

December 21, 2017

TO: COGR Membership
FROM: COGR Staff
SUBJECT: December 2017 Update

TABLE OF CONTENTS

[**Congress Moves to Pass Another Short Term Continuing Resolution**](#)

[**The Administration's Efforts to Cut F&A: YEAR-END STATUS**](#)

[**Procurement and the Micropurchase Threshold \(MPT\)**](#)

[**Payment and Reimbursement under 2 CFR 200.305 and the Compliance Supplement**](#)

[**Costing Policies Committee: Other Issues**](#)

[NIH Notice NOT-OD-18-107: NIH Enforcement of Closeout Policies](#)

[2018 "Skinny" Compliance Supplement](#)

[Securing Student Information, Department of Education \(ED\)](#)

[Single IRB and Direct Charging](#)

[Equitable Treatment of Off-Campus Research Centers in NIH RFAs](#)

[**Ad Hoc Committee on Confidentiality in Research Misconduct**](#)

[**New Work Group on the Barriers of Conducting Marijuana and Hemp Research**](#)

[**Public Access**](#)

[**Funding Pause Lifted on NIH Gain of Function Research**](#)

[**NSF Releases Revised NSF Grants.gov Application Guide**](#)

[**Concerns Over Sovereign Immunity Continue to Increase**](#)

[**March-In Rights and Drug Pricing Controversy Continues**](#)

[**NIST Issues Draft Assessment Procedures for CUI Security Requirements**](#)

[**Updates**](#)

[FAR CUI Clause](#)

[STRONGER Patents Act](#)

[Supreme Court Hears Arguments in *Oil States* Case](#)

[**Human Subjects Research**](#)

[Common Rule Status](#)

[NIH Clinical Trial Definition and Case Studies](#)

[Revisions to NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan](#)

[Amendment to NIH Policy on the Inclusion of Women and Minorities in Clinical Research](#)

[**Animal Research**](#)

[AAALAC Request for Comment](#)

[**Regulatory Reform**](#)

[NIH, USDA, and FDA 21st Century Cures Listening Session](#)

[Research Policy Board](#)

[House Energy and Commerce Committee Hearing on 21st Century Cures Act Implementation](#)

[Senate Hearing on the Implementation of the 21st Century Cures Act](#)

[FDA Seeks Comments on Regulatory Reform Opportunities](#)

[NIH Advisory Committee to the Director Meeting](#)

[Next Generation Research Initiative](#)

[Reimagining HHS and Optimizing NIH](#)

[NSF IPA Program Cost Share Pilot Extension](#)

[Audit](#)

[NSF OIG Semiannual report to Congress](#)

[NSF OIG Audit Work Plan](#)

[HHS OIG Semiannual Report to Congress and Audit Work Plan](#)

Congress Moves to Pass Another Short Term Continuing Resolution

The House is expected to pass a [short-term funding bill](#) to avoid a December 22 government shutdown, which would simply extend government funding at FY17 levels through January 19, 2018. House leaders previously planned to combine the continuing resolution (CR) with defense spending and a disaster aid package but may pivot to passing a clean CR after some members have expressed concerns with the cost of the aid bill. House Majority Leader Kevin McCarthy told reporters the House will pass a spending bill the Senate can accept, and leave for the holidays. COGR will provide updates if there are unexpected developments.

The Administration's Efforts to Cut F&A: YEAR-END STATUS

We have reported on this topic, extensively, in 2017. As we shift gears into 2018, we will be attentive to when the Administration releases its 2019 budget proposal and if F&A is raised. In addition, COGR will continue to work closely within the Associations F&A Working Group, comprised of COGR, the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), the Association of Public Land-grant Universities (APLU), the Association of Independent Research Institutes (AIRI), the National Association of College and University Business Officers (NACUBO), and other partners.

Our community's combined efforts have had a significant impact on rebutting proposed F&A caps. Still, while we, so far, have been successful, we expect to be engaged in more work around this issue in 2018. The COGR Costing Committee is evaluating its role in further advocacy around the politics of F&A, including exploration of themes such as transparency, alternative models, education and myths. As we pursue activities around these themes, we will keep the Membership updated on all developments.

Procurement and the Micropurchase Threshold (MPT)

COGR members are preparing for implementation of the Uniform Guidance Procurement Standards, [2 CFR 200.317-326](#), to become effective on the first day of your new fiscal year. For most, this is July 1, 2018. For several, however, the effective date is January 1, 2018.

