

Welcome!

FASEB Webinar on

“Understanding Federal vs. Institutional Requirements for Animal Research”

*FASEB/COGR Series: Institutional Administrative Requirements for Animal Research
Pt. 2 of 2*

THE WEBINAR WILL BEGIN IN A FEW MINUTES

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FASEB

Federation of American Societies
for Experimental Biology

COGR

Council On Governmental Relations

Understanding Federal vs. Institutional Requirements for Animal Research

**FASEB/COGR Series: Institutional Administrative
Requirements for Animal Research – Pt. 2 of 2**

Speakers



JR Haywood, PhD
Assistant Vice President
Office of Regulatory Affairs
Michigan State University



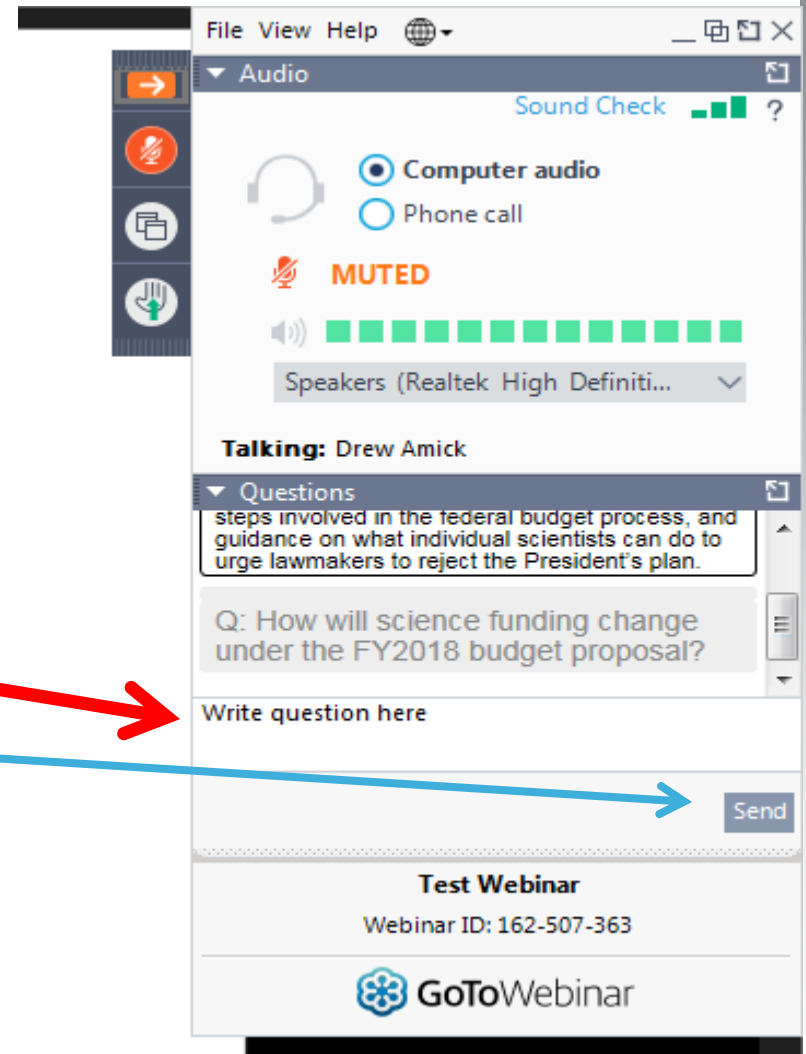
Molly Greene, BA, CPIA
IACUC Advisor
Michigan State University



Gaylen Edwards, DVM, PhD
Chair—Animal Care and
Use Committee
University of Georgia

To Ask A Question

Type your question in the white box and click “Send” (gray button)



Agenda

◆ Topics for discussion:

