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October 28, 2015

The following is a response from the Council on Governmental Relations (COGR) to the National Academy of Sciences Committee on Federal Research Regulations and Reporting Requirements report, [Optimizing The Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century](#) (part 1) released on September 22, 2015.

Regulations and Policies Related to the Acquisition and Use of Federal Research Grants

COGR supports the recommendations specific to proposal preparation including uniform grant proposal documents and greater use of just-in-time (JIT) for submission of supplementary materials. Amendments to legislation and regulation may be necessary to allow for the latter in some cases. For example, just-in-time submission of NSF's postdoctoral mentoring plans will require an amendment to the America Competes Act of 2007 and the PHS requirement that investigators and subrecipients disclose FCOIs no later than the time of application will require amendment of the regulations. Other changes, such as JIT submission of detailed budgets and Current and Pending Support can be implemented through changes in agency policy. We support the development of central repositories and databases for assurances and information. COGR also supports the committee's recommendations related to progress reports including, but not limited to, the need for a uniform annual report that is limited to performance outcomes, and the recommendation that OMB affirm that research institutions may take advantage of the flexibility provided by the Uniform Guidance with regard to the documentation of personnel expenses.

COGR strongly supports the recommendation that OMB amend the Uniform Guidance to clarify that subrecipient monitoring requirements apply to institutions of higher education (IHEs) only to the extent necessary for prudent project and performance monitoring. OMB can best implement that concept by explicitly allowing IHE's and other not-for-profit research organizations who do business with entities subject to the Single Audit Act to rely on the already existing Single Audit process to detect and correct any audit deficiencies. This reliance would expedite the issuance of subawards, eliminate the need for unnecessary duplicative audit review and follow-up, and would allow limited resources to be more effectively deployed in other higher-value aspects of subrecipient monitoring.

Regulations and Policies Related to the Conduct of Research

Conflict of Interest

We support harmonization of agency policy in most instances. Universities and federal agency officials are concerned that creating a federal-wide financial conflict of interest policy will result in federal-wide implementation of the 2011 Public Health Services COI regulations. COGR, AAU, APLU and AAMC have provided data and information demonstrating that many aspects of the PHS policy are ineffective as well as unnecessarily costly and burdensome. Nevertheless, the issuance of disparate COI policies by several agencies in response to the Uniform Guidance has already created significant burdens because of differing definitions of covered individuals and entities and monetary thresholds. The issuance of agency-specific COI policies should be suspended until the effects of the PHS policy have been further studied.

Human Subjects Research

We do not support the concept of excused research. As noted in our response to the Common Rule ANPRM proposed revisions in the current exempt categories can and should be accomplished without the creation of an excused category which was not included in the NPRM.

We are also not in support of a mandate for single IRB, but agree with the need for policies, procedures and infrastructure in support of single IRB. COGR opposes a mandate for the following reasons: the regulations should not include requirements which can be better addressed through thoughtful and effective sponsor/agency policies; a lack of data demonstrating that single IRB, as proposed in the NPRM and NIH draft policy, is more efficient, cost effective and will not diminish human subject protections; significant costs and timelines associated with reliance agreements, ancillary reviews and state/local concerns; institutional IRBs are not necessarily equipped to support reviews involving a significant number of sites; a single IRB is not appropriate for all studies (e.g., different arms of a protocol conducted at different institutions; social and behavioral science). We will strongly urge OHRP to abandon the single IRB concept as a component of the Common Rule. OHRP should address institutional liability issues through guidance and partner with agencies and the research community to develop and test models for single IRB. We strongly support the Committee's recommendation that proposed regulations be piloted to determine whether they efficiently accomplish the intent of the regulations and suggest that they also assess proposed time and cost estimates.

COGR supports the committee's recommendation to align and harmonize agency regulations concerning the protection of human subjects. The language in the Common Rule NPRM on harmonization is weak and would be ineffective. We strongly believe that a much more formal process with third party (i.e., OIRA) evaluation is needed to prevent duplication. The regulatory framework proposed in this report would facilitate these efforts. Regarding biospecimens, COGR agrees that "requiring consent for all research involving biospecimens would substantially increase administrative burdens" and "markedly hinder the conduct of critical science" and suggests that it would not increase human subjects protections. We recommend that the current definition of human subject and practices regarding biospecimens not be altered and that restrictions should not be placed on waiver of consent.

Animal Research

We agree that per the recommendations in this report, and the National Science Board report on reducing investigators' administrative workload, a review of the regulatory environment governing animal research is

necessary. COGR strongly supports the recommendation that reporting, assurances and verifications to agencies should be reduced and streamlined and that processes that are redundant to the IACUC approval process, such as the Vertebrate Animal Section of PHS grant applications and the DOD central administrative protocol review, should be eliminated. The review and frequency of review of protocols should be more risk-based rather than species-based, as is now the case. In accord with the recommendation, research institutions will continue to assess their own regulatory processes to streamline compliance activities in this and other areas and COGR will facilitate these efforts.