COGR has shared two concerns with OMB specific to implementation of the Micropurchase Threshold (MPT):

- 1) Some auditors continue to raise an issue that because the MPT has not been codified in the Uniform Guidance, the threshold defined in the National Defense Authorization Act (see below) is not applicable. While OMB has yet to clarify in writing, in correspondences between COGR and OMB, representatives from OMB are authoritative in stating the MPT per the NDAA is applicable and supersedes the Uniform Guidance. Further [2 CFR 200.101\(b\)\(3\)](#) states: "... *in any circumstance where the provisions of Federal statutes or regulations differ from the provisions of this part, the provision of the Federal statutes or regulations govern*".
- 2) A process for confirming an MPT greater than \$10,000 still is not clear, despite straightforward criteria defined in the NDAA (see below). At issue appears to be what entity is empowered as the "*relevant executive agency*". OMB actively is working on a solution and is aware that there is a sense of urgency and that several COGR members have a fiscal year start date of January 1, 2018.

National Defense Authorization Act for Fiscal Year 2017. Sec. 217 (b): INCREASED MICRO-PURCHASE THRESHOLD FOR UNIVERSITIES, INDEPENDENT RESEARCH INSTITUTES, AND NONPROFIT RESEARCH ORGANIZATIONS.—Section 1902 of title 41, United States Code, is amended—

(A) \$10,000; or (B) such higher threshold as determined by the head of the relevant executive agency and consistent with clean audit findings under chapter 75 of title 31, internal institutional risk assessment, or State law).

Time is of the essence for those institutions with a January 1, 2018 fiscal year start date. It appears unlikely that before the end of the year there will be an official resolution as to which federal entity (i.e., OMB, CAS-HHS, ONR, etc.) will take responsibility for confirming MPTs greater than \$10,000. COGR's position is that because the NDAA requires one of the three criteria to be demonstrated to use an MPT greater than \$10,000, an institution that historically has used an MPT of, for example, \$25,000, should be on safe ground if they continue to use \$25,000. However, we continue to urge OMB to offer a reasonable solution that provides audit cover and NDAA compliance for those institutions whose MPT is greater than \$10,000.

If your institution has any uncertainty or concern on how the MPT should be implemented at your institution, OMB encourages you to contact:

Rhea Hubbard at: Rhea_A_Hubbard@omb.eop.gov
Gilbert Tran at: hai_m_tran@omb.eop.gov

As necessary, COGR also recommends you consult with your Auditors and/or General Counsel at your institution. We will continue to work with OMB with the intent of bringing clarity to the process. And as our community moves toward implementation of the full suite of the Uniform Guidance Procurement Standards in 2018, COGR will be available to address concerns and raise these concerns with the appropriate federal officials.

Payment and Reimbursement under 2 CFR 200.305 and the Compliance Supplement

As COGR has reported, auditors have challenged COGR member institutions by suggesting that grants and cooperative agreements should be subject to a strict interpretation of what constitutes payment/disbursement to a vendor. For example, one auditor position is that prior to billing a federal sponsor for reimbursement, the institution must have evidence that the institution's payment to the vendor has been cleared. This is in conflict with existing policy per [2 CFR Part 200.305\(b\)](#): *... payments methods must minimize the time elapsing between the transfer of funds from the United States Treasury or the pass-through entity and the disbursement by the non-Federal entity.*

Predicating a request for reimbursement on when a payment to a vendor has cleared will make timely reimbursement inefficient, and in many cases, impossible. Furthermore, this discards longstanding, effective, and common-sense disbursement practices typically employed at research institutions where reimbursement is requested after an invoice from a vendor has been approved, identified for payment in the accounts payable system, and posted in the institution's official accounting records.

In response to a request for Public Comments to the [2017 Compliance Supplement](#), COGR sent a [Comment Letter](#) (dated October 20, 2017) to OMB, Gilbert Tran. Some of your institutions also sent letters, either documenting your unique circumstances or simply supporting the COGR letter. Our understanding is that OMB is reviewing the comment letters. A possible outcome is that this issue will be addressed in the 2018 Compliance Supplement. Interestingly, OMB is contemplating a “skinny” version of the 2018 Compliance Supplement (see below), which would focus only on the significant changes between 2017 and 2018. We will keep the Membership posted on all developments.

Costing Policies Committee: Other Issues

The Costing Policies Committee continues its work on a wide range of other issues. Some of these are ongoing and have been covered in past COGR Updates. As appropriate, each one will remain on our list for 2018.

NIH Notice NOT-OD-18-107: NIH Enforcement of Closeout Policies. NIH released [NOT-OD-18-107](#) on November 30th. In numerous forums over the past year, NIH has been adamant about the importance of timely closeout and its statutory mandate to be in compliance with the [Grants Oversight and New Efficiency \(GONE\) Act](#). COGR supports NIH efforts to be in compliance with the GONE Act, though several concerns related to the framing of NOT-OD-18-107 have been raised, including: 1) timing for initiating unilateral closeout (the Notice states: *Without prior approval from the awarding IC, NIH will initiate unilateral closeout for all awards that fail to meet closeout requirements within 120 days as required by the NIH Grants Policy Statement (NIH GPS) Section 8.6*), 2) better leveraging of [2 CFR 200.343\(g\)](#), which allows agencies to complete agency closeout actions within one year of the acceptance of all reports, and 3) utilizing the most user-friendly approach to reminder letters. The exact policy implications of the Notice are not entirely clear, and additional clarification may be necessary. COGR looks forward to working with NIH to address timely closeouts, ensure compliance with the GONE Act, and to do so in a constructive manner that supports investigators and the science.

