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an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS

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Kevin Neyland, Acting Administrator
Office of Information and Regulatory Affairs (OIRA)
Office of Management and Budget
Room 10102, NEOB
725 17th Street NW
Washington DC 20503

SUBJECT: Federal Regulatory Review

Dear Mr. Neyland

We welcome the opportunity to offer comment for the Director's consideration in developing recommendations on Federal Regulatory Review. The Council on Governmental Relations (COGR), an association of more than 175 U.S. research universities and their affiliated academic medical centers and research institutes, concerns itself with the influence of federal regulations, policies, and practices on the performance of research and other sponsored activities conducted at its member institutions. One of our principal tasks is monitoring and, as appropriate, commenting on the design and implementation of new Federal regulations.

We urge OIRA to consider in its recommendations the substantial cumulative effect in terms of cost and administrative burden of Federal regulations particularly on institutions of higher education. Any single new regulation may not meet the current dollar threshold for significance. Nonetheless, each new regulation adds to the burden on this sector and the increased cost associated with meeting regulatory requirements has begun to materially alter the budgetary impact of research grants.

Colleges and universities cannot recover the costs of meeting new regulations because the recovery of university administrative costs has been capped at 26 percent since 1991. Only universities are subject to the 26-percent administrative cap. Private industry, not-for-profit research institutions, and other entities are not affected by this restriction, and in the case of private industry, a profit factor is allowed as an additional reimbursement item. The costs associated with meeting any new regulations must be absorbed by the institution. Facilities and Administrative (F&A) costs incurred by universities are real costs of doing research, and caps result in under-recovery of reimbursement, which then forces universities to cover the unreimbursed costs through other, increasingly limited revenue sources.

The 26 percent cap on administrative costs is exacerbated by agency and/or statutory restrictions. A number of federal agencies establish a reduced rate, either for certain programs or for the entire agency portfolio (e.g., NIH career development awards, Department of Education training grants). Other agencies restrict F&A recovery through statutory requirements (e.g., USDA CSREES awards, DOD basic research awards as specified in the FY08 DOD Appropriations Bill).

OMB and the Federal agencies must integrate a consideration of the unique cumulative regulatory burden on universities and other research organizations into Federal regulatory review. This consideration can be informed by the statutorily required study of the amount and scope of all Federal regulations and reporting requirements called for in the Higher Education Reauthorization Act of 2008 (PL 110-135, Sec. 1108). OMB should ensure that the Department of Education enters into an agreement and provides adequate funding for the study by the National Research Council. COGR is preparing a list of regulations finalized since 1991 that have a direct impact on the conduct of research at universities to inform the NRC study. We have attached a preliminary list here for your consideration. You will observe the list includes new regulations and significant changes to the administration of Federal research grants and contracts. In all cases, the costs associated with these regulations must be carried by the institution.

We have maintained a long and productive research partnership with the Federal government that has been built on the recognition of our shared interest and obligation in conducting research that will contribute to the health, economy and well-being of the US. This partnership is predicated on both parties sharing in the costs of research. While the Federal government role predominates, the universities accept their role and responsibility to make significant contributions to the research partnership as well.

But there is cause for concern when the university share continues to grow at a faster rate than the Federal share. Without any recognition by policy makers of this reality, the risk is that additional financial burdens will move universities closer to a "tipping point". The result could be decline in the quality of research infrastructure and compliance initiatives, as well as a gradual degradation of research laboratories and facilities. This issue needs to be addressed broadly in the context of the historically productive Federal Government-University research partnership and, more specifically, in the increasing regulatory burden faced by universities.

Thank you for the opportunity to comment.

