Summary Presentation

Optimizing the Nation's Investment in Academic Research

A New Regulatory Framework for the 21st Century, Part 1

Federal Demonstration Partnership Meeting

January 2016

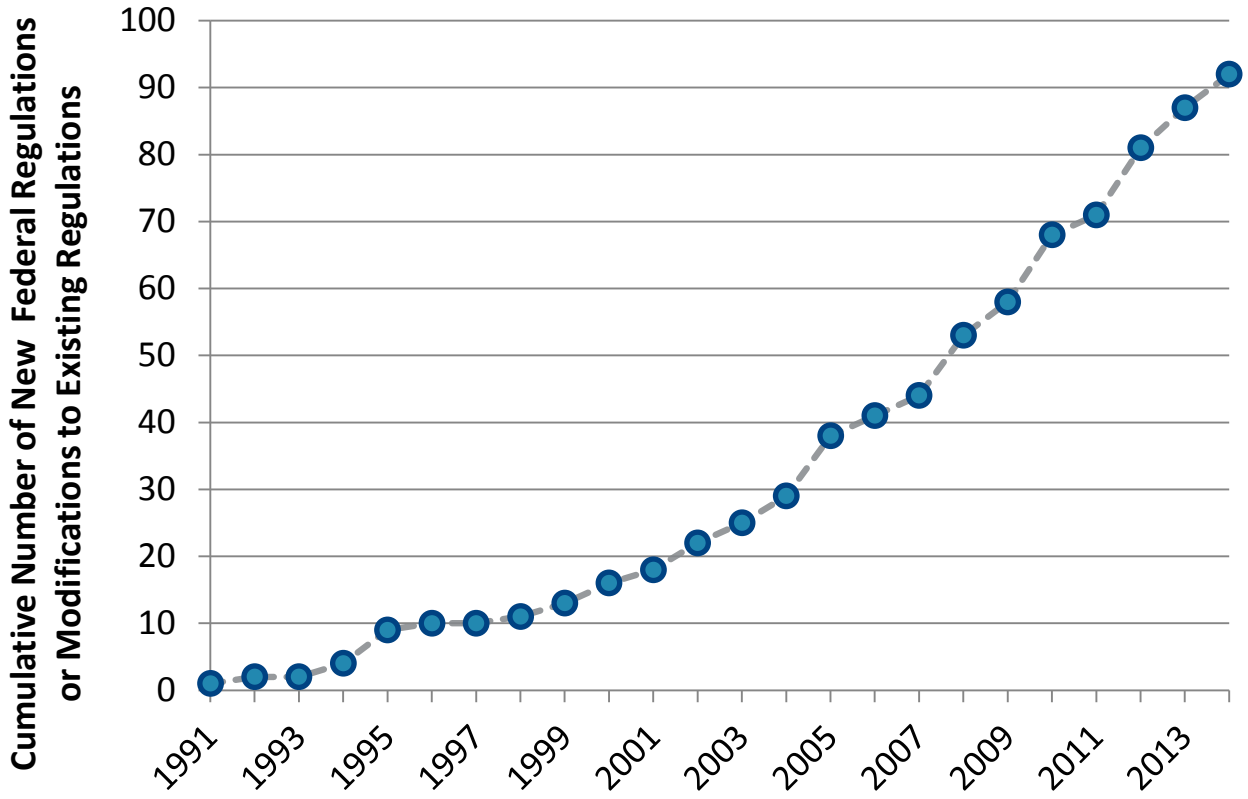
The Problem

"Concerns have been raised repeatedly that federal laws, regulations, rules, policies, guidances, and reporting requirements, while essential to a well-functioning, responsible system of research, have led over time to an environment wherein a significant percentage of an investigator's time is spent complying with regulations, taking valuable time away from research, education, and scholarship."

Report Summary, "Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century", 2015

Regulatory Burden

Cumulative Number of New Federal Regulations or Modifications



Data from COGR and FASEB

Time for Action

There is no question that when effective and well coordinated, federal regulation protects the government, universities, investigators and the public and helps prevent fraud, waste and abuse.

However, there is a growing concern that the unintended cumulative effect of federal regulation is undermining research productivity and diminishing the return on federal investment in research.