2018 “Skinny” Compliance Supplement. As mentioned above, OMB is contemplating a “skinny” version of the 2018 Compliance Supplement. This would focus only on the significant changes between 2017 and 2018 with the intent of making for a more efficient update to the Compliance Supplement. Under this model, we would expect a return to the full version in 2019. We should learn more about this possible approach after we return from the Holiday break.

Securing Student Information, Department of Education (ED). COGR has worked with several of our Association partners to raise concerns as to how ED has proposed audit objectives related to safeguarding data specific to an institution’s information security program (i.e., Safeguards Rule). ED withdrew their initial inclusion of overly-complex audit guidance from the 2017 Compliance Supplement. While COGR’s position is that the Compliance Supplement is not the correct vehicle for this guidance, ED is now working with the community to include more manageable guidance in a possible release of a 2018 “Skinny” Compliance Supplement.

Single IRB and Direct Charging. The Research and Regulatory Reform (RRR) Committee continues to follow this topic, including developments related to the new January 25, 2018 implementation date. From a

costing perspective, the primary focus has been on the costing FAQs. The most recent version of [FAQs for the NIH Policy on the Use of a Single IRB for Multi-Site Research Costs](#) is available at the NIH Office of Science website.

Equitable Treatment of Off-Campus Research Centers in NIH RFAs. This has been an ongoing “niche” issue to encourage NIH to devise a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. Off-campus research centers are at a competitive disadvantage; i.e., by being required to include lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. We hope to resolve this longstanding issue in early 2018.

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

Ad Hoc Committee on Confidentiality in Research Misconduct

In the [June meeting report](#), COGR indicated that a new Ad hoc Committee on Confidentiality in Research Misconduct was being formed to address and seek solutions to issues related to confidentiality during and after the active assessment, inquiry, investigation, and determination process.

As reported in the [October Meeting Report](#), RCA hosted Ann Pollack, UCLA and Chair of the Ad Hoc Confidential Committee to provide an update of issues/topics raised over the last several months. Initial Questions addressed by the committee include:

- How are the regulations/policies interpreted and how are they applied by institutions? How do institutions apply the regulations after research misconduct proceeding has been completed? Are communications different depending on whether there is a finding of research misconduct or not?
- Is communication from the federal Office of Research Integrity about maintaining confidentiality once an institution’s process has ended consistent? If not and/or if not clearly understood, is there value in approaching ORI to seek clarification and/or change?
- Is there value in benchmarking the confidentiality provisions in the research misconduct policies of COGR member institutions? To what end?
- What are reasonable deliverables?

The COGR 2002 brochure on “Recognizing and Managing Personal Financial Conflicts of Interest” was identified as a model for the kind of document the committee is working towards. Members of the working group have submitted first drafts of a variety of scenarios centered on the handling of confidentiality in research misconduct. An update on the group’s progress will be provided to the COGR Membership during a Thursday morning session at the February 2018 COGR meeting.

As noted in our [October meeting report](#), RCA provided input on the deliverable and recommended that this be brought to the Board for approval to move forward. The Board approved during its October meeting and work on the deliverable has started. All deliverables produced by COGR go through Committee and Board review.

Approval will also go through Board review with the Association of Research Integrity Officers (ARIO). COGR will continue to provide status updates as necessary. For questions, please contact Jackie Bendall at jbendall@cogr.edu.

New Work Group on the Barriers of Conducting Marijuana and Hemp Research

COGR has formed a new ad hoc working group to advocate its concerns regarding the barriers of conducting marijuana and hemp research on university campuses. Our first call took place on December 8 in which we had an informative discussion around what the current issues our institutions are facing, details on the program in place at the University of Mississippi, and what the deliverables should be from this working group. The group will work towards an educational document for COGR membership and will be looking at how best to focus our advocacy efforts in the future on this issue. Current legislation on the matter includes [H.R. 3391- Medical Marijuana Research Act of 2017](#) and [S. 1803 Marijuana Effective Drug Studies Act of 2017](#); which aims to amend the Controlled Substances Act to make marijuana accessible for use by researchers for medical and other purposes. We will have a panel discussion on Thursday afternoon of the February 2018 COGR meeting to discuss a variety of issues with the membership. If you have questions, please contact Jackie Bendall at jbendall@cogr.edu. Stay tuned for further updates.