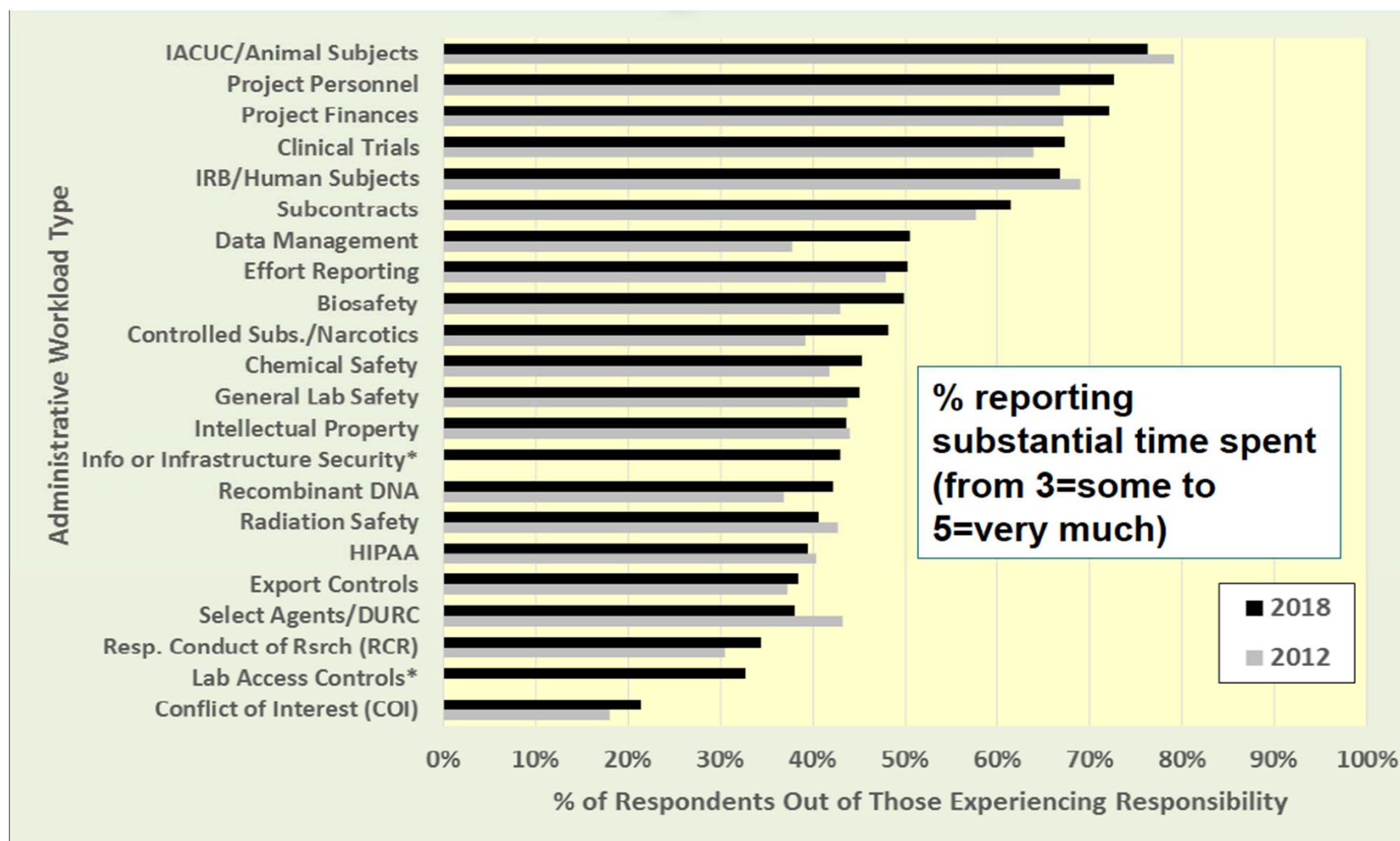
- Surveys assessing burden on faculty/scientists
- What faculty/scientists can do to affect change
- Specific IACUC issues

◆ Q & A

Reducing Burden ~~=~~ Reducing Animal Welfare

Reducing Burden = More resources for animal care & enrichment
More time for scientists to practice science

FDP Burden Survey Results



From: S. Schneider, Presentation at FDP 1/24/19

2018 COGR Survey Report

- ◆ 2018 survey of COGR members on actions that institutions can take to reduce administrative burden associated with animal research.
- ◆ Ninety-four of COGR's 188 members responded.

