FASEB
Federation of American Societies for Experimental Biology

COGR
Council On Governmental Relations

Animal Research Regulatory Reform: Report and Recommendations of the FASEB/AAMC/COGR Working Group

Federal Demonstration Partnership Meeting

September 8, 2017

Presenters

Taylor Bennett, Senior Scientific Advisor, National Association for Biomedical Research

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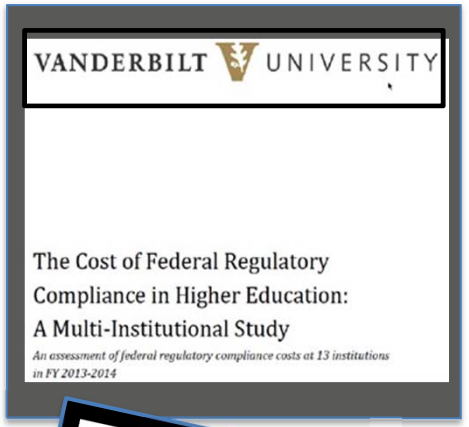
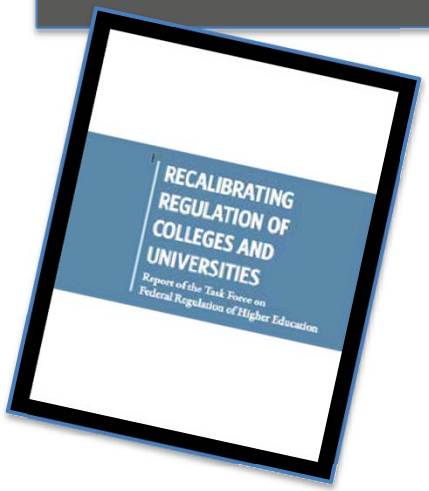
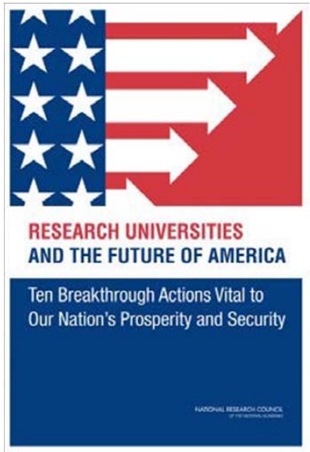
Reports and Assessments







NIH Initiative to Reduce Regulatory Burden


ARCHIVED - NIH INITIATIVE TO REDUCE REGULATORY BURDEN

Related Archives

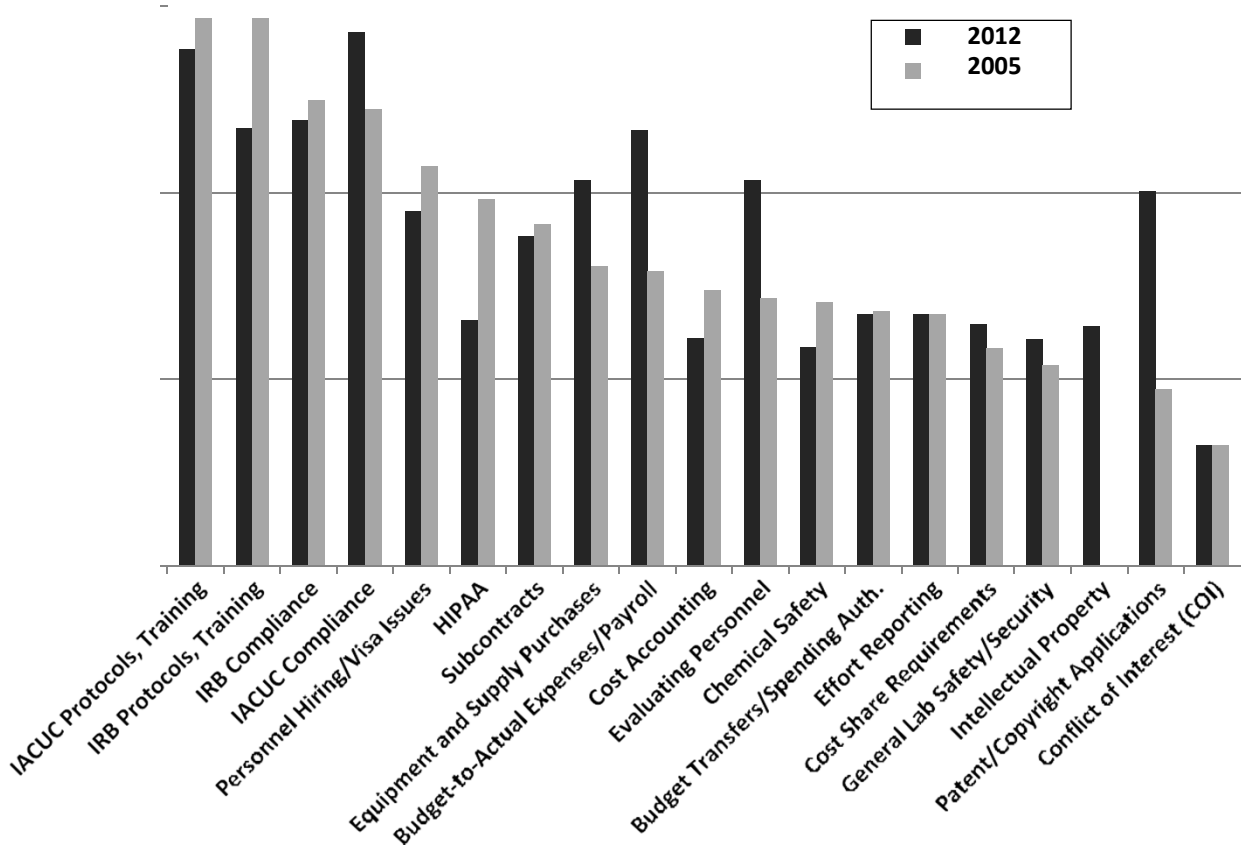
Identification of Issues and Potential Solutions

