowledgeable, articulate scientists. One year after its launch, Rick Weiss, Director, and Meredith Drosback, Associate Director for Science, provided an overview of the organization's mission and services at the October 25-26 COGR meeting. Slides from this session are available here.

SciLine matches journalists to scientists with expertise on the topics and issues they are reporting on. In addition to matching, SciLine produces evidence-based fact sheets for journalists on scientific issues in the news. These have included topics such as Immunotherapy in Cancer, Gravitational Waves, Wildfire Trends in the U.S., and Concussions and Brain Health. Media briefings have been held on topics such as Gene Drives and Understanding Sea Level Rise, and SciLine staff have been visiting newsrooms across the country to spread the work about this free resource.

SciLine is looking to greatly expand its database of scientists across the spectrum of scientific disciplines and they need your help! Please contact Meredith Drosback to discuss how your institution can connect our nation's scientists with journalists in need of expertise.

Nonprofit Funder – Research Institution Partnership Workshop

COGR and the Health Research Alliance held a second day-long workshop of the Nonprofit Funder – Research Institution Partnership on November 7, 2018. The workshop, which aims to foster effective relationships between non-profit research-funding organizations and research-performing institutions, was supported by the National Academies Government University Industry Research Roundtable and held at the Academies Keck Center in Washington, DC.

The workshop focused on progress to date on efforts by the intellectual property and technology transfer, research project support costs, and streamlining administrative requirements working groups and nine subgroups. Feedback was sought from meeting participants and efforts were made to move ongoing initiatives forward.

Meeting materials are available on the COGR website. Additional materials, including summaries of breakout discussions, will continue to be posted to the website. A third meeting will be scheduled in 2019.

National Science Board – New Members and November 28-29, 2018 Meeting Information

On November 8, 2018 the White House announced its intent to appoint five new members to the National Science Board (NSB) and to re-appoint two former members. New members include Maureen Condic (University of Utah), Suresh Garimella (Purdue University), Steven Leath (Auburn University), Alan Stern (Southwest Research Institute), and Stephen Willard (Cellphire, Inc.), and previous members Geraldine "Geri" Richmond (University of Oregon) and Maria Zuber (Massachusetts Institute of Technology). Details on new and re-appointed members can be found here. The NSB will hold its next meeting November 28-29, 2018. Details can be found here.

NIH Advisory Committee to the Director December 13-14, 2018 Meeting

The NIH Advisory Committee to the NIH Director will meet next on December 13-14, 2018. Several topics on the agenda may be of interest to COGR members. Agenda items for day one include a Foreign Influences on Research Integrity Working Group Report; NextGen Working Group Recommendations; and an Update on NIH Policies/Approaches to Prevent and Address Sexual Harassment, among others. Day two includes a BRAIN 2.0 Working Group Update and an Artificial Intelligence Working Group Update among other sessions. The meetings are webcast.

Foreign Influence on Academic Research

October 24 Meeting with NIH Staff and ACD Working Group

The Research and Regulatory Reform, Research Compliance and Administration, and Contracts and Intellectual Property committees met with Carrie Wolinetz, Acting Chief of Staff and Associate Director for Science Policy, NIH, on October 24 in conjunction with the COGR meeting. The group discussed the August 20, 2018 letter from Francis Collins to investigators regarding failure to disclose "substantial contributions of resources from other organizations, including resources from foreign governments." At issue, at least in part, are collaborations involving funding or commitments outside of institutional time.

NIH is interested in any affiliations tied to funding; any funding that investigators are receiving in support of research. NIH wants to know if there is duplicative funding for the same or similar projects (domestic or foreign) which would impact their decision to fund research and/or the level at which to fund it. Examples include copying an NIH funded grant proposal and submitting it to Chinese funding agencies where it is subsequently funded. Questions that NIH staff have suggested institutions consider include whether there are arrangements (e.g., joint and summer appointments) that universities should track more closely; whether institutions have a policy in place that tracks external sources of research funding; whether such policies are being enforced; and whether institutions want such a policy if not already in place.

During an August 23 Senate hearing *Prioritizing Cures: Science and Stewardship at the National Institutes of Health*, Dr. Collins announced that NIH has created a working group of the Advisory Committee to the Director (ACD) to address the concerns outlined in the August 20 letter. The working group has been asked to identify "robust" methods to improve accurate reporting of all sources of research support, financial interests, and affiliations; to mitigate risk to IP security; to explore additional steps to support the integrity of peer-review; and to carry out these actions in a way that reflects the "long tradition of partnership between NIH and grantee institutions, and that emphasizes the compelling value of ongoing honorable participation by foreign nationals in the American scientific enterprise." The working group is expected to make recommendations at the December 13-14, 2018 ACD meeting.