As a result, Congress called upon the National Academy of Sciences to examine the regulations and policies of federal agencies that support the research enterprise.

In turn the National Academy of Sciences formed an ad hoc "**Committee on Federal Research Regulations and Reporting Requirements: A New Framework for the 21st Century**"

Committee Charge and Organization of the Report

Committee on Federal Research Regulations and Reporting Requirements: A New Framework for the 21st Century

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Charge to the Committee

The committee will conduct a study of Federal regulations and reporting requirements with specific attention to those directed at research universities. In conducting its analyses, the committee will be aware of:

(a) the context and intended benefits and circumstances under which a particular regulation was issued and may have evolved, and
(b) whether those contexts or circumstances still remain of public concern.

The committee will develop a new framework for Federal regulation of research universities in the 21st century that addresses the needs of Congress, Federal agencies, and the broader public while advancing to the maximum extent feasible the missions of research universities.

Charge to the Committee

Specifically, the committee will:

1. Identify by research agency and statutory authority the Federal regulations with significant impact, and the reporting requirements with which research universities must comply;

2. Work with research universities and associations to gather and review information on personnel time and costs of compliance with Federal regulations and reporting requirements;

3. Work with research universities and associations to gather and review information on methodologies for most efficiently and effectively estimating time, costs and resulting benefits;

Charge to the Committee

4. Work with federal research agencies to identify regulations and requirements with significant impact that the committee should review;

5. Work with professional staff of congressional committees with jurisdictional responsibility for regulatory oversight and research funding;

6. Work with the stakeholders such as the Federal Demonstration Partnership to demonstrate methodologies for estimating the personnel time and costs of compliance for a subset of regulations and reporting requirements specific to research universities;

Charge to the Committee

7. Develop a framework and supporting principles for the Federal regulation of research universities in the 21st century, taking into account: (a) the purposes, costs, benefits, and reporting requirements of regulation, (b) the processes used to promulgate regulations and reporting requirements, (c) the roles of Congress, Offices of Inspectors General and Federal agencies, including the Office of Science and Technology Policy and the Office of Management and Budget, and (d) the missions of research universities;

8. Recommend steps needed to implement the framework;

Charge to the Committee

9. Assess how a subset of regulations and reporting requirements fit within the framework, and offer suggestions for evaluating those regulations and reporting requirements that are outdated or redundant, or where compliance burdens have become disproportionate with expected benefits; and

10. Identify regulations and reporting requirements that will require additional analysis in order to assess their fit with the framework and to develop improved approaches.

“A Unique Opportunity”

Although the study was originally planned for 18 months, 3 months after the committee’s first meeting, Senator Lamar Alexander, Chair, Senate Committee on Health, Education, Labor and Pensions, asked the committee to deliver an expedited report by summer’s end, 2015.

As Senator Alexander explained, fall 2015 presented a unique opportunity to reconsider, in a bipartisan manner, the regulatory environment governing federally funded research, as Congress would be considering several legislative actions involving higher education, research policy, and medical innovation where it would be appropriate to make changes to the current regulatory structure.

Committee Activities

In preparing the expedited report, the committee met 5 times (3 times in Washington DC, and once in San Francisco and Woods Hole).

At these 1.5 day meetings, the committee gathered information from a host of guests representing Federal Agencies, OSTP, OMB, Inspectors General, Professional Societies, Universities and Advocacy Groups.

There were many conference calls both for the whole committee and for the smaller working groups that were formed to tackle particular areas of the report.

At various stages the report went through countless edits and the final version represents the view of the committee as a whole.

In preparing for Part 2 of the report, due this Spring, the Committee met in Houston and will meet again later this week in Washington DC.

Organization of Report

Chapter 1:	Introduction
Chapter 2:	Government-Academic Research Partnership
Chapter 3:	Process of Federal Grant Funding
Chapters 4 – 6:	Regulations and Policies impacting Research Partnership
Chapter 7:	Overarching Findings and Framework for National Strategy to renew Research Partnership

Chapter Format

- Introduction
- Nature of Concern
- Analysis
- Findings
- Recommendations
  - With subparts to specific parties

Overarching Findings

1. Effective regulation is essential to the overall health of the research enterprise.

2. Continuing expansion of the federal regulatory system and its ever growing requirements are diminishing the effectiveness of the nation's research.