The following is a report provided to the NIH by a consultant, Mr. John Mahoney. This report was originally posted on March 10, 1999, for a public comment period of 60 days.

- Establish a group of advisors comprised of institutional representatives who would collaborate with the OPRR, USDA, and AAALAC in the formulation and interpretation of policies and guidelines.
- Reduce the number of redundant reviews and inspections.
- Recommit to efforts to develop a common reporting format.
- Establish a common protocol (review) frequency depending on the level of risk.

FDP 2012 Faculty Workload Report

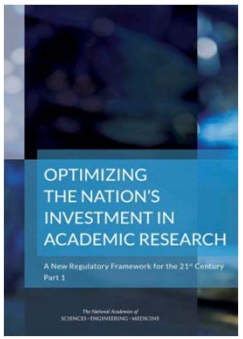
The most time-consuming responsibilities were associated with animal and human subjects research in both 2005 and 2012.



NSB Recommendations

- **An evaluation of the regulations, policies, guidance, best practices, and FAQs of all regulatory, independent, and certification bodies governing animal research should be considered to identify policies and guidance that increase investigators' administrative workload without improving the care and use of animals.**

National Academy of Sciences



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

21st Century Cures Act

One Hundred Fourteenth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday, the fourth day of January, two thousand and sixteen

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

Signed into law December 13, 2016

Section 2034 - Reducing administrative burden for researchers

Within two years of enactment:

- **NIH, USDA and FDA shall complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.**

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Workshop on Reforming Animal Research Regulations

April 17, 2017

Workshop Participants

In addition to AAMC, COGR, FASEB and NABR, representatives from:

American Psychological Association
American Physiological Society
American Veterinary Medical Association
AAALAC International
Association of American Universities
Association of American Veterinary Medical Colleges
Association of Public and Land-Grant Universities
Association for Research in Vision and Opthalmology
Baylor College of Medicine
Harvard University/Federal Demonstration Partnership
Johns Hopkins School of Medicine
Michigan State University
Society for Neuroscience
University of Alabama at Birmingham School of Medicine
University of Iowa
University of Maryland School of Medicine
University of Miami Miller School of Medicine
University of Oklahoma Research Park
University of Texas Southwestern Medical Center

Questions

1. **Are there regulations, policies, and guidance documents governing the use of animals in research that could be eliminated or modified without impacting animal welfare?**
2. **Are there regulations, policies, and guidance documents governing the use of animals in research:**
   a. **That could be harmonized among NIH and FDA?**
   b. **That could be harmonized among NIH and USDA?**
   c. **That could be harmonized across all Federal agencies?**
3. **What recommendations would you make for reducing administrative burden related to animal research in activities such as grant submissions, protocol review, program review, and facility inspections?**
4. **If institutions are fully accredited, how can agencies reduce the burdens and requirements for those institutions?**

Questions

5. **What changes would you recommend with respect to The Guide for the Care and Use of Laboratory Animals to reduce administrative burden while ensuring animal welfare and maintaining accountability?**
6. **What additional changes would you recommend for reducing administrative/regulatory burden while ensuring animal welfare and maintaining accountability?**
7. **What recommendations would you make for reducing administrative work such as grant submissions, protocol review, and facility inspections and/or harmonizing requirements with respect to inspection and review requirements by Federal agencies?**