Public Access

As discussed in the [October update](#), RCA met with members from the Open Science interagency working group during the RCA Committee meeting. In follow-up, RCA is drafting a letter to the Open Science Committee members requesting they take the lead not only in policy but also with guidance on remaining critical success factors such as data standards, federally funded data storage options, and specific considerations for how and what data is reported. In addition, COGR recommends that the agencies issue funding opportunities to address the challenges voiced by the scientific community. Funding opportunities in this area will benefit federal agencies and researchers by providing the additional time needed to seek practicable solutions the scientific community continues to struggle with (e.g., cost, burden, resources, incentives, defining data, etc.) As technological advances in curation and storage will likely look much different in the years to come, further research in these areas, with the ability to make modifications to existing repositories over time, will eventually reduce burden on investigators and may eliminate the need to develop Data Management Plans to begin with.

COGR staff also attended a closed workshop in October that focused on the value of data sharing. A recent [blog](#) from the NIH Office of Science Policy describes the ongoing questions that surfaced during the workshop in addition to common themes such as the difficulty of measuring how data is shared. In November, the Association of American Universities (AAU) and Association of Public and Land Grant Universities (APLU) released a [report](#) developed by the Public Access Working Group (PAWG), a group comprised of university leaders that details principles and recommended actions universities and federal agencies can take to advance timely access to data from federally-sponsored research grants.

As work continues in this area, we are told that the NIH plans to release a Request for Information (RFI) in the near future. COGR will work with its members to draft a response. Stay tuned for further updates.

Funding Pause Lifted on NIH Gain of Function Research

The National Institutes of Health [announced](#) on December 19th it is lifting the October 2014 [funding pause](#) on gain-of-function (GOF) experiments involving influenza, SARS, and MERS viruses. The release comes on the same day that the DHHS released Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS PC30). The framework takes into consideration scientific merits and potential benefits of gain of function research as well as the potential to create, transfer or use an enhanced potential pandemic pathogen. The National Science Advisory Board for Biosecurity and the National Academies of Sciences, Engineering and Medicine has been extensively involved with other public and private sector experts to deliberate on the issues surrounding GOF research. Through these collaborative efforts, the federal government has decided to lift the moratorium to allow GOF research to move forward.

NSF Releases Revised NSF Grants.gov Application Guide

On December 18, 2017, The NSF released its updated [NSF Grants.gov Application Guide](#) effective for proposals submitted, or due, on or after January 29, 2018. The updated Guide aligns with changes to the *Proposal & Award Policies & Procedures Guide* (PAPPG) (NSF 18-1). Information about FastLane system registration has been removed and replaced with guidance for registering in Research.gov. Editorial changes have also been made to either clarify or enhance the intended meaning of a sentence or section or to ensure consistency with data contained in NSF systems or other NSF policy documents.

Concerns Over Sovereign Immunity Continue to Increase

The [October Meeting Report](#) discussed last month's House hearing and the concerns about sovereign immunity defenses in *inter partes review* (IPR) proceedings brought before the Patent Trial and Appeal Board (PTAB). It also mentioned legislation introduced by Sen. McCaskill that would abrogate tribal immunity for IPRs. It noted that legislation might be introduced in the House that would abrogate both tribal and state sovereign immunity in such cases.

Concerns have continued to increase. These are based partly on reports that a law firm is seeking to negotiate deals with a number of public universities similar to those in the tribal immunity case discussed in the [Meeting Report](#). Our understanding is that patent rights would be "rented" to these institutions in exchange for the ability to invoke sovereign immunity to protect the patents from validity challenges in PTAB proceedings.

We do not know what institutions may have been approached. However, the situation is of sufficient concern that on December 15 a joint [AAU/APLU Presidential Memorandum](#) was sent to Presidents and Chancellors alerting them. It urged them to ask their institution's tech transfer and endowment managers to carefully consider the potential for adverse reactions from the Congress and the public if approached with such a proposal.

Very recently on December 19, an expanded PTAB ruled against the University of Minnesota's assertion of sovereign immunity in an IPR proceeding. In this case the University had filed a patent infringement in federal district court. The PTAB found that by filing this action the University had waived its right to claim sovereign

immunity in the IPR proceeding. Since a party served with a patent infringement complaint must file an IPR challenge to the patent within a year, the PTAB viewed the University as having consented to an IPR. The Board viewed it as similar to consenting to compulsive counterclaims in the court action. In the PTAB's view it would be unfair to allow the institution to seek to enforce the patent through federal court action, but assert immunity from challenges to the patent in another federal forum.

The decision may be appealed to the Federal Circuit, where the outcome is uncertain. However, for now it calls into question the legal strategy to "rent" patent rights in exchange for the right to invoke sovereign immunity. In the tribal immunity situation, it appears that filing of any patent infringement action will be deemed to be a waiver of sovereign immunity.

The PTAB ruling and related commentary may be found at <http://www.ipwatchdog.com/wp-content/uploads/2017/12/PTAB-decision-denying-11th-Amendment.pdf> . Also see <https://www.reuters.com/article/us-usa-court-patent/u-s-administrative-court-deals-major-blow-to-patent-transfer-deals-idUSKBN1ED2WU> . (For additional developments related to IPR see 4.c. below).

