COGR
an organization of research institutions

COUNCIL ON GOVERNMENTAL RELATIONS
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December 16, 2016

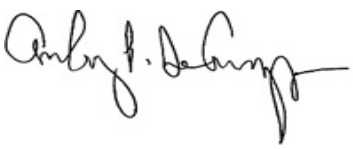
Dear President-elect Trump,

The Council on Governmental Relations (COGR) is an association of 190 leading public and private research universities and affiliated academic medical centers and research institutes – our members account for over 95% of all federal research awards made to the higher education community or over $60 billion in research expenditures. As the national authorities on the financial and regulatory infrastructure, and the corresponding compliance requirements, COGR is committed to fostering productive relationships between the research community and federal policymakers; advocating for innovation and change that avoid unnecessary regulatory burden.

As you transition into office, we offer our ongoing advice and assistance on matters related to the federal research enterprise, the regulation of federally funded research and opportunities for regulatory reform. The following topic areas reflect current thinking, priorities and actions on the regulation of federally funded research and academic research regulatory reform.

We would be happy to provide additional documentation and meet with your staff at their convenience, and look forward to working with your administration during the transition and beyond. COGR staff can be reached at 202-289-6655.

Sincerely,



Anthony DeCrappeo
President
Council on Governmental Relations

Academic Research Regulatory Reform

Increasing Federal Regulation of Research

Growing concerns about the steady increase in regulations governing federally funded research, and the amount of researcher time and federal and institutional funding dedicated to regulatory compliance, has been detailed in numerous published reports. Recent publications include the 2014 National Science Board (NSB) report *Reducing Investigators' Administrative Workload for Federally Funded Research*; the 2016 National Academies report *Optimizing the Nation's Investment in Academic Research; A New Regulatory Framework for the 21st Century*; and the 2016 Government Accountability Office (GAO) report *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements*. In 2016 alone there are seven new regulations, policies and reporting requirements with significant implications for research and additional requirements are anticipated before year end. Principal Investigators responding to the Federal Demonstration Partnership's 2012 Faculty Workload Survey "estimated that an average of 42% of their research time associated with federally-funded projects was spent on meeting administrative requirements rather than conducting active research."[1] The following is a brief summary of recent regulatory challenges, efforts to reform research regulations and examples of specific regulatory concerns.

Regulatory Process and Stakeholder Engagement

The rulemaking process permits interested parties to submit written comments in response to proposed regulations and the research community invests considerable time developing responses that convey the anticipated impact on federally funded research and development (R&D) and offer alternatives as necessary.[2] With respect to a number of recent regulations and policies, these comments, while perhaps noted in the preamble to a final rule, have generally not brought about substantive revisions. The Office of Information and Regulatory Affairs (OIRA) in the Executive Office of the President (EOP) oversees the rulemaking process. Stakeholders have the opportunity to meet with OIRA staff and agency officials prior to issuance of a revised or final rule, however, recent meetings with respect to the regulation of clinical research have not resulted in measurable revisions. Rules are developed without input from the regulated community, rules are proposed, extensive comments are submitted, and rules move forward with few if any changes. This regulatory process is also not applicable to agency policy and guidance. Therefore, policies can be issued with little or no input from the regulated community despite institutions' role in funding and facilitating research and substantial and increasing administrative cost share.[3] The general sense from the research community is that research is being overregulated, that the regulations are inefficient and unnecessarily burdensome, and that the emphasis on regulation and reporting has come at a significant cost to research productivity in addition to the cost in dollars for universities to comply – costs that are increasingly covered with university funds.

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[1] FDP 2012 Faculty Workload Survey Research Report. Retrieved from: http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf

[2] Administrative Procedures Act. Retrieved from: http://www.nmfs.noaa.gov/pr/pdfs/laws/apa.pdf

[3] Universities Report Fourth Straight Year of Declining Federal R&D Funding in FY2017. NSF NCSES Info Brief Retrieved from: https://www.nsf.gov/statistics/2017/nsf17303/nsf17303.pdf

The high cost to universities of complying with government regulation was highlighted as part of a broader discussion on college costs during the presidential campaign.

Federal Regulations for the Protection of Human Subjects, the "Common Rule"

Regulatory Concerns

Proposed revisions to the Federal Policy for the Protection of Human Subjects, also known as the "Common Rule," present a case study in the concerns raised above with respect to the regulatory process. Developed by federal officials in the absence of stakeholder input and published in July 2011, the proposed rules were strongly opposed by the research community.[4,5] In September 2015, a revised proposal, or Notice of Proposed Rulemaking (NPRM), was published. The proposed rule retained provisions strongly opposed by stakeholders, including proposals to expand the definition of "human subject" to include non-identified biospecimens and to mandate broad consent for their secondary research use. A COGR-APLU analysis of the 2,186 public comments submitted in response to the NPRM found significant opposition to most major proposals. In addition, a number of responses suggested that the NPRM is overly complex, poorly written, and not supported by data; highlighted areas that could have a substantial impact on a final rule but were not included in the NPRM (e.g., proposed security safeguards, a consent template, a list of minimal risk studies and a decision tool); and suggested that some of the proposals would adversely affect human health with little perceived benefit. The findings were consistent with those of the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) which found that a "strong majority of commenters oppose these proposals" and that there was "opposition across all subgroups."