Regulations and Oversight

- **Health Research Extension Act of 1985 Public Law 99-158 "Animals in Research"**
- **Animal Welfare Act – USDA APHIS**
- **U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training**
- **The Public Health Service Policy on Humane Care and Use of Laboratory Animals (Policy) – NIH Office of Laboratory Animal Welfare (OLAW)**
- **Federal guidance and frequently asked questions**
- ***Guide for the Care and Use of Laboratory Animals* - Institute for Laboratory Animal Research (ILAR),National Research Council, National Academy of Sciences**
- **Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International**

Major Recommendations

Executive Office of the President (EOP)

- **The EOP, including OMB, should explore whether regulatory efficiencies could be gained, and burden reduced, by consolidating animal research oversight under a single federal office or entity with one primary set of regulations and guidance documents. An advisory group of experts engaged in animal research from entities that receive federal research awards should be invited to assist with this effort.**

- **The EOP and OMB should consider requiring at least a 60-day comment period on the merits and impact of any proposed policies, guidance documents, frequently asked questions, or interpretive rules before they are issued. Final policies and guidance should include material changes that reflect germane comments received from the regulated community.**

Major Recommendations

NIH

- **The Guide is not a regulatory document. Given that, OLAW should use the Guide as it was intended, namely, "to assist institutions in caring for and using laboratory animals in ways judged to be professionally and humanely appropriate." The Guide allows facilities to produce welfare outcomes for animals in diverse and innovative ways by permitting alternative strategies to "should" statements upon approval by the IACUC. Thus, OLAW should revise FAQ C7 and PHS Policy IV.B.3.c to ensure that IACUC-approved alternative strategies from "should" statements in the Guide are not deemed departures or deviations and are not required to be included in the semiannual report to the Institutional Official.**

Major Recommendations

NIH

- **Eliminate the requirement for verification of protocol and grant congruency in NIH Grants Policy 4.1.1.2.**
- **Revise the NIH guidance in NOT-OD-05-034 regarding prompt reporting to include only those incidents that jeopardize the health or well-being of animals.**
- **Streamline the assurance for animal research. In addition, for Category 1 institutions, allow proof of accreditation in lieu of the detailed program description.**

Major Recommendations

USDA

- **Revise Section 2.31(d)(5) of the AWA Regulations as follows: "The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, including a review as required in Section 2.31(d)(1-4) at least *once every three years*" (Emphasis added). This would make review frequency consistent with the PHS Policy on Humane Care and Use of Laboratory Animals.**

Major Recommendations

USDA

- **Amend the language in USDA Animal Care Policy #12 with respect to literature searches to make it consistent with the language of AWR 2.31 (d)(1)(ii), which charges the IACUC to determine "that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources…"**

Major Recommendations

USDA

- **Revise USDA Policy 14 to reflect the language in the AWA §2143 and AWR 2.31.d.1.x.A-C, allowing approval of multiple survival operative procedures at the discretion of the IACUC and as justified by scientific and animal welfare reasons. This will enhance the community's efforts to reduce the number of animals involved in research.**

Major Recommendations

NIH and USDA

- **Establish a risk-based process for review of animal research protocols that is similar to that of human subjects research. USDA and OLAW could amend the protocol review requirement to define types of studies involving low-risk, noninvasive or minimally invasive procedures that may be deemed exempt from full IACUC consideration or eligible for administrative or single member review without concurrence by the full IACUC.**

Major Recommendations

NIH and USDA

- **NIH and other federal agencies engaged in the review of regulations and policies for the care and use of laboratory animals mandated by the 21st Century Cures Act should appoint an external advisory group of experts engaged in animal research from entities that receive federal research awards to serve as advisors. This will foster progress and impartiality in the conduct of this review.**

Major Recommendations

NIH and USDA

- **As part of the review mandated by the 21st Century Cures Act, all current Public Health Service and USDA regulations, policies, guidance documents, frequently asked questions, and interpretive rules, as well as the process for generating them, should be reviewed by an external advisory group of experts engaged in animal research from entities that receive federal research awards.**

Completion and Roll-out

Expected release date: Early- to Mid-October

Distribution:

- **Members of Congress and the Executive Branch (NIH, USDA, FDA, OSTP, OMB and others);**
- **National Academies;**
- **Related organizations and societies;**
- **University Vice Presidents and Chancellors for Research;**
- **AAMC, COGR, FASEB and NABR listserves**

Questions?