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Reducing Regulatory and Institutional Burden Associated with Animal Research

June 8, 2017

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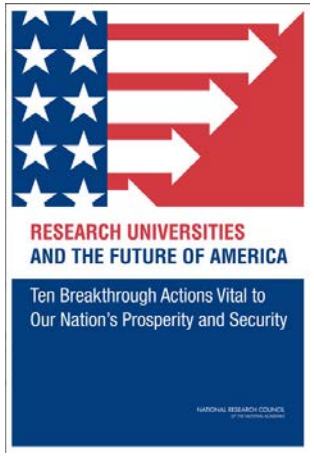
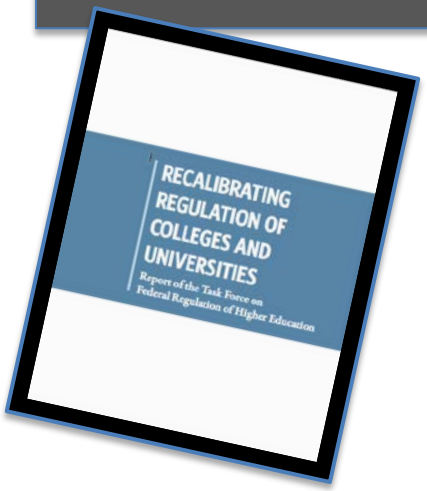
Reports and Assessments





NIH Initiative to Reduce Regulatory Burden


ARCHIVED - NIH INITIATIVE TO REDUCE REGULATORY BURDEN

Related Archives

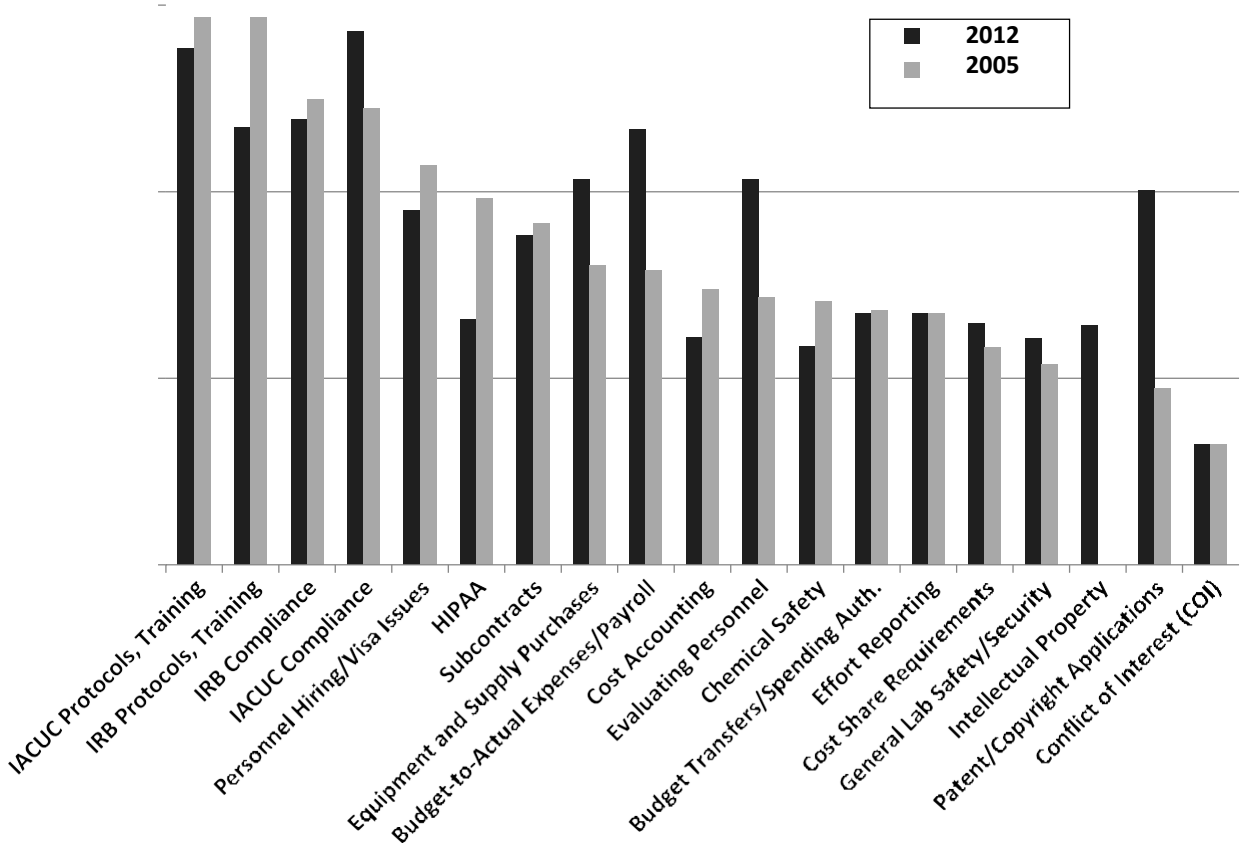
Identification of Issues and Potential Solutions