March-In Rights and Drug Pricing Controversy Continues

We've discussed many times the controversy over use of Bayh-Dole Act march-in rights to address drug pricing concerns (see [September Update](#) for full discussion). Knowledge Ecology International (KEI) long has advocated and repeatedly petitioned NIH to use march-in rights for this purpose, as discussed in the [Update](#).

At a November 30 hearing before the House Energy and Commerce Subcommittee on Health, held to mark the anniversary of the 21st Century Cures Act, NIH Director Francis Collins was asked by Rep. Shakowsky (D—IL) about the NIH position. In response Dr. Collins stated that NIH does not have authority under Bayh-Dole to march in solely to address drug pricing issues. His position was immediately [attacked by KEI](#).

Dr. Collins did express willingness to work further with the Congress to address pricing concerns. Clearly KEI will continue its crusade. We also are concerned about the mandate to DOD in the NDAA to use march-in authority to address drug pricing issues for DOD-funded inventions (see [October Meeting Report](#)). Undoubtedly KEI will continue also to press DOD on the issue. We plan to discuss this further with DOD.

The GAO just issued a report on Drug Industry Profits, R&D Spending, and Mergers and Acquisitions (GAO-18-40). Among other things it found a 67% increase in the average annual profit margins of all drug companies between 2006 and 2015. There was a slight increase in R&D spending, and a fluctuation in new drugs approved in the U.S. ranging from 179 to 263 annually. 13% of these approvals involved novel drugs, with biologics accounting for a growing share. GAO also found that fewer competitors in the drug industry are associated with higher prices, particularly for generics.

[The report](#) made no recommendations, but undoubtedly will receive more Congressional attention.

NIST Issues Draft Assessment Procedures for CUI Security Requirements

On November 28 NIST issued draft procedures and methodology for assessing compliance with the Controlled Unclassified Information (CUI) security requirements of NIST SP 800-171. The draft is intended as a

companion document (NIST SP 800-171A; <https://csrc.nist.gov/publications/detail/sp/800-171a/draft>). It does not set forth new or additional security requirements. The procedures are intended to be flexible and can be customized. For each security requirement assessment objectives are defined and methods specified that can produce findings. Methods include *examine*, *interview* and *test*, with the depth of coverage varying among the requirements. There is no expectation that all assessment methods and objects will be used for assessing each requirement. They are intended as a starting point for organizations to develop assessment plans and approaches that can produce the evidence needed to determine risk mitigation or compliance with the particular security requirement. For each assessment procedure a determination is to be made that the assessment objective has been “satisfied” (fully acceptable result) or “other than satisfied” (findings indicate potential anomalies that may need to be addressed). The emphasis is on information gathering, not security producing. They are to be informed by the system security plan that each non-federal organization that handles or processes CUI is required to develop.

Despite these assurances, a Cautionary Note indicates specific assessment approaches may be specified in contracts or agreements. They could include self-assessments; independent third party assessments; or assessments conducted by sponsoring government agencies. A separate Appendix contains what may be a helpful mapping of the NIST 171 security requirements to the requirements for federal agencies set forth in NIST SP 800-53, as well as to ISO/IEC control mapping. While potentially enhancing understanding, there has been persistent confusion among agencies as to the applicability of the 800-53 requirements to non-federal organizations. There may be a concern that this material will lead to additional confusion. Another Appendix contains Supplemental Guidance for implementing and assessing the 171 requirements based on 800-53. These will be replicated in the next update to NIST SP 800-171.

NIST indicates that they are seeking feedback. However, the document originally was issued with a 30-day public comment period which expired Dec. 27. The comment period now appears to have been extended to January 15. Still, the draft is 132 pages long with a 9 page introduction. The relatively short comment period does not appear conducive to encouraging maximum feedback, particularly at this time of year. We also are concerned that the draft may be overkill, especially with the detailed Appendices. The draft refers to compliance requirements in the FAR, but the FAR guidance is not expected to be issued in the near term (see below). Despite the emphasis on flexibility, the procedures, methods and objects for each security requirement could come to be viewed as compliance requirements by agencies (and auditors). We will consider providing comments to NIST.

Updates

FAR CUI Clause.

We discussed the status with NARA. The current (12/15) FAR Open Case report now shows a due date for the draft of 1/10. This is almost six months after the original due date. NARA confirmed that things are moving slowly, complicated further by some health issues that have been experienced by the responsible NARA staff.

STRONGER Patents Act

Additional co-sponsors still are being sought for Sen. Coons' STRONGER Patents Act (see [June](#) and [September](#) updates). The higher ed. associations remain supportive of the legislation.

Supreme Court Hears Arguments in *Oil States* Case

The [September Update](#) discussed this case (*Oil States Energy Services v. Green's Energy Group*). It involves the constitutionality of the PTAB IPR proceedings. The precise issue identified by the Court was "Whether IPR, an adversarial process used by the PTO to analyze the validity of existing patents, violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury." BIO and AUTM had submitted an *amicus* brief contending that patents convey private rights that are not sufficiently protected by the IPR process (as opposed to public rights like Social Security benefits).

