Actions Directed by Recent Legislation

COGR Engagement in Implementation

Research Policy Board (CURES - Section

2034) - A public-private entity recommended by the National Academies "to foster more effective conception, development and harmonization of research regulations" The National Science Board similarly recommended an interagency, intersector committee. The RPB was included in the 21st Century Cures Act. OMB is directed to establish the board to consist of 10 or fewer federal members (OIRA, OSTP, HHS, NSF and others that support or regulate research) and 9-12 representatives of academic or other non-profit research institutions or organizations with relevant expertise. Appointed through a formal process including nomination by members of the research community, the board is charged with coordinating and improving regulations and policies; discussing policy and regulatory gaps and challenges; and ongoing assessment of regulatory burden. Expert subcommittees can be formed as needed.

COGR has prepared a letter to Representative Mick Mulvaney who has been nominated to be the next OMB Director highlighting areas of Cures and other recent legislation to be implemented by the OMB Director and requesting a meeting. The letter can also be sent to the current OMB Director with a copy to Karen Lee. COGR to consider appropriate models for nominating non-federal members of the research community in consultation with other oranizations and members of the National Academies Committee on Federal Research Regulations and Reporting Requirements as a means to develop recommendations for a nominating process. COGR and other organizations to consider a list derived from the NAS, NSB and GAO reports of recommended areas for the committee to address with consideration for what has been implemented by statute. Discuss the timing of the GAO report with Senate staff. A letter from Senate staff to GAO could move up the timeframe. Partner with AAU.

Interagency Working Group on Research Regulations (AICA Section 201) - Included in the

American Innovation and Competitiveness Act, the working group is to be established by OMB in coordination with OSTP. Charged with reviewing existing regulations and making recommendations for eliminating, streamlining or improving regulations and processes with the goal of reducing burden on researchers and IHEs, and to refocus on performance-based goals. Directed to consult with stakeholders. Report to Congress after one year and annually for three.

Included in the letter to Rep. Mulvaney. Speak with Jean Feldman and possibly others. Despite the AICA generally being applicable only to NSF, NASA and NIST, the working group would appear to be applicable to all federal agencies that fund scientific research but may not be on their radar. How will this fit with the Research Business Models subcommittee and the Research Policy Board.

Subrecipient Monitoring (CURES - Section

2034) - reduce unecessary or redundant oversight.

Recommendations - National Academies - amend the UG to clarify applicability to IHEs only for project and performance monitoring. GAO - target higher risk subrecipients. Cures: NIH Director directed to reduce administrative burden, including possible exemption where the subrecipient is subject to single audit and use of collaborative grant models or other structures allowing for multiple prime awardees.

COGR to discuss with Mike Lauer on February 22. This may be something that can be addressed at the OMB-level for consistency across agencies and/or will be addressed when OMB releases the Federal Register notice and FAQs. Separately, NIH has indicated in the past that the agency is considering greater use of cooperative agreements, with several primes rather than a prime and subrecipients. Address the status of these discussions with Mike.

Micropurchase Threshold (AICA and

NDAA) - Increase to \$10,000 with the opportunity for higher thresholds. Recommendations - National Academies. GAO - target higher risk purchases. \$10,000 or higher threshold as determined by the head of the relevant executive agency and consistent with audit findings, institutional risk assessment, or State law.

AICA applicable only to NSF, NASA and NIST. NDAA applicable to all agencies but must be renewed annually. This needs to be addressed by OMB. Per Dave's call with OMB on 1/26, they fully understand that the NDAA and AICA language needs to be clarified through OMB. It is expected that this will be addressed in the anticipated Federal Register notice.

Review Financial Conflict of Interest Policies (CURES - Section 2034) - harmonizing policies and reducing burden - Recommendations: National Academies - Federal-wide policy to be developed by Congress and OSTP; NSB and GAO - evaluation of the 2011 revisions to the PHS COI regulations. Within two years of enactment. Led

by the HHS Secretary. Review to include the minimum

threshold for reporting and just-in-time reporting.

COGR has had discussions on this in the past with the Deputy Secretary of HHS and other HHS staff as well as NIH OPERA staff. The topic of HHS COI was addressed in a letter sent to Rep. Tom Price in December. Once a new HHS Secretary is appointed COGR will send a letter and reach out to try to schedule a meeting with staff. Partner with AAU.

Evaluation of Financial Reporting Procedures (CURES - Section 2034) and requirements with the goal of minimizing burden.

Specific to HHS/NIH. Avoid duplication between HHS and NIH and minimize burden. This could be a new avenue for addressing existing concerns and could potentially be included in a letter to Rep. Price if confirmed. Discuss with Mike Lauer on Feb. 22. One possible consideration is to eliminate redundant financial reports: evaluate the need for the Federal Cash Transaction Report (FCTR) which is now redundant and duplicative as NIH has shifted to award level reporting. NSF eliminated these reports following implementation of award-level accounting. Engage costing.

Review Animal Research Regulations (CURES - Section 2034) - goal of reducing

administrative burden. Recommendations - National Academies: OSTP to convene - goal of unified federal approach. NSB - engage all regulatory, independent and certification bodies. Within two years of enactment. NIH, USDA and FDA are charged with identifying and eliminating inconsistent, overlapping or unecessarily duplicative regulations and policies and improving coordination.