Senator Grassley Sends a Letter to NIH Seeking Information on Foreign Threats to Research

On October 24, 2018, Senator Chuck Grassley sent a letter to Dr. Francis Collins, NIH Director, regarding the agency's vetting process for foreign researchers and grants. The letter suggests that it is not clear that financial conflict of interest disclosure requirements "adequately address the significant and pervasive threats posed by foreign entities to our research institutions and the integrity of taxpayer funded studies." The letter poses a series of questions, among them:

- "Please describe in detail the process by which NIH, or any affiliated entity, conducts background checks of researchers and institutions prior to awarding NIH grants. Please describe these processes in both the intramural and extramural program at NIH.
- With respect to the recipients of NIH funds, how many systematic reviews, or audits, have been performed of those entities in the past five years for potential violations concerning foreign affiliations and financial contributions? Please list each entity and the results of the review.
- Please provide the committee a list of all entities currently under investigation for employing individuals that failed to disclose contributions from foreign governments. Do you plan to make that list public? If not, why not?"

We understand that NIH is in the process of responding to the questions. Less than a dozen institutions have received letters from NIH to date regarding violations of the peer-review process or failure to disclose foreign contributions. Additional letters are anticipated.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Patrick Schlesinger, University of California-Berkeley (Chair), Alexandra Albinak, The Johns Hopkins University, Elizabeth Peloso, University of Pennsylvania, Kevin Wozniak, Georgia Tech Research Corporation, David Winwood, Louisiana State University, Fred Reinhart, University of Massachusetts, John Ritter, Princeton University, Wendy Streitz, University of California, Jennifer Ponting, Harvard University, Dan Nordquist, Washington State University, Cindy Kiel, University of California, Davis, Michael Moore, Northwestern University

Panel Discusses Foreign Threats to U.S. Research and National Security

A panel at the COGR October meeting discussed current issues and concerns related to efforts, particularly by China, to acquire U.S. technology, including from universities. Rebecca Kaiser, head of NSF's Office of International Science and Engineering, pointed to the importance of NSDD 189, which was recently reaffirmed by the National Science Board (see https://www.nsf.gov/nsb/news/news_summ.jsp?cntn_id=297039&org=NSB&from=news). She cited the importance of maintaining scientific openness and freedom of inquiry, as stated by the NSB. She also cited the impacts of other countries on published scientific papers. At the same time, NSF recognizes the need to protect research integrity. Recently that integrity may have been compromised by unauthorized sharing of proposal information. NSF always has asked for disclosure of foreign support but plans to clarify its disclosure requirements to include any financial compensation including gifts. It also plans to further automate its disclosure forms. She also discussed NSF's criteria for international engagement, and plans to leverage international expertise. A copy of Dr. Kaiser's presentation is posted on the COGR website.

Robert Daly, Director of the Wilson Center's Kissinger Institute on China and the U.S., discussed China's efforts to obtain strategic technologies from the U.S. China aims to become a comprehensive international power like the U.S. and views innovation as the key. U.S. security agencies view universities as a vulnerability in our response to this effort. Mr. Daly cited a number of specific examples, but also noted that while the government's concerns are reasonable there is a short list of actual harms. He expressed the view that universities can best respond to these threats with greater vigilance, including more awareness by faculty of the need to report foreign affiliations, training of faculty and staff in Chinese collection goals and methods and best practices, greater sharing among universities of experiences, more partnering and cooperation with security agencies, greater advocacy of U.S. higher education as a national asset, greater transparency (no unpublished international agreements!), and more attention to in house analysis of developments. He closed by noting there is some indication that China may be pulling back on some of its collection activities.

Dr. Bindu Nair, Acting Director of the DOD Basic Research Office, discussed DOD's recognition of the critical role of universities in maintaining the defense research base. She expressed DOD's commitment to NSDD-189, but also noted that the current global economic competition is of a different nature than

the security threats that led to NSDD-189. She discussed the NDAA provisions, particularly Sec. 1286. It establishes an initiative for DOD to work with academic institutions on protection of intellectual property (broadly construed) and information about critical technologies, to limit undue influences of countries through foreign talent programs in exploiting U.S. defense technologies, and to develop more domestic talent in science and engineering (see COGR September Update). She noted that the required security training for universities is an unfunded mandate. There also is a requirement for regulations to limit threats from foreign talent programs. DOD needs to understand the burdens that would result from such regulations. Pilots would be useful. She stressed the importance of feedback from universities on the Sec. 1286 initiative. Discussions also are underway with the National Academies (NAS) about establishing the forum called for by the NDAA at NAS with DOD co-funding. DOD also is discussing with the National Academy of Engineering establishment of a "Deans Roundtable" to discuss these issues. Data on research performers beyond PI's also would be helpful. DOD plans to rely on its program managers in developing the list of critical technologies called for by Sec. 1249 of the NDAA. They are just starting to work on a strategy for developing procedures for limiting foreign access to technologies through DOD funding awards (Sec. 885).

