

**University of Washington**  
**Faculty Council on Research**  
March 13, 2019  
9:00 a.m. – 10:30 a.m.  
Gerberding 142

**Meeting Synopsis**

1. Call to order
  2. Review of the minutes from January 9, 2019
  3. Presentation by Lisa Jones-Engel, regarding her letter to George Sandison, Faculty Senate Chair, and concerns relating to the University of Washington’s Institutional Animal Care and Use Committee (IACUC)
  4. Discussion on “Foreign Influences on Research Integrity”
  5. Discussion and vote on contract waiver request: APL-UW waiver request from Michael Gabbay
  6. Good of the order
  7. Adjourn
- 

**1. Call to order**

The meeting was called to order at 9:00 a.m.

**2. Review of the minutes from January 9, 2019**

The minutes from January 9, 2019 were approved as written.

**3. Presentation by Lisa Jones-Engel, regarding her letter to George Sandison, Faculty Senate Chair, and concerns relating to the University of Washington’s Institutional Animal Care and Use Committee (IACUC)**

Frevert, the chair, introduced Lisa Jones-Engel, Research Assistant Professor in Anthropology, to the council. Jones-Engel wrote a letter (Exhibit 1) to George Sandison, Faculty Senate Chair expressing her concerns related to amendments to Executive Order (EO) 53. The chair also introduced Cynthia Pekow, Veterinary Medical Officer, and Thea Brabb, Department of Comparative Medicine Chair. The chair invited Pekow and Brabb to provide additional information.

At the council, Jones-Engel further explained her concerns using a PowerPoint presentation (Exhibit 2).

Brabb noted that there are no mentions of ethics within the Animal Welfare Act. Pekow asserted that they are sympathetic toward ethical concerns that balance harm/benefits analysis, but there are no federal regulations that impose this.

A member asked how individuals are appointed to the IACUC. Another member responded that Dave Anderson makes IACUC appointments. The member then asked if a full committee review was too difficult to manage. The member commented that the University should not compare or try to match what other peer institutions are doing; but rather, the University should set the standard. The member asked if Jones-Engel had spoken with Anderson about appointing members (that go beyond the required membership) to serve on the IACUC. Jones-Engel responded that she has spoken to Anderson and the IACUC Chair, but received pushback.

Members discussed how IACUC reviews take place and how they are triggered. Members typically have seven days to review, but it is not known how many people actually review the case. Only members who leave a comment or question are tracked.

Pekow noted that the discussion has focused on the IACUC, but the public is also concerned about increased transparency. There are steps that the University could take that do not solely revolved around the IACUC to increase transparency in labs.

The council further discussed the balance between regulatory burden to the advancement of science and ensuring the welfare of animals. The chair presented an additional checkpoints in improving experimental design to enhance reproducibility (Exhibit 3). Some members felt that the peer review process (before the IACUC) was important and sufficient to ensuring the quality (animal welfare) and reproducibility of research.

A council member asked Jones-Engel what measures she would like the FCR to take. Jones-Engel responded that she would like the FCR to make a request to the administration to do more than the minimum requirements. The member responded that the FCR is an advisory committee and that one concrete output of the council is a resolution describing a desired change in policy for the Faculty Senate to consider. The chair further noted that the council cannot propose a resolution during this meeting and that it would take some time. Ben Marwick volunteered to draft a Class C resolution for the council to consider. The chair asked Stewart Tolnay to work with Ben on the resolution. The chair noted that before the council passes a resolution the council will need to hear from additional voices (e.g. the Office of Animal Welfare, Dave Anderson, etc.)

#### **4. Discussion on “Foreign Influences on Research Integrity”**

Due to time constraints, the council will table this discussion for a future meeting.

#### **5. Discussion and vote on contract waiver request: APL-UW waiver request from Michael Gabbay**

The council reviewed a restricted research contract from the Applied Physics Laboratory and the Department of Defense. Dr. Michael Gabbay is the Principal Investigator (PI).

A member recommended that the council should be consistent in approving proposals with the same level of scrutiny. Some contracts are routinely approved while others with similar language receive pushback.

The council approved the contract.

#### **6. Good of the order**

Nothing was stated.

#### **7. Adjourn**

The meeting was adjourned at 10:25 p.m.