The Principal Results:

- ◆ **Institutions are more likely to take action to reduce administrative burden when federal agencies provide clear directives and address uncertainty.**
- ◆ Agencies could provide significant assistance to institutions by distinguishing between requirements and best practices.
- ◆ A contributing factor is the complexity of multiple sets of regulations, policies, and guidelines. Steps to align agency requirements would help to alleviate this.

Topics for Discussion

- Protocol Review Processes: FCR, DMR, VVC
- Frequency of Review: Annual and/or Triennial
- Animal Numbers
- Literature Review

Protocol Review Processes

DMR – Designated Member Review

This is the default in the regulations

FCR – Full Committee Review

Only required when requested by a member of the IACUC

VVC – Veterinary Verification & Consultation

For modifications and amendments

Designated Member Review

2018 COGR Report:

66% of institutions **do** use DMR as the default.

29% not planning to implement.

Suggestions:

- Creating a hierarchy of protocols that require Full Committee Review (FCR) can be an effective approach and ensure that the most invasive studies are appropriately reviewed.
- There is also value, however, in having some flexibility to determine what goes to DMR/FCR.
- Institutions should review their approach to ensure that it is improving animal welfare without creating unnecessary administrative burden.

Veterinary Verification and Consultation

2018 COGR Survey:

77% percent have adopted this process.

13% do not plan to adopt it.

**VVC process was implemented and encouraged by OLAW and
USDA to support expedited review of procedures already
approved by IACUC**

**Can decrease the number of changes/amendments IACUC needs
to review and approve**

Veterinary Verification and Consultation

Items that Do and Do Not Require IACUC approval

<u>Not</u> eligible for VVC	Eligible for VVC
Changing from non-survival to survival surgery or increase in degree of invasiveness	Anesthesia, analgesia, sedation, or experimental substances
Changes which result in greater pain, distress, or degree of invasiveness	Euthanasia to any method approved in the AVMA Guidelines
Change in housing/using animals in a location not part of the animal program overseen by IACUC	Duration, frequency, or number of procedures performed on an animal
Change in species	Increase in number of animals
Change in PI	Change in personnel, other than the PI
Change in study objectives	Correction of typographical errors and grammar
Change that impacts personnel safety	Contact information updates Change in Title of project and/or Funding agency

Frequency of Review

Annual or Triennial

Annual Protocol Review

2.31.d.5: The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually;

This requirement applies to USDA-covered species and DoD funded protocols only.

- PHS has no requirement for Annual Review.
- There is no requirement for the PI to submit a report, the requirement is for the IACUC to conduct a review.

Ways to accomplish continuing review:

- Postapproval monitoring
- Semiannual review
- Laboratory visits (IACUC coordinator or veterinarian)
- Self-reports to IACUC from technicians, animal care staff, investigators, etc.