3. Well-intended efforts often result in unintended consequences that needlessly encumber the nation's investment in research.

4. Many regulations fail to recognize the significant diversity of academic research.

Overarching Findings

5. When regulations are inconsistent, duplicative, or unclear, universities may place additional requirements on research investigators.

6. Approaches to similar shared goals and requirements are not harmonized across the agencies.

7. Behaviors in conflict with the standards and norms of the scientific community must be addressed aggressively by the academic research institutions themselves.

Overarching Findings

8. Academic research institutions may be audited by any agency's Inspector General. The IG may apply audit approaches that are inconsistent with the policies of their own agencies.

9. The relationship between federal research funding agencies and academic research institutions has, for the past seven decades, been considered a partnership. Yet, there exists no formal entity, mechanism, or process by which both partners can consider the effectiveness of existing research policies and review proposed new policies needed to sustain a maximally dynamic, efficient, and effective research enterprise.

Overarching Recommendations

RECOMMENDATION ONE

The regulatory regime (comprising laws, regulations, rules, policies, guidances, and requirements) governing federally funded academic research should be critically reexamined and recalibrated.

RECOMMENDATION TWO

To advance the government-academic research partnership, research institutions must demand the highest standards in institutional and individual behavior.

RECOMMENDATION THREE

Inspectors General responsibilities should be rebalanced so that appropriate consideration is given both to uncovering waste, fraud, and abuse and to advising on economy, efficiency, and effectiveness.

The relationship between Inspectors General and research institutions should be based on a shared commitment to advancing the nation's interest through a dynamic and productive research enterprise.

RECOMMENDATION FOUR

The committee recommends the creation of a new mechanism, the **Research Policy Board**, to include an active public-private forum and a designated official within government, to foster a more effective conception, development, and harmonization of research policies.

Specific Recommendations were Given to the Following Groups

- **Congress:** 12 requests
- **White House OMB:** 6 requests
- **Federal Research Agencies:** 3 requests
- **Research Institutions:** 2 requests

Specific Recommendations

Financial Management

Compensation for Personnel Expenses:

1. The committee recommends that Congress, in concert with OMB, affirm that research institutions may take advantage of the flexibility provided by the Uniform Guidance with regard to the documentation of personnel expenses.

Uniform Guidance:

1. Procurement Standards – Raise threshold to $10,000 and amend list of criteria for noncompetitive bids

2. Financial Reporting – establish mandatory 120-day timetable for all financial reports

3. Cost Accounting – amend UG to eliminate submission of a DS-2 each time there is a change to their accounting practices

The Audit Climate:

1. Inspector Generals should **resolve issues regarding their interpretation of agency policies and priorities with the agency before** conducting formal audits of research institutions.

2. Inspector generals should include in their semiannual reports and highlight in their presentations to Congress examples of **effective, innovative, and cost-saving initiatives undertaken by research institutions and federal research agencies** that both advance and protect the research enterprise.

3. They should provide to Congress and make publicly available information generated each year on the total costs (agency and institutional) of Inspectors General audits of research institutions, **the total amounts of initial findings, and the total amounts paid by institutions after audit resolution**.

The Audit Climate (cont.):

4. Inspector Generals **should reexamine the risk-based methodology in identifying institutions as candidates for agency audits** to take into account the existing compliance environment and oversight on campuses, recognizing that many research institutions have clean single audits, are well managed, and have had long-standing relationships with the federal government.

5. Encourage all agency Inspector Generals to report **only final audit resolution findings** on their websites and in their semiannual reports to Congress.

Specific Recommendations

Acquisition and Use of Federal Funds

Proposal Preparation:

1. Congress should in concert with the OMB, conduct a transparent and comprehensive review of agency research grant proposal documents for the purpose of **developing a uniform format to be used by all research funding agencies**.

2. Research proposal information should be limited to the minimal information necessary to permit peer evaluation of the science and the ability of the team to carry out the research. Any **supplementary information should, if requested, be provided *just-in-time***.

3. Agencies should develop a central depository for all institutional assurances similar to the **Single Audit Clearing House of the FDP**.

Proposal Preparation (cont.):

4. Congress should task a single agency with overseeing and unifying efforts to develop a central database of investigator information

Progress Reports:

1. The committee recommends that OMB require that research funding agencies **use a uniform format for research progress reporting**.