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

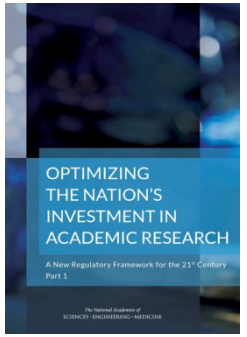
The most time-consuming responsibilities were associated with animal and human subjects research.



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.

FASEB
Federation of American Societies for Experimental Biology

AAMC
Association of American Medical Colleges

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Workshop on Reforming Animal Research Regulations

April 17, 2017

Workshop on Reforming Animal Research Regulations – Draft Recommendations

Executive Office of the President

The Executive Office of the President (EOP) and Office of Management and Budget (OMB) should consider consolidating animal research oversight under one federal agency or office with one set of regulations, policies, guidance documents and reporting requirements for all federal agencies involved in the funding and oversight of animal research.

The EOP and OMB, Office of Information and Regulatory Affairs (OIRA) should consider rules that would require the public have at least 60 days to comment on the merits and impact of any proposed policy, guidance document, or frequently asked question (FAQ) before it is issued. Final policies and guidance should include material changes that reflect comments received.

Workshop on Reforming Animal Research Regulations – Draft Recommendations

NIH and USDA

Establish a risk-based, tiered-level of oversight for review of animal research protocols that is similar to that for human subjects research.

Current Public Health Service (PHS) and USDA regulations, policies, guidance documents and FAQs should be reviewed by an external advisory committee to ensure that they emphasize matters of core importance to animal welfare identified in the statutory language of the Health Research Extension Act (HREA) and Animal Welfare Act (AWA).

To foster progress and impartiality, NIH and other federal agencies engaged in the review of regulations and policies for the care and use of laboratory animals mandated by Cures should appoint a committee of animal research experts from research institutions, possibly an expert subcommittee of the Research Policy Board recommended in the 21st Century Cures Act, to serve as advisors in the conduct of this review.

Workshop on Reforming Animal Research Regulations – Draft Recommendations

NIH

Eliminate the PHS requirement for compliance with the *Guide to the Care and Use of Animals* (*Guide*). Instead, use the *Guide* as a best practices document, as it was initially intended, to assist institutions in caring for and using laboratory animals.

Eliminate the requirement for protocol and grant congruency from NIH Grant Policy 4.1.1.2 Verification of IACUC Approval consistent with human subjects research.

Revise the NIH guidance on prompt reporting to only include those incidents that jeopardize the health or well-being of animals and allow institutions to report other incidence of serious deviation from the Guide as part of the annual reporting process.

Workshop on Reforming Animal Research Regulations – Draft Recommendations

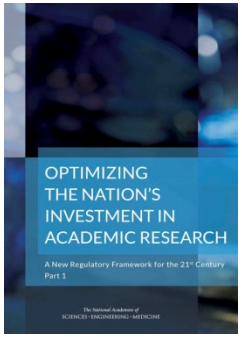
USDA

Revise Section 2.31(d)(5) of the Animal Welfare Regulations (AWR) to allow for continuing review at least once every three years consistent with PHS policy.

Amend the language in USDA Animal Care Policy #12 with respect to literature searches to be consistent with the language in the final rule that if the IACUC "determines that the written narrative prepared by the principal investigator provides adequate assurance that alternatives were considered, the Committee's meeting minutes need only reflect this determination."

Amend the AWR to allow for risk-based inspection of research facilities.

Recommendations to Institutions



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- **Conduct a review of institutional policies developed to comply with federal regulation of research to determine whether the institution has created additional and unnecessary administrative burden.**
- **Revise institutional policies that go beyond those necessary and sufficient to comply with federal, state, and local requirements.**

Feedback from FASEB-AAMC-COGR Workshop

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- Protocol review is one of the largest burdens for investigators. How to streamline review and protocol forms?
- Individuals in senior level positions at institutions still remember the era of "more is better" resulting in unnecessary administrative work.
- Some institutions feel obliged to have librarians dedicated to carrying out literature searches for each protocol which adds unnecessary expense to regulatory compliance.
- Institutions should not take FAQs and guidance documents to be mandatory.