As discussed in the previous [Update](#), COGR and the other higher ed. associations had been proponents of IPR. However, we did not necessarily expect the high rate of invalidation of patent claims that has resulted, nor developments such as the rental of patent rights for sovereign immunity assertions.

The Supreme Court heard arguments in the case last month. There appears little agreement among observers as to likely outcomes. There also seemed no consensus among the justices as to whether patents should be considered as private or public rights. For additional discussion of the varying perspectives see <http://www.ipwatchdog.com/2017/11/28/predicting-oil-states-supreme-court-oral-arguments/id=90558/>.

Human Subjects Research

Common Rule Status

In the [October 2017 COGR update](#) we reported that on October 7 a proposed delay to the implementation of the Common Rule was posted to the White House Office of Information and Regulatory Affairs (OIRA) website. In a [letter](#) to Dr. Jerry Menikoff, Director of the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP), dated June 21, 2017, COGR, AAMC, AAU and APLU requested a one year delay in the compliance date with an effective date for most provisions [those other than cooperative research] remaining January 19, 2018. To date, a notice of proposed rulemaking has not been published.

On December 12, 2017, COGR and other higher education association staff met with OIRA and agency staff to discuss the status of the Common Rule. OHRP staff members Jerry Menikoff, Ivor Pritchard, Julie Kaneshiro, Julia Gorey and Irene Stith-Coleman called into the meeting. Also on the line was Don Wright, Acting Assistant Secretary for Health. We restated our request for a one-year delay in the compliance date with no change to the effective date per our [June 21 joint association letter](#). Copies of the letter, and a [two-page handout](#), were distributed to OIRA and agency staff. Noting that we were just shy of one month from the effective date of the final revised rule, we asked whether there might be alternative mechanisms for extending the compliance date that would allow the date to be changed in the near-term in the absence of a 30-day comment period. OIRA staff indicated that rulemaking was necessary but that there are alternative mechanisms that could be employed such as an interim final rule which could change the effective (or compliance) date upon publication. While the

tone of the meeting was positive, whether this option will be pursued is not known and the effective date remains January 19, 2018.

NIH Clinical Trial Definition and Case Studies

Two articles addressing the on-going controversy over NIH clinical trial case studies were recently published in the journal Nature Human Behavior. The article [Not your parent's NIH clinical trial](#) by Jeremy Wolfe and Nancy Kanwisher provides the investigator perspective, and [NIH Policies on Experimental Studies with Humans](#) by Bill Riley, Melissa Riddle, and Mike Lauer, the NIH perspective.

The NIH-authored article acknowledges that NIH interprets “health-related” (and therefore “clinical trial”) broadly and suggests that “it is reasonable to assume that if an investigator is applying to NIH for funding, the investigator has determined that the outcomes of interest are health-related.” NIH suggests that they continue to refine the case examples, however, there is fundamental disagreement on what meets the criteria for a clinical trial and that is unlikely to be resolved through minor modifications to the case studies. Higher education associations, universities and investigators continue to engage NIH on this issue.

Revisions to NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan

On December 19, 2017, NIH issued [revisions](#) to policy and guidelines on the inclusion of research participants across the lifespan. As indicated in the notice, changes to the policy include applicability to individuals of all ages, including children and older adults, clarification on excluding individuals based on age, and a requirement to provide data on participant age at enrollment in progress reports.

The policy applies to all NIH-supported human subjects research, including research that is exempt from federal regulations, for all competing grant applications with due dates on or after January 25, 2019. Applications will need to include “a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed.” Investigators will be required to provide de-identified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment in progress reports.

Amendment to NIH Policy on the Inclusion of Women and Minorities in Clinical Research

In a [notice](#) dated November 28, 2017, NIH announced revisions to agency policy on the inclusion of women and minorities in research. The notice indicates that recipients conducting “[applicable NIH-defined Phase III clinical trials](#)” will need to ensure that “results of [valid analyses](#) by sex/gender, race, and/or ethnicity are submitted to Clinicaltrials.gov.” The amendment applies to all new, competing grants and cooperative agreements awarded on or after December 13, 2017. It does not apply to Phase III trials not considered to be applicable clinical trials under the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11.

Animal Research

AAALAC Request for Comment

AAALAC International is seeking comments on proposed changes to its position statement on the “Definition of Laboratory Animal.” Additional information can be found [here](#). Comments are due by December 22. COGR has submitted [comments](#).

Regulatory Reform

NIH, USDA, and FDA 21st Century Cures Listening Session

NIH OLAW, USDA APHIS and FDA staff will be conducting a listening session in relation to a review of regulations and policies involving research with laboratory animals directed under section 2034 (d) of the 21st Century Cures Act, Animal Care and Use in Research. The session will be held in follow-up to the Federal Demonstration Partnership meeting in Washington, DC on January 9, from 12 – 1 pm EST. Additional details and a link to register can be found [here](#). Registration is free and FDP membership is not required for participation.