---

*Minutes by Lauren Hatchett, lehatch@uw.edu, council analyst*

**Present:** Faculty: Chuck Frevert (chair), Benjamin Marwick, Michael Rosenfeld, Francis Kim, Sara Kover, Nicole Gibran, Mike Averkiou  
**Ex-officio reps:** Jennifer Muilenburg, Larry Pierce, Stewart Tolnay

**Guests:** Susan Camber, Lynette Arias, Lisa Jones-Engel, Thea Brabb, Cynthia Pekow, Kris Deibler

**Absent:**

**Faculty:** Donald Chi, Paul Fishman

**President's designee:** Mary Lidstrom

**Ex-officio reps:** JoAnn Taricani, Angelia Miranda, Laura De Vos

**Exhibits**

Exhibit 1 – Jones-Engel Letter.pdf

Exhibit 2 – FCR Presentation IACUC JonesEngel March 13 2019.pdf

Exhibit 3 – IACUC FCR Meeting\_03.13.19.pptx



## UNIVERSITY OF WASHINGTON

*Department of Anthropology*

January 6, 2019

To: Professor George Sandison, PhD, FCCPM, FAAPM  
Chair of the UW Faculty Senate  
From: Lisa Jones-Engel, PhD  
Research Assistant Professor, Dept of Anthropology  
Re: Executive Order 53 "Use of Animals"

Dear Professor Sandison,

I am writing to express my concerns relating to the proposed amendments to Executive Order (EO) 53 entitled "Use of Animals". I have served on the University of Washington's Institutional Animal Care and Use Committee (IACUC) since August 2017 and have been at the UW since 2002, initially as a Research Scientist with an active animal use protocol that examines primate zoonoses and more recently as a faculty member in the Department of Anthropology.

In response to public outrage stemming from exposés of animal abuse in research laboratories, the Animal Welfare Act (AWA) was amended in 1985 and IACUCs were mandated to oversee animal use at institutions receiving federal grants. IACUCs must review and approve protocols, inspect animal housing and use facilities, verify that personnel are appropriately trained, be responsive to any concerns that may be raised regarding animal use and ensure the quality of animal welfare.

While IACUCs derive their regulatory authority from AWA, their nascence is directly tied to the public's demand for increased oversight of animal welfare. This is particularly critical as public opposition to the use of animals in research is growing. One of the biggest complaints that the public has about IACUCs is that they have been turned into what they were not intended to be, an organization predominantly occupied with technical and bureaucratic details rather than an oversight committee assuring the welfare and ethical use of animals in research, teaching and testing.

The UW has one of the largest animal use programs in the country with 500 active research protocols being supported by ~ \$250M/yr in grants. Animal studies by UW researchers rely upon rats, mice, rabbits, dogs, birds, wolves, ungulates, marine mammals, large cats, sheep, fish, frogs, pigs, ferrets and nonhuman primates. We have one of the seven National Primate Research Centers.

The IACUC, like the Institutional Review Board (IRB human subjects), is an ethical body responsible for overseeing federally funded research. UW's policy regarding the use of animals in research should be no less comprehensive, transparent and ethical than our policy on the use of human subjects. The current Administrative Policy Statement 12.4 ('Animal Use'), falls far short of the IRB's standard, failing to consider several important issues that should factor into how the UW articulates and executes its responsibilities to the animals that we use in research. Unfortunately, the newly proposed EO53, which will replace APS 12.4, not only fails to address deficiencies of the prior policy, its vagueness and lack of specificity promise to further compromise the IACUC's effectiveness. If the amendment of EO 53 is to

be seen as a 'policy development process', it is critical that during this process EO 53 be amended to explicitly describe the authority, autonomy, composition and ethical responsibilities of the IACUC (much like it is described in EO 24 "Research with Human Participants").  
<http://www.washington.edu/admin/rules/policies/PO/EO24.html>

The 1985 Amendment to AWA stipulates that the composition of the IACUC have at least 5 members---an Attending Veterinarian, Chair, Scientist, Community/Public Member, and Unaffiliated Member. These 5 members were to reflect the necessary veterinary and scientific expertise and the nonscientific (public) concerns that surround the use of animals in research. As currently composed the UW IACUC has 18 members. Only one of those is a public member. The remaining 17 members, including myself, use animals in research or function in administrative positions that facilitate animal research. This monoculture, or 'stacked deck', is efficient in facilitating and expediting animal protocol approvals but it does not reflect the intent of the AWA and is certainly not consistent with best practices. As currently composed more than nine-tenths of our IACUC members are personally and/or institutionally invested in animal research. This is highly problematic as studies continue to show that increasing the breadth and depth of IACUC membership is critical to improving research reproducibility, overall research quality and animal welfare.