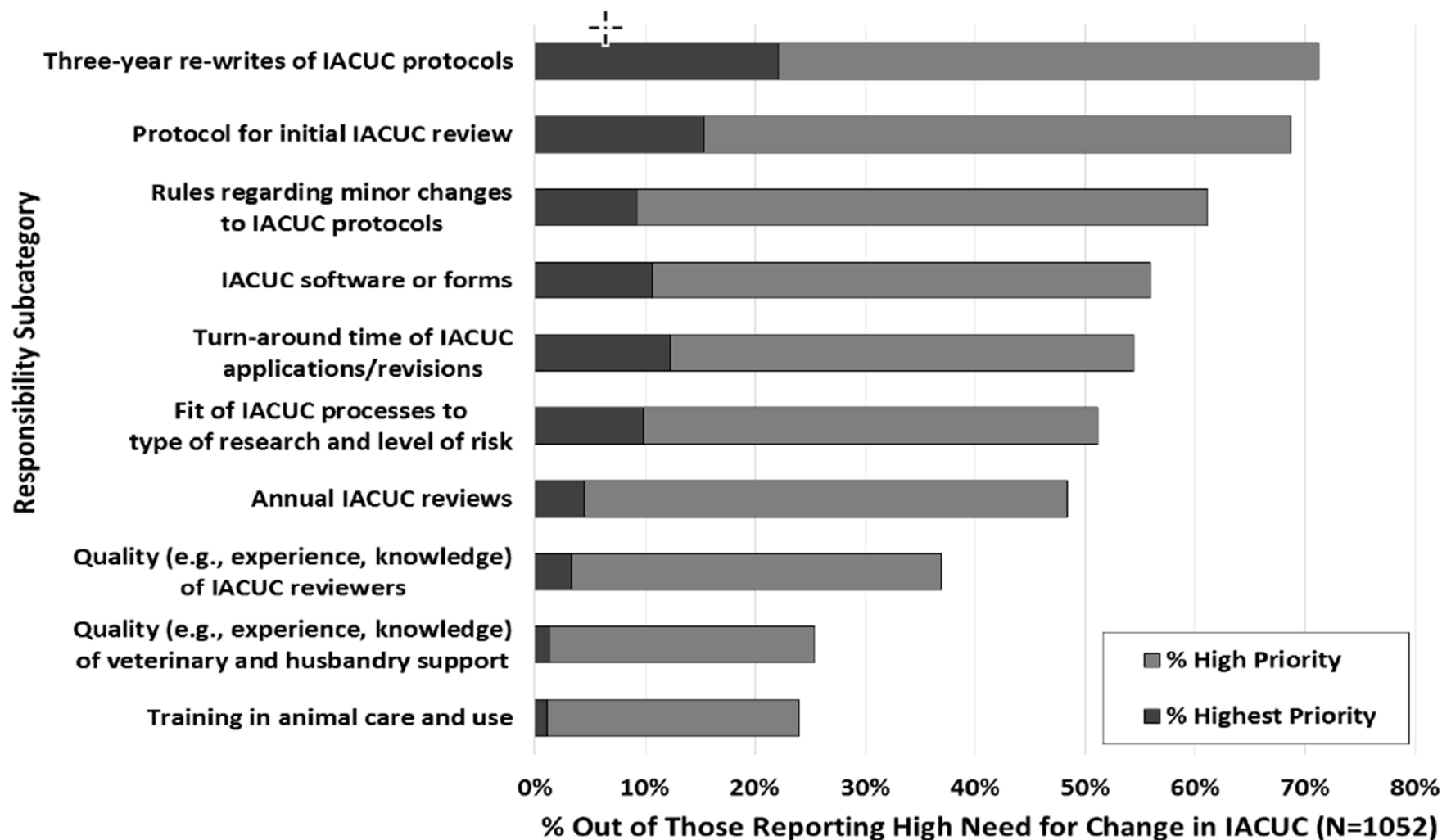
Annual Protocol Review

2018 COGR Report:

47% have eliminated annual review for non-USDA species and non-DoD protocols

42% not planning to make this change, even though this activity is not required

FDP Survey: IACUC Related Issues



Triennial Review

2018 COGR Report:

33% institutions do not require a protocol rewrite.

52% plan to continue to require a rewrite, even though it is not required.

This triennial review requirement applies to PHS and NSF-funded projects only.

PIs ranked the so-called triennial review as the most onerous task in the 2018 FDP survey

Triennial Review

Policy IV.C.5: *“The IACUC shall conduct continuing review of each previously approved, ongoing activity..., including a complete review in accordance with IV.C.1.-4...”.*

A rewrite of the protocol is not required
nor does it require a brand new submission.

It requires a *“continuing review of each previously approved, ongoing activity”*

It is not a new project. It is a renewal of ongoing activity.

- Updates and changes need to be included
- Obsolete information should be removed.
- Use of electronic protocol systems has made it easier to clone or make changes.
- This document should then be reviewed by the IACUC using the criteria in IV.C.1-4

Animal Numbers

2018 COGR Report:

44% of allow for an approximate number or range of animals needed for a research project.

44% don't plan to implement this change.