COGR, FASEB and AAMC will work together to create a white paper and recommendations to submit to NIH, FDA and USDA. Reviewing existing reports and recommendations and will see additional feedback from the community.

Clarify or Affirm Alternatives to Effort Reporting (CURES - Section 2034) - Recommendations - NSB: OMB issue a memo of clarification indicating that the payroll certification method is acceptable to the Federal Government. National Academies: OMB affirm that IHEs may take advantage of the flexibility of the UG for documentation of personnel expenses. Directs the HHS Secretary to clarify applicability of the Uniform Guidance for management and certification systems, including those for documentation of personnel expenses. It would be our understanding that the intent is that the HHS Secretary affirm the flexibility under the UG in documenting personnel expenses.	COGR could recommend langauge to address this provision.
Unified Grant Format (AICA Section 201) - Recommendations - National Academies Working group to consider a simplified, unified grant format for use by all agencies.	Agencies would aruge that they do have a standard format. Discuss with Jean Feldman and others.
Preliminary Proposals (AICA Section 201) - Recommendations: NSB and GAO. Consideration by interagency WG.	NSF is using/piloting preliminary proposals but other agencies less so. Review the GAO report.
Simplified Budget Proposals (AICA Section 201) - Recommendations - NSB; GAO Consideration by interagency WG	NSF is using/piloting simplified budgets at initial proposal but other agencies less so. Review the GAO report.
Greater Use of Just-in-time (AICA Section 201) - Recommendations - NSB and Academies reports	Interagency working Group to consider. Review NSB and National Academies reports and discuss with Jean Feldman and Michelle Bulls. They have been looking at this for years but little action has been taken with the exception of NSF pilots.

Create a Centralized Researchers Profile Database (AICA Section 201) -

Recommendations - National Academies Directs the interagency working group to establish a centralized database for biosketches, CVs, licenses, and related documents.

Consider incorporating existing databases. To be utilized for all grant proposals "to the extent practicable."

Review the Academies recommendation. Discuss the status of SciENcv with NSF staff. Should this be an independent effort. Can this work now that it is in statute?

Create a Centralized Assurances Repository (AICA Section 201) -

Recommendations - National Academies: "similar to the Single Audit Clearinghouse of the FDP." For all assurances required for federal grants. Provide guidance to institutions of higher education and Federal science agencies on the use of the centralized assurances repository.

Review the Academies recommendation. Engage FDP and RCA.

Review and Simplify Progress Reports (AICA Section 201) - Recommendations - NSB.

National Academies: single uniform format.

Consider limiting reports to performance outcomes. Develop a strategy for simplifying reports. Consult with investigators, institutions and organizations and other stakeholders. The RBM working group has created the Research Performance Progress Report (RPPR; and a final RPPR), a unified federal progress report. Is there potential for further simplification and limiting the RPPR to performance outcomes. Review the Academies and NSB recommendations. The RPPR has been revised. Lisa to discuss AICA with Jean Feldman. Possible cross-cutting item, RRR and RCA.

Privacy Protection for Human Research Subjects - Certificates of Confidentiality (Cures - Section 2012)

Directs the HHS Secretary to issue Certificates of Confidentiality to "researchers that receive federal funding" and to "to minimize the burden of compliance." NIH has indicated that they hope to implement this within 6 months. They want COC's to issue automatically and were working to determine how to carry this out. COGR had recommended that the COCs issue automatically in earlier correspondance with Senate and NIH staff. Follow-up with Mike Lauer on 2/22.

Data Sharing (Cures - Section 2014)	Allows the Director of NIH to require grant recipients to share the data that is generated from NIH-funded research. Still in planning phase. Certinaly the RFI responses and NIH meetings with experts will factor in. Follow-up with Mike Lauer on 2/22. RCA will conttinue to follow.
"Other transactions authority" (Cures - Section 2036)	Authorizes NIH ICs to use transactions other than a contract, grant or cooperative agreement for the Precision Medicine Initiative and up to 50% of Common Rule funds with approval from the NIH Director. CIP to follow.
Clinical Trials Database - (Cures - Sections 2051-2054)	Review. Section 2054 requires the HHS Secretary to consult with agencies and other stakeholders to receive recommendations related to enhancements to the clinical trial registry. COGR to consult with U. Michigan and others on recommendations. Anticipate discussion with the Director of ClinicalTrials.gov at the June COGR meeting.
Accessing, Sharing, and Using Health Data for Research Purposes (Cures - Section 2063)	Review.
Protection of Human Research Subjects (Cures - Section 3023)	Requires the HHS Secretary to harmonize differences between the Common Rule and the Federal Food Drug and Cosmetic Act. Review and discuss whether RRR should provide recommendations.
Informed Consent Waiver or Alteration for Clinical Investigations (Cures - Section 3024)	Provides the FDA the flexibility to waive or alter informed consent requirements for clinical trials with minimal risk, similar to the Common Rule. Review and consider writing a letter to the FDA Commissioner and HHS Secretary or others.
CLIA Waiver Improvements (Cures - Section 3057)	Review.
Grant Subrecipient Transparency and Oversight (AICA Section 206)	Directs the NSF OIG to submit an audit report on NSF's policies and procedures governing the monitoring of pass-through entities with respect to subrecipients within one year of enactment.