



Reducing Investigators' Administrative Workload for Federally-Funded Research

National Science Board

National Research Council

**Committee on Federal Research Regulations and
Reporting Requirements**

February 12, 2015

Arthur Bienenstock



Background

Federally supported scientists spend an average of *42 percent* of their research time on administrative tasks.

— FDP Survey, 2005 and 2012

“the problem of excessive regulatory burdens...puts a drag on the efficiency of all university research,” potentially costing “billions of dollars over the next decade.”

— 2009 NRC report





NSB Task Force Study and Report



Released: April 2014

Community Engagement

Request for Information

- 3,178 respondents, mostly scientists

Roundtable Discussions

- Scientists and university administrators at several universities and other forums.



Most Problematic Areas

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

Focus on the Science *Proposals*

Focus proposal review on merit and achievement.
Postpone requirements that are not critical to a
proposal's merit review:

- Employ preliminary proposals
- Broaden just-in-time submission
- Simplify budget requirements



Focus on the Science *Proposals*

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NSF IS
WORKING ON
PILOTS OF ALL
OF THESE

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- Employ preliminary proposals
- Broaden just-in-time submission
- Simplify budget requirements



Focus on the Science *Reports*

Annual progress reports should be limited to research and broader impact 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.



Eliminate or Modify Ineffective Regulations

Target regulations that are ineffective, create unnecessary work, or are inappropriate for research settings.

The Board recommends particular attention to:

- Effort reporting
- Human subjects
- Animal research
- Conflict-of-interest



Effort Reporting

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.

FDP has conducted a pilot study. We are awaiting an assessment of the results by a group of Inspectors General.



Harmonize and Streamline Requirements

A substantial lack of consistency and standardization across agencies persists.

- Agencies should accelerate efforts to harmonize and streamline requirements
 - e.g., Research Performance Progress Reports (RPPRS), Standard award terms and conditions, Public Access
- Establish a mechanism to ensure uniform and consistent audit practices
- Establish a permanent high-level (OSTP), interagency, inter-sector committee, with both OMB and stakeholder representation



Human Research Subjects

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

- Encouraging the use of a single IRB
 - *New NIH policy being considered*
- Eliminating continuing review for all expedited/minimal-risk protocols
- Expansion of current exemption categories



Human Research Subjects

- Declare all research involving minimal risk as eligible for review using the expedited procedure.
- Eliminate 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

- Evaluate regulations, policies, guidance, best practices, and FAQs of all regulatory, independent, and certification bodies governing animal research.
- Identify policies and guidance that increase investigator's administrative workload without improving the care and use of animals.

Laboratory Safety and Security

Safety and security requirements that primarily target industry — but are also applied to research settings — should be re-examined and appropriate alternatives identified and implemented.



Conflict of Interest

- Evaluate 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.



Increase University Efficiency and Effectiveness

- Audit fear
- Reduce inconsistencies among state, federal, and university system requirements
- Identify and disseminate model programs and practices
- Universities should review their human and animal research review processes and training to enable rapid approval of high quality protocols and reduction of unnecessary burden



Eliminate or Modify Ineffective Regulations

- A prioritized list of regulations and policies that should be harmonized, modified, or eliminated is needed.
 - We recommended a stakeholder process, either in concert with agencies or through a National Academies-type committee. (YOU!)
- Establish a high-level, inter-agency, inter-sector committee, with OSTP leadership, OMB and stakeholder representation.



Recommended Priorities

- Laboratory safety and security
 - Regulations designed for industrial scales
- Conflict of Interest
 - Harmonization but not based on PHS
- Human subjects
- Animal research
 - Harmonization but not based on USDA
- Effort reporting
- Streamlining proposals and reporting





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The End



NSF Implementation



- Running merit review pilots (e.g., pre-proposals)
- Discussing pilots of just-in-time and streamlined proposals
- Improved automated compliance checks to aid proposal writing
- Holding Directorate-level conversations on additional ideas
- Leadership role in interagency efforts to harmonize and streamline (typically through NSTC's RBM committee):
 - Uniform Guidance: implemented on time, 1000 attendees at webcast
 - Research Performance Progress Reports (RPPRs); Next: final reports
 - Standard award terms and conditions for 26 agencies (with NIH)

Organizations Likely to Help



- Association for Assessment and Accreditation of Laboratory Animal Care
- Association for the Accreditation of Human Research Protection Programs
- Association of American Universities
- Association of Public and Land Grant Universities
- Council on Government Relations
- Federal Demonstration Partnership
- Federation of American Societies for Experimental Biology
- National Science Board

Task Force

Dr. Arthur Bienenstock, *Chair*

Dr. Bonnie Bassler

Dr. Kelvin Droegemeier

Dr. Alan Leshner

Dr. Carl Lineberger

Dr. Diane Souvaine

Information Collection

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



Outreach

- **USDA Animal and Plant Health Inspection Service and the NIH Office of Laboratory Animal Welfare**
- **NSF Board, Director, and Policy staff**
- **Office of Science and Technology Policy , NIH Office of Extramural Research, RBM, and FDP**
- **COGR, AAU, APLU, FASEB, AAALAC, and AAHRPP**