We previously reported that COGR, the Federation of American Societies for Experimental Biology, the Association of American Medical Colleges, and the National Association for Biomedical Research, released the report [Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden](#) on October 24, 2017. The report was sent to NIH, USDA and FDA staff and follow-up conversations have occurred. We anticipate additional opportunities for public comment on animal research regulatory reform efforts in 2018.

Research Policy Board

A core recommendation made in the 2016 National Academies report, *Optimizing the Nation’s Investment in Academic Research*, and subsequently contained in the 21st Century Cures Act is the creation of a Research Policy Board. Recent meetings with agency officials suggest that efforts to stand-up the Research Policy Board are under way, including the development of the board’s charge and identification of federal members. As directed by Cures, the Board, consisting of federal and non-federal members including university representatives and university affiliated non-profit organizations, will advise the federal government on the effects of federal research regulations and reporting requirements and recommend ways to modify, streamline and harmonize them. Nominations for non-federal participants may be sought through a Federal Register notice in the new year.

House Energy and Commerce Committee Hearing on 21st Century Cures Act Implementation

The House Energy and Commerce Committee held a hearing on November 30, 2017, titled [Implementing the 21st Century Cures Act An Update from FDA and NIH](#). NIH Director Francis Collins and FDA Commissioner Scott Gottlieb testified.

Dr. Collins focused his oral testimony on the status of the BRAIN, Cancer Moonshot, Regenerative Medicine

and Precision Medicine Initiatives, all of which received funding boosts from Cures. Dr. Collins was asked about March-in rights with respect to drug pricing. He suggested that Bayh-Dole applied only in circumstances where a drug is not available and that the law doesn't put NIH in a position to step in otherwise. It was suggested that Congress and NIH need to work together to address drug pricing.

Senate Hearing on the Implementation of the 21st Century Cures Act

The Senate Committee on Health, Education, Labor and Pensions also held a [hearing](#) on the implementation of the 21st Century Cures Act on December 7, one year after the Senate passed the legislation. Both Dr. Collins and Dr. Gottlieb testified and remarks and questions were similar to those of the House hearing held on November 30.

Cures provisions aimed at reducing research regulatory burden were generally not discussed, however, Senator Whitehouse asked Dr. Collins what steps NIH was taking to reduce the burden of subrecipient monitoring as directed by Cures. Dr. Collins indicated that NIH has put together a proposal to reduce the burden of "low-risk" sub-recipient monitoring.

There were several questions about other transactions authority (OTA) which NIH was granted through Cures. Dr. Collins indicated that OTA has allowed NIH to fund partnerships quickly and also to cut funding quickly when objectives are not being met. Dr. Collins suggested that OTA would also be very beneficial in addressing the opioid crisis by exploring new ways to treat addiction. Collins suggested that OTA could accelerate partnerships between academia and industry that might take nine months using grants and contracts but could take six weeks under OTA. Dr. Collins indicated that NIH will be careful in how the agency exercises this authority.

There were questions about the Next Generation Research Initiative and how each IC will address it. Dr. Collins indicated that he and other NIH staff published a [paper](#) last month describing the policy and its implementation and that it will be discussed at the Advisory Committee to the Director meeting December 14-15.

FDA Seeks Comments on Regulatory Reform Opportunities

We previously reported that federal agencies, including the FDA, are seeking comment on regulations, policies and guidance documents in need of reform pursuant to Executive Orders 13771 and 13777. FDA has [extended the comment period](#) through February 5.

NIH Advisory Committee to the Director Meeting

The Advisory Committee to the Director met on December 14-15, 2017. Meeting agendas and links to the archived webcasts can be found [here](#).

Next Generation Research Initiative

COGR previously reported on this initiative in the [September 2017 COGR update](#). The NIH [policy](#), issued on August 31, prioritizes awards for Early Stage Investigators (ESIs) and Early Established Investigators (EIs) with the goal of awarding 200 additional ESI and 200 additional EI awards annually. In FY17, approximately 100 additional EI awards were made.

At the ACD meeting NIH Principal Deputy Director Larry Tabak provided an update on the initiative and the efforts of a related working group. Dr. Tabak noted that this has been an area of intense interest. The current policy serves as a guide and its implementation depends on NIH institutes and centers (ICs). In that respect, funding for applications in the top 25th percentile is a target and will vary from IC to IC and this has caused some confusion among investigators. Concerns have also been raised that no funds were provided to implement the policy and that the policy should focus less on age with respect to EEI's that might lose all funding and instead focus broadly on investigators in danger of losing all funding.