Expert Committees Respond to the NPRM

The Presidential Commission for the Study of Bioethical Issues, in its comments on the NPRM, suggested that the proposals "will stall certain kinds of research using deidentified biospecimens that pose no risk to human subjects' and are unlikely to impact participants' autonomy interests." The HHS Secretary's Advisory Committee for Human Research Protections (SACHRP) suggested that "To the extent that the NPRM's core proposal is meant to ensure that subjects provide meaningful consent to future research with biospecimens and to prevent biospecimen re-identification, the NPRM would do nothing of the sort." SACHRP has recommended that "HHS conduct a comprehensive re-write of the NPRM and focus efforts on selected issues for which there is broad support." The National Academies Committee on Federal Research Regulations and Reporting Requirements recommended that the executive branch withdraw the Common Rule NPRM and called for an independent, free-standing national commission to recommend regulatory approaches to unresolved questions. Among them, the scope of human research activities that should be covered by federal regulations; addressing the

[4] Cadigan, RJ, Nelson, DK, Henderson, GE, et al. September-October 2015. Public Comments on Proposed Regulatory Reforms That Would Impact Biospecimen Research: The Good, the Bad, and the Puzzling. IRB Ethics and Human Research; 37(5). Retrieved from: http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=7554

[5] Bartlett, EE. February 2012. ANPRM: Summary of Comments. Retrieved from: http://www.hhs.gov/ohrp/sachrp/mtgings/2012%20Feb%20Mtg/anprmsummaryebartlett.pdf

boundaries between research and medical care; and balancing individual rights with collective obligations to advance public health. Despite the deep concern expressed by the research community, patients, industry and expert committees, and calls for the NPRM's withdrawal, HHS has indicated that it plans to move forward with a final rule and hopes to publish it before the end of 2016.

Research Policy Board and Administrator for the Research Enterprise

Active Stakeholder Engagement in Reform Efforts

The National Academies Committee on Federal Research Regulations and Reporting Requirements, in its report, recommended the creation of a Research Policy Board. As proposed, this public-private entity would bring together federal officials from research grant-making agencies and non-federal representatives of research universities to evaluate the effects of existing regulations, policies and guidance and offer recommendations to correct existing regulatory problems; facilitate the coordination of requirements across agencies; and make recommendations with respect to the conception and development of new regulations and policies. A Research Policy Board has been included in both the House and Senate 21st Century Cures packages along with other measures aimed at reducing regulatory burden for federally funded research. The legislation passed with overwhelming bipartisan support and was signed into law on December 12. This board would be key to addressing the many regulatory concerns documented in the NSB, National Academies and GAO reports on federal research regulatory burden referenced above; reducing unnecessary and costly regulatory requirements while ensuring accountability and proper government oversight. Reports to Congress and GAO oversight, included in the legislation, should help to facilitate discussions between federal and non-federal members and bring about a tangible reduction in regulatory burden.

Unified Oversight of the Federal Research Enterprise

The position of Associate Director, Academic Research Enterprise recommended by the National Academies to "serve as the principal federal official responsible for the coordination of federal agency policy and regulation relating to federally funded research in academic institutions" would also be extremely valuable for reducing unnecessary and duplicative regulation and streamlining new and existing regulations and policies. H.R.5583, the University Regulation Streamlining and Harmonization Act of 2016 includes an Associate Administrator for the Academic Research Enterprise to fulfill this role, however, the position was not included in the Cures Act recently signed into law. Such an advisor could reside within OIRA, as indicated in H.R. 5583, or this function could be served by a joint appointment between OIRA and the Office of Science and Technology Policy (OSTP) and employ a rotating university administrator via the Intergovernmental Personnel Act which would not necessitate the creation of a permanent position funded by the EOP. Regular contact between the university community and OSTP through such a position, as well as existing positions such as that of the Associate Director for Science and Assistant Director Federal R&D, is needed to ensure the productivity of the U.S. research enterprise which is vital to our Nation's economic prosperity.

Export Controls

The International Traffic in Arms Regulations (ITAR) and Export Administration Regulations (EAR) that govern exports have been subject to ongoing reform since 2009. The Departments of State and Commerce have engaged stakeholders, but universities remain concerned about the State Department's final definition of fundamental research and that this exclusion has not been applied to research conduct as well as reporting. A revised ITAR definition is expected to be published as a proposed rule early in 2017. The revised EAR definition confirmed institutions' understanding of fundamental research and the 1985 National Security Decision Directive 189 (NSDD 189) which established the principle that the products of fundamental research remain unrestricted to the maximum extent possible. COGR supports an ITAR definition that further affirms NSDD 189 and is consistent with the EAR.

Data Storage

The 2013 OSTP Memorandum *Increasing Access to the Results of Federally Funded Scientific Research* directs Federal agencies to develop plans to make publicly available "to the greatest extent possible" final peer-reviewed manuscripts, published articles and data resulting from federally funded research. Federal agencies are independently creating or updating data sharing plans. Universities are concerned about a lack of harmonization of requirements and processes across agencies, as well as the quantity of data that agencies may require to be publicly posted; the location and accessibility of data storage; researcher and administrator time spent making the data available; and the cost of making data available. COGR strongly recommends that OSTP take a leadership role in determining what high-value data should be prioritized for sharing and in harmonizing agency plans for data sharing and storage.

Summary

All parties (universities, national associations and federal partners) have generally come to agree with a number of key observations regarding the current state of federal regulatory burden. These include:

- That the regulation of research continues to steadily increase at a rate that is not sustainable, both directly and indirectly impacting faculty in the conduct of their research;
- That there is a lack of standardization across agencies that is very costly both to agencies and universities; and,
- That federally funded research could be regulated much more efficiently.