Subrecipient Monitoring:

1. OMB should amend the Uniform Guidance to clarify that subrecipient monitoring requirements apply to institutions of higher education **only to the extent necessary for prudent project and performance monitoring**, and do not require monitoring of subrecipients' institutional compliance with all federal statues, regulations, policies, and institution-wide business practices.

2. Immediately, **OMB should permit research institutions to use subrecipients' publicly available Single Audit Reports** to verify that subrecipients have not been otherwise debarred or suspended with respect to the receipt of federal funds.

Specific Recommendations

Research Oversight

Conflict of Interest:

1. Congress in concert with OSTP and in partnership with research institutions, should develop **a federal-wide financial conflict of interest policy to be used by all research funding agencies**.

Human Subjects Research:

(To be reviewed further in light of the 9/8/15 NPRM for the Common Rule)

1. Congress should direct federal agencies to institute a risk-stratified system of human subjects protections that reduces regulatory burden on minimal-risk research while reserving more intensive regulatory oversight for higher risk research.

2. Congress should direct federal agencies to require, for multisite research studies, that a single IRB with the necessary staff and infrastructure serve as the IRB of record for all domestic sites.

3. **Congress should direct agencies to align and harmonize their regulations (and definitions) concerning the protection of human subjects.**

Human Subjects Research (cont.):

4) In instances of minimal-risk research where requiring informed consent would make the research impracticable, the committee recommends that Congress amend the FDA's authority so as to allow the FDA to develop criteria for waiver or modification of the requirement of informed consent for minimal-risk research.

5) Congress should instruct HHS to work with other agencies to ensure that **research involving biospecimens is eligible for a waiver or modification of informed consent**, so long as the proposed research meets the conditions for waiver or modification of informed consent as specified in the Common Rule.

Animal Research:

1. Congress should direct OMB to convene representatives from federal agencies and the research community to assess and report back to Congress on the feasibility and utility of **developing a unified federal approach for the development, promulgation, and management of policies and regulations pertaining to the care and use of research animals**.

   - Feasibility of Federal-wide Assurance
   - Ensure regulations are evidence-based and distinguish oversight from terms and conditions of funding to provide consistency
   - Empower IACUCs to streamline protocol review process and focus on ongoing protection of subjects (training and post-approval monitoring)

Animal Research (cont.):

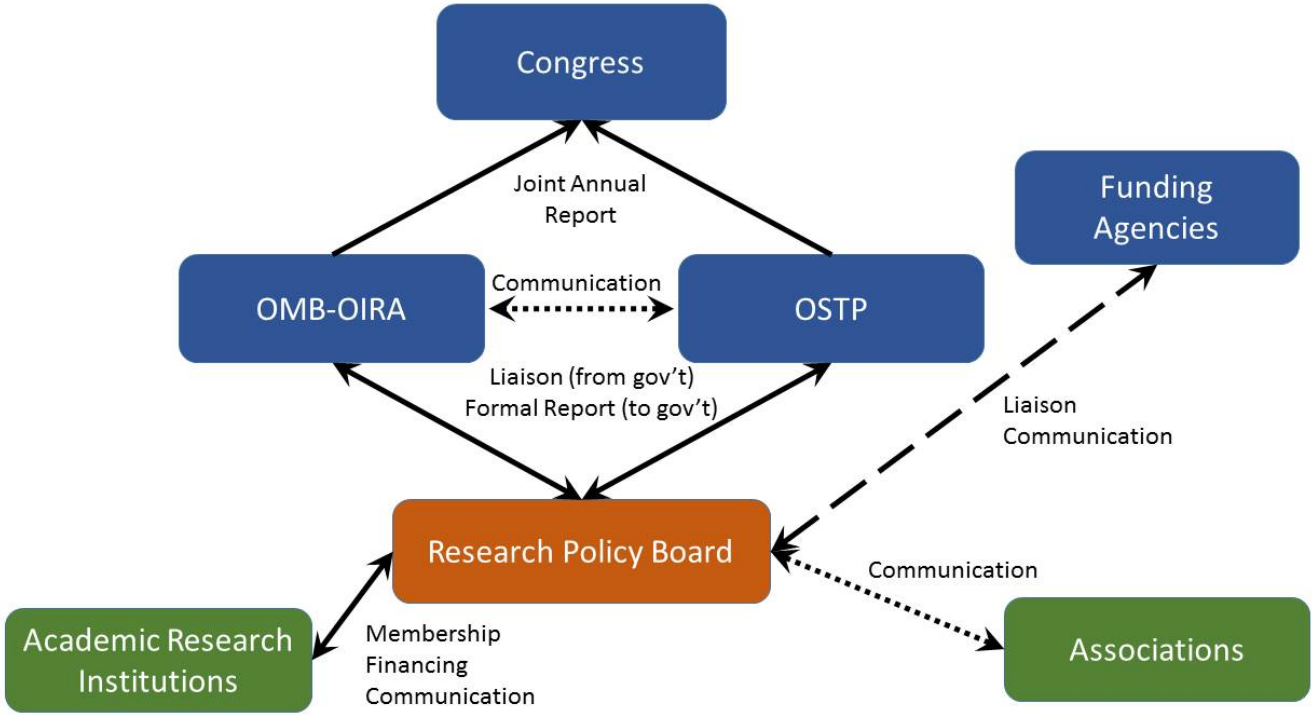
2. **Reporting, assurances, and verifications to agencies should be reduced and streamlined**.