AAU/APLU Release Science and Security Effective Practices Survey Form

On October 30 AAU and APLU sent an effective practices survey to their senior research officers and campus government relations officers. The form asks about current practices universities are using to ensure the security of research and protect against theft of intellectual property and academic espionage. It asks for examples of policies, practices, tools and other resources which other campuses might benefit from learning about. One effective practice per survey form may be submitted; there is no limit to the number of examples a campus may submit. The survey forms may be completed and submitted by multiple people on campus, depending on who has appropriate knowledge of each practice. Institutions that submit examples may choose the level at which they would like each example shared and whether they would like their name and institution associated with it. The survey is to remain open through Nov. 19 and can be found here.

NIST Previews ROI/RFI Response

The COGR CIP Committee met with a senior NIST official during the October meeting. We were briefed on the likely draft report on the ROI/RFI (see September Update) and some of the likely recommendations.

The recommendations will fall into three buckets: policy, regulatory and statutory changes. Most of the latter will involve the Stevenson—Wydler Act which governs technology transfer at the federal labs. However there may need to be some corresponding changes in the Bayh-Dole Act.
Proposed regulatory changes to Bayh-Dole may involve the scope of march-in rights and the government use license. In our response to the RFI we had urged NIST to reaffirm NIH's consistent interpretation that march-in not appropriate to address pricing concerns. NIST may propose a clarification that the "practical application upon reasonable terms" invention requirement has to do with the business terms in a license which would not include consideration of consumer pricing. NIST also may propose boundaries on the scope of the government use license (we had not addressed this in our comments, but there have been calls to use the government use license to address concerns about drug pricing).

NIST also will address the need for more streamlined and uniform invention reporting. We have expressed concerns about the iEdison reporting system many times, and included this concern in our comments. NIST will seek input from the community as to whether iEdison or other agency invention reporting systems (i.e. NASA) or a new replacement system are preferred. Part of the streamlining process will address waiver requests, another concern we had raised.

The NIST report will not address SBIR or new POC funding programs. These might be addressed by the NSTC Lab—to—Market working group. It also will not address ownership or copyright of data developed under federal awards or recommend any changes to the current disposition of patent rights in Bayh-Dole (Sec. 202). However, it will recommend statutory changes to allow the government or federal employees to assert copyright. The current prohibition in the ethics rule is a disincentive to commercialization (e.g. software developed by federal employees).

NIST plans to send the draft report out for public comment, hopefully by mid-November. They also plan to publish the 104 comments received in response to the RFI (the RFI is not considered regulatory so the requirements are not required to be published). Some of these comments are quite lengthy (the joint higher ed. association comments were close to 30 pages). There will be a 30-day comment period. NIST hopes to issue a final report with findings and recommendations in February.
While the ROI Initiative has high visibility within the government, it is not clear how much traction the findings and recommendations will have within the Administration. We have been and will continue to closely follow developments.

Drug Pricing to be Part of Democratic House Agenda

We mentioned in the September Update a House bill (H.R. 6505) that would give HHS the authority to offer license to competitors to make generic versions of patented Medicare Part D drugs when negotiations over the price of a drug are unsuccessful. This bill is likely to be reintroduced in the next Congress, with a hearing scheduled for February. The issue is high on the new House majority Democratic legislative agenda. For more details see https://www.statnews.com/2018/10/30/what-happens-to-pharma-if-democrats-take-the-house/?utm_source=STAT+Newsletters&utm_campaign=2187db7c40-Daily_Recap&utm_medium=email&utm_term=0_8cab1d7961-2187db7c40-150085937.

It also is an area where there is a possibility of some bipartisan agreement. See https://www.statnews.com/2018/11/07/mcconnell-could-work-with-democrats-on-drug-prices/.
The current House bill's primary impact is considerably downstream from any direct threat to universities' ability to license drug-related technologies. However, we need to seek to assure that as this and other legislative initiatives are considered that they do not seriously impact the licensing of early stage university inventions and innovations.