Furthermore, unlike our IRB, the IACUC lacks members with expertise in ethics. The UW Institutional Official has stated that ethicists are unnecessary as "our veterinarians are trained in the welfare of animals". I strongly disagree with this assertion. Veterinarians, like physicians, do not have the required training to assess complicated ethical questions. This lack of formal training in bioethics coupled with the need to conform in order to prosper in the institutional environment leads to an inherent conflict of interest for the veterinarians.

Complex ethical questions frequently arise in animal research, as benefits to human society are balanced against the harm caused to animals. In order to be true to its vision of holding itself "to the highest standards of ethics and a beacon for our community and the world" the UW requires an IACUC that is diverse and that incorporates the specialized knowledge of ethicists. An IACUC that is dominated by animal researchers and institutional employees whose livelihoods are linked to animal research leads to committee bias, group think and the adoption of procedural workarounds that relieve perceived regulatory burden. This imbalance also undermines the public's confidence in the objectivity and integrity of the animal research review process.

I urge the Senate to encourage President Cauce to re-examine the composition, practices and oversight of our IACU. UW, as an international leader in biomedical research requires a robust policy that allows for the thorough examination of the ethical issues inherent in the use of animals as research subjects.

Sincerely,

Lisa Jones-Engel, PhD

CC Michael Townsend, PhD  
Janelle Taylor, PhD



International agreements, regulations and guidelines pertaining to the use of animals in research emphasize that such use is a privilege granted by society to the research community to facilitate scientific advancement under the condition that animal use is necessary, and conforms to principled and effective animal welfare procedures.



Lisa Jones-Engel, PhD



# Outline



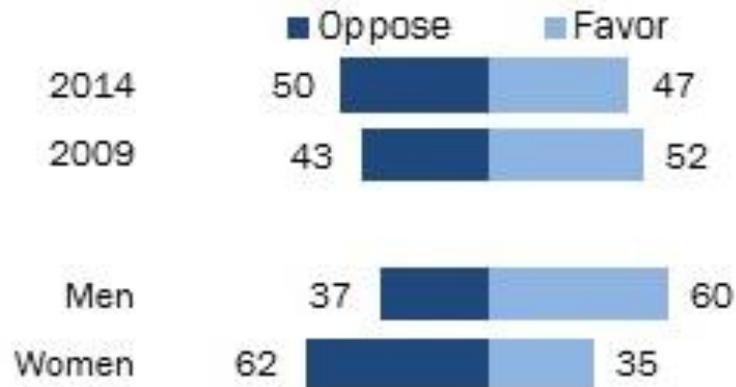
- ▶ Brief History of the Origin/Mission of the Institutional Animal Care and Use Committees (IACUC)
- ▶ Concerns about how the UW IACUC is fulfilling its mission and how this has consequences for the quality of our science and how we are perceived by the public
- ▶ Proposed changes to the UW IACUC structure which will enhance reproducibility and translatability of research findings that rely on animal models

# Americans are increasingly divided over whether animals should be used in scientific research Pew Research Center

## 2015

### Use of Animals in Scientific Research

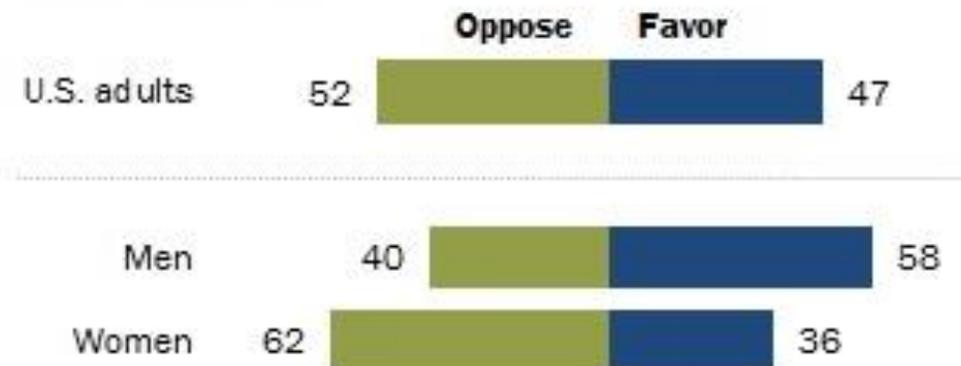
*% of U.S. adults saying they favor/oppose the use of animals in scientific research*