    - Agencies should adjust their requirements for reporting such that animal-related noncompliance reports are tiered to the level of significance or impact on animals and included in an annual report rather than on an individual event basis.
    - **Annual reports to individual agencies about animal care programs should be replaced by a single annual report** under the proposed Federal-wide Assurance mechanism.

3. Research institutions should assess their own regulatory processes to determine where their compliance activities can be streamlined while still complying with federal regulations.

Research Policy Board

Schematic Representation of Relationships in a New Regulatory Framework



Model Follows the Example of the Financial Standards Accounting Board (FASB)

- A private-sector entity formally linked to and overseen by the SEC.
- Functional and effective since 1973.
- Funded by mandatory assessments of public companies.
- Organized and financially able to undertake relevant projects on a current-need or anticipated-need basis.

Concept of the Research Policy Board

- A private-sector entity formally linked to and overseen by OSTP and OMB, using a governance basis to be determined.
- Funded by mandatory assessments of research institutions.
- Organized and financially able to undertake relevant projects on a current-need or anticipated-need basis.
- Able to work flexibly with associations.

Characteristics and Roles of the RPB

- Mission: To improve and maintain a regulatory environment that is conducive to optimal performance of the research partnership.
- 9-12 members from academic research institutions, 6-8 liaisons from federal agencies, all designated through formal processes.
- Should become the primary policy forum relating to the regulation of federal research programs in academic institutions.

Characteristics and Roles of the RPB (cont'd)

- General responsibility *to recommend* regarding conception, development, and harmonization of regulations.

  - Thorough and informed analysis during the regulatory and policy-making process.

  - Identify negative or adverse consequences of existing policies and make actionable recommendations for improvement.

  - Conduct an ongoing assessment and evaluation of regulatory burden.

Characteristics and Roles of the RPB (cont'd)

- Should be future-oriented.
  - Cognizant of trends affecting overall regulatory load.
  - Should anticipate future regulatory challenges, especially from new science and technology.
  - Organize expert project teams as needed.

Characteristics and Roles of the RPB (cont'd)

- Should become a more systematic, integrated, and effective operational forum on research-related matters than any or all of the historic professional associations.

  - A strong focus by the Committee on a more integrated entity, formally connected to the regulatory process.

  - RPB could become a means for leveraging future work by the professional associations.

Guiding Principles for Regulatory Framework

- Regulations are a shared commitment
- Regulations should be harmonized across agencies
- Regulations should be written with RPB input
- Extent of a problem should be assessed before regulations are written
- Acknowledgement of zero risk is important
- Regulations should be reviewed periodically
- New regulations should be piloted
- Academic institutions must take action against those who violate community standards

Looking Forward:
We are at a Fork in the Road

- With completion of document and potential action by Congress, the community needs to start the discussion
- Report is not all-inclusive, but more of a guide to focus on topics – defined areas, recommendations, and guiding principles
- Role for all parties – special opportunity for the FDP