Preliminary policy goals include an urgent need to protect junior investigators, to stabilize the career trajectory of successful mid-career investigators, to make evidence-based decisions, and to create a feedback loop to re-evaluate decisions. It was suggested that more predictive models are needed to identify investigators at risk. There was discussion on data indicating that mid-career investigators may be put at greater risk with greater focus on funding early-stage and early-established investigators. There has also been further discussion on the possibility of a cap.

The group plans to provide interim recommendations to the ACD at its June meeting and final recommendations are anticipated for the December 2018 ACD meeting. Changes to how NIH administers this initiative are likely to be implemented over time.

Reimagining HHS and Optimizing NIH

At the ACD meeting Dr. Tabak also presented on the status of efforts to reimagine HHS. This is part of a government-wide effort to improve efficiency and effectiveness directed by OMB. Two thousand ideas were reportedly distilled into 28 initial "solutions" and six "strategic shifts". The latter includes putting people at the center of HHS programs; leveraging the power of data; generating efficiencies through streamlining (with a focus on grants, both individual and block); restoring market forces; HHS as a more innovative and responsive organization; and, moving to a 21st century workforce.

The agency reform plan was submitted to OMB in September and implementation is underway. NIH is the pilot agency for efforts to make HHS more innovative and responsive and will work to increase collaboration and data sharing across operating divisions. This effort, termed "Optimize NIH", will initially focus on management of ethics, FOIA, and committee management across ICs with the goal of enterprise-wide service centers. Efforts are being driven by stakeholder teams and will involve employee feedback. With the acceptance of NIH's plan on Oct. 18 the Director's hiring authority was reinstated.

NSF IPA Program Cost Share Pilot Extension

NSF has announced that the agency is extending the Cost Share Pilot for Personnel on Intergovernmental Personnel Act (IPA) Assignment to NSF. As reported previously, in FY17, NSF piloted a required 10% cost share of the IPA's base salary and fringe benefits for all new agreements. NSF will extend the pilot through FY 2018 "to ensure a full evaluation can be conducted." Questions should be referred to [Allison Radford](#).

Audit

NSF OIG Semiannual report to Congress

The [NSF OIG Semiannual Report to Congress](#) covering April 1 through September 30, 2017 was recently released. In addition to management of major multi-user research facilities, the report highlights oversight of agency awardees, including questioned travel costs, expenses claimed near the end of an award period, subaward charges and pre-award costs. The report also reviews recent reports on NSF's controls for identifying and mitigating conflicts of interest for individuals appointed under the agency's IPA program, and investigations of program integrity and research misconduct, including compliance with required plans for providing training in the responsible conduct of research.

The semiannual report notes the NSF OIG's evaluation of compliance of the Federal Demonstration Partnership payroll certification pilot with the Uniform Guidance and that, as previously indicated, "the recommendations we made in our audit reports are still applicable for programs under the Uniform Guidance." The report also includes a review of the quality of single audits for all reports for which NSF is the cognizant agency for audit, including 43 audit reports, covering over \$658 million in NSF expenditures. Per the report, "the percentage of reports that fully met Federal reporting requirements showed marked improvement over the past several periods, rising from 58 percent in the most recent period to 70 percent in the current period."

NSF OIG Audit Work Plan

The NSF OIG has released its FY 2018 audit [work plan](#). Among the required projects noted is an audit of NSF's processes to oversee awardees' monitoring of their subrecipients as required by the American Innovation and Competitiveness Act of 2017. The report also notes that based on risk, projects that are likely to be undertaken in FY18 include: NSF's accountability over major facilities; NSF's management of contracts; NSF's processes for monitoring foreign awardees; Assessing the amount of outstanding Major Overhaul and Stabilization

Account surpluses across University-National Oceanographic Laboratory Systems; Audits of incurred costs of NSF awardees and compliance with applicable requirements; and, review of the quality of Single Audits, including desk reviews of approximately 120 Single Audit report packages and quality control reviews of the audit work for two Single Audits.

We noted in the [November COGR update](#) that the NSF OIG is currently updating its risk matrix and how risk is allocated. This was confirmed in recent conversations with the IG and Assistant IG. NSF is also trying to build more flexibility into the process to avoid unnecessary protracted audits. The OIG also plans to let the agency know earlier on of potential findings and recommendations to ensure that they are on the right track with respect to audit findings.

HHS OIG Semiannual Report to Congress and Audit Work Plan

The HHS OIG released its [Semiannual Report to Congress](#) on November 30th. A message from the HHS Inspector General highlights the agency's growing use of data analytics as a means to detect "vulnerabilities and fraud trends". The report largely focuses on Medicare and Medicaid.

In the area of human subjects research the report highlights reviews of Office for Human Research Protection activities, including an earlier report on OHRP independence and a more recent report on [whistleblower protections](#) for reports of noncompliance. The OIG also reviewed Single Audit findings for 552 audits of State and local governments, colleges and universities, and nonprofit organizations receiving HHS awards. Of these, 516 (93%) required no changes or minor changes. With respect to the OIG audit [work plan](#), recently added items were unrelated to research institution grants or oversight.