Regulations and Policies Related to the Financial Management of Research Grants

Inspectors General (IGs) and Audit

We fully agree with the recommendations specific to IGs. Failure to resolve issues regarding the NSF OIG's inaccurate interpretation of NSF policy, and failure to audit to the policy, has resulted in significant costs to universities and unnecessary damage to their reputations. Identifying the full cost of audits and only posting findings following audit resolution would bring about the transparency needed to discourage these practices. Implementation of these and other recommendations specific to IGs is likely to require an amendment to the Inspector General Reform Act of 2008.

Uniform Guidance

COGR supports the recommendations in this section with a few modifications. We agree with recommendations specific to procurement by micro-purchase, including that the threshold should be raised to \$10,000, but do not agree with the language that it should not exceed this amount. Many institutions currently have thresholds of \$10K or more. Universities should have some discretion in assessing the level of risk based on their profile of number of procurement transactions and dollars spent. Procurement system reviews and single audits can be used to evaluate the effectiveness of an institution's policies and procedures.

We agree that OMB should amend the Uniform Guidance to establish a mandatory 120-day timetable for the submission of financial reports, but we would extend this to all reports, financial, technical, property and others, required by the terms and conditions of the federal award. This would enhance institutional accuracy and compliance with close-out requirements without compromising federal efforts to ensure timely closeout of programs which might actually improve since institutions will have less need to modify previously submitted reports. As important as the establishment of the 120-day timetable is the requirement that there be federal-wide forms and formats for both financial and progress reporting.

Regarding the DS-2, we maintain that the DS-2 should be eliminated. The DS-2 sets forth an institution's accounting practices with regard to federal funds that are already documented elsewhere and readily available to auditors. It is now a burden both for universities and the government that has far outlived any usefulness. In a survey of COGR members conducted in October 2014 at the request of OMB, 77 institutions reported that in 87% of the total federal audits conducted in the last 5 years (1,048 of 1,204 federal audits), a DS-2 was not requested. These data make it clear that because of today's widespread electronic access to institutional policies, practices and procedures, the DS-2 is a tool that is no longer actively needed nor used for audit purposes. All other recipients of federal funds, including State, Local, and Tribal governments and nonprofits are excluded from this requirement.

New Regulatory Framework

We support the Committee's recommendation that Congress create a new mechanism, to include an active public-private forum and a designated official within government, to foster more effective conceptualization, development, and harmonization of research regulations.

- A mechanism for retrospective review and modification or elimination of ineffective and burdensome regulations, policies and guidance; harmonization; and university-agency discussions on the development and implementation of new regulations, policies and major guidance is needed.

Research Policy Board (RPB)

Establish a new entity, a Research Policy Board. The RPB would be a self-funded, government-linked entity. We fully support this recommendation with some modifications.

- Broader representation is necessary with greater use of existing university-funded structures in the form of COGR, AAU and APLU representation. These associations are university-funded; represent hundreds of universities; are well-versed in all academic-research related policy topics; and have existing staff to support the Board's efforts, negating the need for additional funding from non-profit entities to address inefficiencies in federal agency regulations, policies and procedures.
- Alternative models (i.e., to FASB) should be considered further. This entity should be flexible enough to address any issue. It should be structured such that there is one core board with numerous ad hoc panels or simply ad hoc panels themselves to address the very diverse policy objectives that exist. COGR will continue discussions on the proposed regulatory framework and looks forward to ongoing communication with the committee on this topic.

Associate Director, Academic Research Enterprise, OSTP

We fully support, with some modifications, the creation of a contact to oversee the government-academic research partnership and to manage regulatory burden as has previously been suggested by COGR, AAU and APLU and included in other reports.

- OIRA would likely be better suited to take on this position as it has the necessary authority to implement change per executive orders 12866, 13563, 13610 and 13422 in addition to Agency Good Guidance Practices, The Paperwork Reduction Act and other authorities to oversee and coordinate rulemaking. To make the role of the proposed Board and Associate Director both viable and sustainable, the individual must be able to effect change. Without the authority granted by executive order or public law to require agency engagement with IHEs in the development, implementation, harmonization and review of agency regulations and policies this position and the work of the research policy board or similar entity would largely be ineffective. The need for revisions to the Uniform Guidance and the lack of uniform implementation; a review of the PHS COI regulations and discussion of amendments; and areas of the Common Rule NPRM that require development and where stakeholder comments appear to have been ignored are just a few examples of areas that would benefit from the creation of this position with the necessary authority needed to effect change.

- A dual-appointment between OIRA and OSTP could also be considered. A new executive order could be issued to allow for review and oversight specific to research regulations, policies and guidance as needed.

COGR agrees with the need for stated principles to guide the regulatory framework, and the need to pilot proposed regulations as appropriate; the need for harmonization and regular review for effectiveness and burden; and recognition that risk levels will never be reduced to zero. Regarding standards of behavior, research institutions treat violations of trust and integrity very seriously and will continue to take timely and appropriate actions where necessary. We disagree with the need for additional sanctions on universities beyond those already available to the funding agency and do not see a role for the RPB in this process.

COGR appreciates and supports the work and findings of the committee. We look forward to an ongoing dialogue on the findings and recommendations in the report.