February 2014 COGR Meeting Afternoon Presentation Artie Bienenstock

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Reducing Investigator's Administrative Workload for Federally Funded Research

National Science Board

Council on Governmental Relations Meeting
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Task Force on Administrative Burdens

December 2012

Charge

To examine the administrative burden imposed on federally supported researchers at U.S. colleges, universities, and non-profit institutions and offer recommendations where appropriate on relieving the administrative workload.

Task Force

Dr. Arthur Bienenstock, *Chair*

Dr. Bonnie Bassler
Dr. Kelvin Droegemeier
Dr. Alan Leshner
Dr. Carl Lineberger
Dr. Diane Souvaine

Liaisons: Dr. Lisa Nichols and Dr. John Veysey

Executive Secretary: Mr. Jeremy Leffler

Information Collection

- Request for Information March 2013
- Roundtable discussions April-May 2013
- Analysis of findings completed August 2013

Most Frequently Reported Areas

- Financial management
- Grant proposals
- Progress and other outcome reporting
- Human subjects research and IRBs
- Time and Effort reporting
- Research involving animals and IACUCs

Outreach

- USDA Animal and Plant Health Inspection Service and the NIH Office of Laboratory Animal Welfare
- NSF Board, Director, and Policy staff; NIH Office of Extramural Research; Office of Science and Technology Policy; RBM; and FDP
- COGR; Association of American Universities; Association of Public and Land-grant Universities

Focus on the Science
Proposal Requirements

The Board recommends that agencies modify proposal requirements, including only those essential to evaluating the merit of the proposed research and making a funding determination. This can be achieved through use of these or other mechanisms:

- Preliminary proposals
- Broadening just-in-time submission
- Simplifying budget requirements

Focus on the Science Progress Report

Annual progress reports should be limited to research outcomes, reported in simplified formats and commensurate with the size of the award.

Additional data requests should be limited to only what is essential for assessment of performance and compliance.

Focus on the Science
NSF

The Board advises NSF to fully review and consider the agency-specific comments received in response to the Board's RFI, as well as piloted modifications to the proposal process, and to report to the Board on review and progress within 6 months of the publication of this report.

Payroll Certification

The Board proposes that OMB identify appropriate means by which the piloted payroll certification approach may be used by universities and accepted by auditors and Inspectors General.

Human Subject Research

The Board supports a number of recently proposed reforms to regulations governing human subjects research, including:

- Encouraging the use of a central IRB
- Eliminating continuing review for all expedited/minimal-risk protocols.
- Expansion of current exemption categories.

Human Subject Research

Further, the Board endorses the Association for the Accreditation of Human Research Protection Programs (AAHRPP) recommendation to declare all research involving minimal risk as eligible for review using the expedited procedure.

The Board recommends eliminating the requirement that IRBs review grant proposals and likewise the requirement to submit IRB approved research protocols for review by agency IRB or peer review.

Animal Research Subjects

An evaluation of the regulations, policies, guidance, best practices, and frequently asked questions (FAQs) of all regulatory, independent, and certification bodies governing animal research should be considered to identify policies and guidance that increase investigator's administrative workload without improving the care and use of animals.

Conflict of Interest

The Board recommends an evaluation of recent changes to Public Health Services (PHS) COI regulations to assess cost and effectiveness. The Board does not recommend adoption of the PHS COI regulations by other Federal agencies.

Universities Subject to Industry Safety Requirements

The Board recommends that safety and security requirements or aspects of these requirements that target industry but are also applied to research settings be re-examined and that appropriate alternatives be identified and implemented.

Harmonize and Streamline Requirements

The Board urges Federal agencies to accelerate efforts to harmonize and streamline the grant proposal and submission process and post-award requirements.

Harmonize and Streamline Requirements

The Board recommends that a mechanism be established to ensure uniform and consistent audit practices. Audits that focus on larger expenditures, outcomes, and infrastructure for compliance and risk management, would significantly reduce investigator's workload while maintaining necessary oversight.

The Board urges agencies and institutions to consider requiring receipts and justifications only for larger purchases.

Implementation

To address the recommendations in this and other reports and to properly develop and implement new requirements affecting investigators and institutions, the Board recommends that a permanent high-level, interagency, inter-sector, committee be created, with stakeholder and OMB representation.

Doing the Homework

Upon formation, the committee, and its stakeholder participants, should create a priority list of regulations and policies that should be eliminated, modified, or harmonized to reduce the administrative workload of PIs and institutions.

University Requirements

The Board recommends that institutions communicate the origin of various compliance requirements to researchers and avoid adding unnecessary requirements to those already mandated unless compelling reasons exist to do so.

Model Programs and Effective Practices

The Board recommends that Federal agencies collaborate with research institutions, and organizations representing investigators and institutions, to identify and disseminate model programs and effective practices (e.g., for financial management and IRB/IACUC review) that could be adapted for use at other institutions. This effort could be aided by the recommended interagency, inter-sector committee.

IRB and IACUC Reviews

The Board recommends that universities review their IRB and IACUC processes and staff organization with the goal of achieving rapid approval of high quality protocols that protect research subjects.