Feedback from FASEB-AAMC-COGR Workshop

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- **Institutions should be encouraged to not apply USDA descriptions or requirements to non-USDA covered species:**
  - **Requirement that animals used in potentially painful studies must describe the methods and sources used to determine that these studies could not be conducted using some other method (i.e., refinement).**
  - **Annual reviews are unnecessarily conducted on all protocols.**
- **USDA annual review does not mean annual approval – steps institutions can take to reduce administrative work in the absence of regulatory changes.**
- **Targeted training.**

IACUC-Admin Listserv Survey

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Fifty-eight academic institutions: 19% Academic health science and/or medical center; 41% Academic w/ medical school(s); 40% Academic, no medical

Protocol review:

Average number of active protocols is 400. Average number of Full Committee Reviews (FCR) annually is 84. 21% FCR

- **69% do annual review of all protocols. 33% do annual review of USDA and DOD protocols only.**
- **67% require a report from the PI for annual review.**

Average number of amendments/modifications per year is 446.

- **Average number of amendments reviewed by Designated Member Review (DMR) is 312. 70% DMR**
- **69% use Veterinary Verification and Consultation (VVC) process for review of amendments, when applicable.**
- **Average number of amendments reviewed by FCR (not reviewed by VVC) is 23. 5%**

IACUC-Admin Listserv Survey

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Inspection:

69% require at least 2 IACUC members for all areas of semiannual inspections.

59% use agents of the IACUC for non-USDA areas for semiannual inspections.

Literature Searches:

83% require a literature search for Category D&E procedures in all species.

45% require a literature search for Category C procedures for all species.

COGR Guidance for Institutions

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- **COGR has reviewed the FDP Faculty burden Survey report and NSB report on investigator burden to identify major areas of concern to faculty.**

- **With input from COGR Committee members we compiled a list of approximately 100 actions that have been taken by member institutions to reduce administrative burden, 14 of which are specific to animal research and IACUCs.**

COGR Checklist

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Thirteen institutions submitted completed checklists:

- University of Pennsylvania
- Yale University
- Stanford University
- University of Michigan
- Emory University
- University of Washington
- Tufts University
- Michigan State University
- Washington State University
- University of Southern California
- University of Arizona
- University of Miami
- University of North Carolina

Animal Research/IACUCs

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14 Actions:

USDA versus Non-USDA

- **Eliminate annual protocol renewals for non-USDA species and non-DOD protocols**
  Yes (4); Limited review (2); Planning to implement (4); No (3) – Why not? - Annual renewals capture information that otherwise would cause additional burden for the PI; effective PAM measure; changes could be overlooked.
- **Discontinue the USDA pain and distress classifications for non-Animal Welfare Act regulated species**
  Yes (4); Planning to implement (2); Under discussion (1); No (6) – Why not? – would conflict with AAALAC and state requirements.
- **Allow investigators to provide an approximate number or range of animals needed over the course of a research project rather than an exact number**
  Yes (4); Considering (2); Partially (4); No (2) – Not permitted by law.

Animal Research/IACUCs

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- **As the default, implement Designated Member Review rather than Full Committee Review**
  Yes (9); Planning to or considering implementing (3); No (1) – Why not? – Protocols are relatively complex. Doesn't necessarily reduce burden.
- **Adopt NIH OLAW's allowance for "expediting" protocol amendments via a new Veterinary Verification and Consultation (VVC) process**
  Yes (9); Planning to implement (3); No (2) - not supported by ULAR and the IACUC; would cause more burden
- **Expand the scope of administrative approval authority by allowing small changes to protocols to be handled administratively**
  Yes (12); No (1) – Not allowed. Clearly delineated by OLAW.
- **Review SOPs on a less frequent basis (e.g., every two to three years) based on potential risk**
  Yes (10); Partially implemented/under review (1); No (2)

Does it help the animals?

Legislative Options

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- **Conditions Ripe for Reform?**
  - Intense White House focus on reducing regulatory burden
  - Single party control in legislative and executive branch
- **21st Century Cures Act and Limitations**
- **Legislative Options for Addressing OLAW Burden**
  - Appropriations committees, Authorizing committees, NIH Director
- **Legislative Options for Addressing USDA/AWA Burden**
  - Farm Bill primary vehicle for AWA amendments
  - Field hearings have started

Public Policy Options

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Non-legislative/Administrative Options

Questions?