Sincerely,

Anthony P. DeCrappeo
President

Enclosure

Regulatory Changes, Since 1991

- Federal Policy for the Protection of **Human Subjects (Common Rule, 1991)**
- Nonindigenous **Aquatic Nuisance Prevention & Control Act** of 1990(Implemented, 1992)
- NIH Guidelines for Research Involving **Recombinant DNA Molecules (1994)**
- Deemed Exports (1994, EAR & ITAR)**
 - DFARS Interim Export Control Compliance Clauses (July 2008)**
- Conflict of Interest**
 - Public Health Service/NIH Objectivity in Research (1995)
 - NSF Financial Disclosure Policy (1995)
- Lobbying Disclosure Act of 1995**
- Cost Accounting Standards (**CAS**) in OMB Circular A-21(1995)
- Health Insurance Portability & Accountability Act of 1996 (**HIPAA**) Privacy Rule
- OMB Elimination of **Utility Cost Adjustment (UCA)** (1998)
- Data Access /**Shelby Amendment** (FY 1999 Omnibus Appropriations Act); related amendments to OMB Circular A-110
- Policy on Sharing of **Biomedical Research Resources** (NIH, 1999)
- Misconduct in Science** (Federalwide Policy, 2000)
 - NEH, 2001
 - NSF, 2002
 - EPA, (Directive, 2003)
 - Labor, 2004
 - HHS/PHS, 2005
 - NASA, 2005
 - Energy, 2005
 - Veterans Affairs, 2005
 - Education, 2005
 - Transportation, 2005
 - USDA (Proposed, 2008)
- HHS Centers for Medicare and Medicaid Services (**CMS**) **National Coverage Determination for Routine Clinical Trials** (Clinical Trials Policy), 2000
- Executive Order 13224**, Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit or Support Terrorism (September 2001, also EO 12947, 1995)
- Select Agents & Toxins** (under CDC and USDA/APHIS) Public Health Security & Bioterrorism Preparedness & Response Act of 2002; companion to the USA PATRIOT Act (2001)
- FISMA** Federal Information Security Management Act (Title III, E Government Act of 2002) OMB Circular A-130, Management of Federal Information Resources, Appendix III, **Security of Federal Automated Information Systems**
- CIPSEA** Confidential Information Protection and Statistical Efficiency Act (OMB Implementation Guidance 2007, Title V, E Government Act of 2002)
- Federal Policy on Embryonic **Stem Cell** Research (2003)
- Data Sharing Policy** (NIH, 2003)

Homeland Security Presidential Directive (**HSPD**) – 12, Common Identification Standards for Federal Employees and Contractors (2004)
Higher Education Act, Section 117 **Reporting of Foreign Gifts, Contracts and Relationships** (20 USC 1011f, 2004)
Model Organism Sharing Policy (NIH, 2004)
Constitution & Citizenship Day (2005, Consolidated Appropriations Act FY 2005)
Genomic Inventions Best Practices (2005)
Combating **Trafficking** in Persons (2008)
Code of Business Ethics & Conduct (FAR) 2008
Homeland Security Chemical Facilities Anti-Terrorism Standards (**CFATS**) 2008
E-Verify 2008
Military Recruiting and ROTC Program Access (2008, Solomon Amendment, National Defense Authorization Act for FY 2005)
Nuclear Regulatory Commission Order Imposing **Fingerprinting and Criminal History Records Check** Requirements for Unescorted Access to Certain Radioactive Materials (Feb 2008, Section 652, Energy Policy Act of 2005)
National Institutes of Health **Public Access Policy** (2008, Consolidated Appropriations Act of 2008, Division G, Title II Section 218)
Certification of Filing and Payment of Federal Taxes (Labor, HHS, Education and Related Agencies Appropriations Act of 2008, Division G, Title V, Section 523)
Health and Human Services/FDA **Clinical Trials Registry**

Implementation/Interpretation Changes, Since 1991

Foreign Nationals (See COGR/AAU/FDP Troublesome Clause Report, 2008)
Publication Restrictions (see COGR/AAU/FDP Troublesome Clauses, 2008)
PL 106-107/Grants.gov: Electronic Applications, Financial Reporting, Progress Reports, iEdison Invention Reporting, etc.
CCR/DUNS Registry requirements
Subrecipient Monitoring (OMB Circular A-133, Compliance Supplement)
Changes to A-21 **F&A Proposal Format**
Federal Policy for the Protection of Human Subjects:
Federalwide Assurance (2004), mandatory training
IRB Registration (2008)
Title IX of Education Amendments of 1972: Access to science and math educational programs (2007+)
EPA Hazardous Waste, Subpart K (2008)
IRS 990 Reporting

Significant Proposed Changes

Export Controls: Export Administration Regulations (EAR) & International Traffic in Arms Regulations (ITAR) (2003)
Responsible Conduct of Research Training – NSF (America COMPETES Act 2006)

Federal Funding Accountability and Transparency Act (FFATA) Subrecipient
Reporting (2006)

National Science Advisory Board for Biosafety (NSABB) **Oversight of Dual Use Life
Sciences Research** of Concern

Nuclear Regulatory Commission – Considerations concerning the Security and
Continued Use of Cesium-137 Chloride Sources (July 2008)

USAID **Partners Vetting System** (re: EO 13224 et al re: terrorist financing)

USDA **Animal Welfare Act, Contingency Planning** (2008)