USDA 2.31(e)(1)	<i>“approximate number of animals to be used.”</i>
PHS IV.D.1:	<i>“approximate number of animals to be used;”</i>
USGP III:	<i>“minimum number required to obtain valid results.”</i>

NIH VAS:	<i>“...total number of animals by species”</i>
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Institutions should establish mechanisms to document and monitor number of animals acquired and used. There is no requirement to document using fewer animals than requested.

Literature Search Category D&E Procedures

2018 COGR Report:

25% have eliminated the requirement for a literature search for category D and E procedures **for non-USDA species.**

62% do not plan to implement this change.

This is a USDA requirement which applies to USDA-covered species **only.**

Literature Search for Category C Procedures

2018 COGR Report:

62% have eliminated the requirement for a literature search for category C procedures.

28% do not plan to eliminate this requirement even though it is not required by any regulation.

A literature search is required when animals are used in procedures which involve pain or distress or use of pain relieving drugs. Category c is No or Momentary Pain or Distress

Literature Search for Duplication

2018 COGR Report:

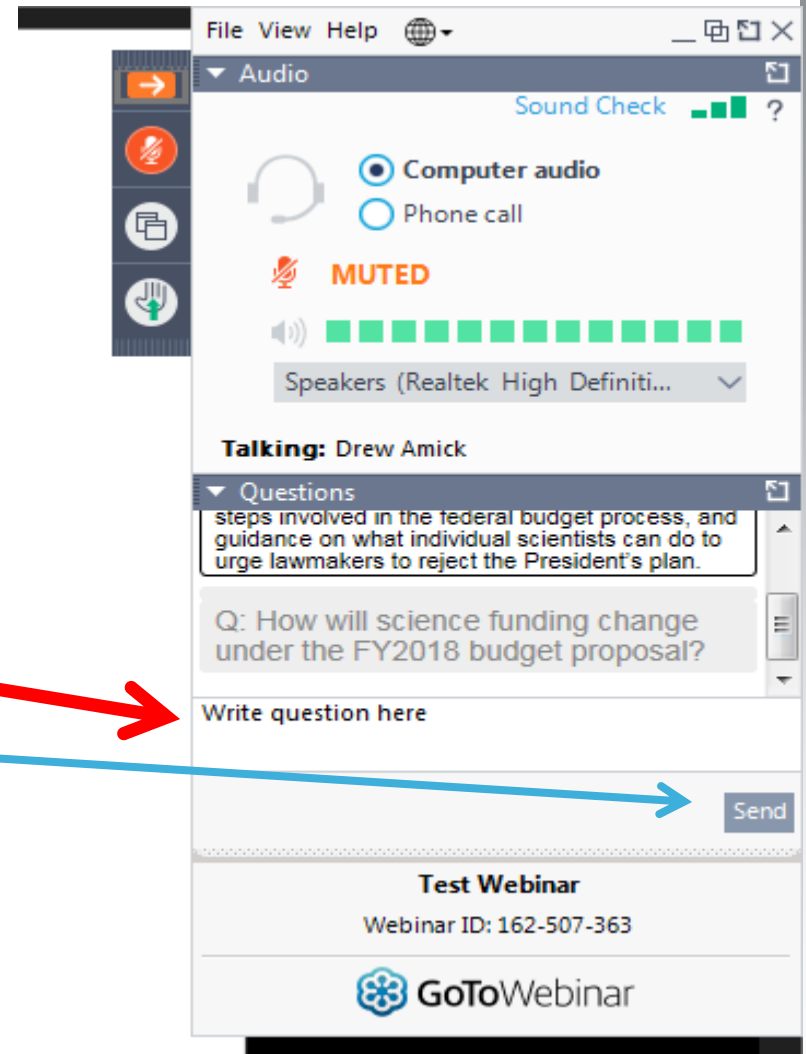
63% have eliminated the requirement for a literature search for unnecessary duplication.

18% do not plan to eliminate this requirement even though it is not required by any regulation.

USDA 2.31.d.1 : *“The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments;”*

To Ask A Question

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Other Questions?

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Burden Surveys and Reports



Findings of the FASEB Survey on Administrative Burden

FEDERAL DEMONSTRATION PARTNERSHIP (FDP)



2012 Faculty Workload Survey RESEARCH REPORT