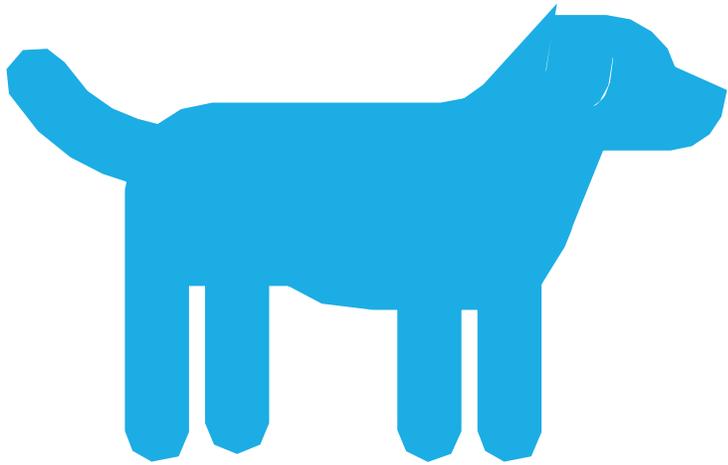


## 2018

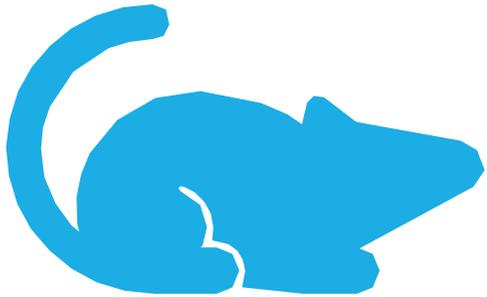
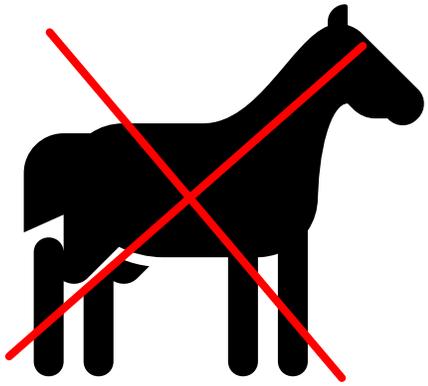
### Americans divided over whether animals should be used in scientific research

*% of U.S. adults who say they \_\_\_\_ the use of animals in scientific research*





# 1966 Animal Welfare Act



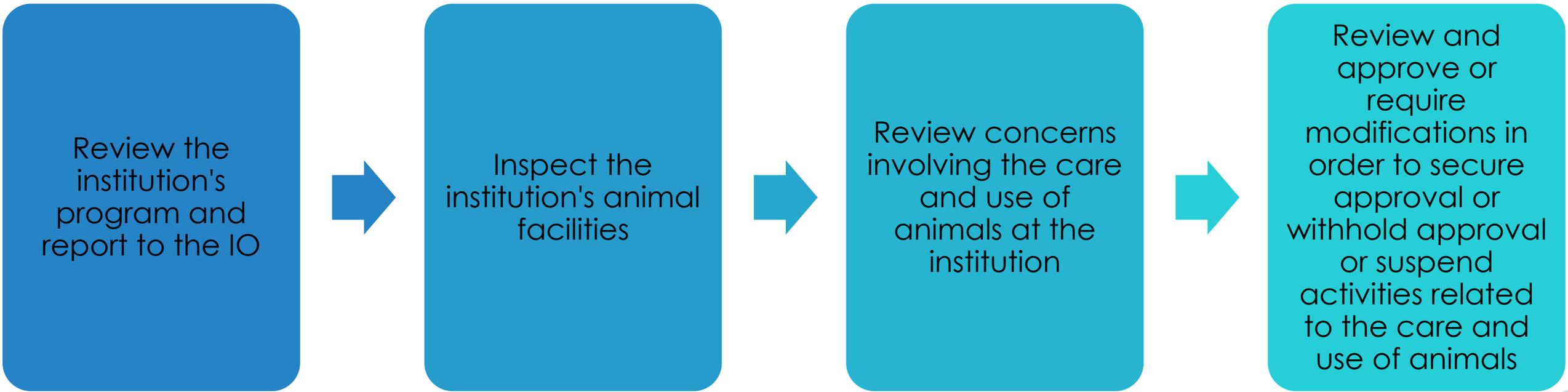
# Amendments to the AWA

SHAPED AND EXPANDED UPON BY  
POLITICAL AND SOCIAL  
INFLUENCES

1985 Amendment:

“The Improved Standards for Laboratory Animals Act”

The establishment of the **Institutional Animal Care and Use Committee (IACUC)** is introduced with a description of its roles, composition, and responsibilities



# Federally-Mandated Functions of the IACUC



THE COMMITTEE SHALL  
CONSIST OF NOT LESS  
THAN FIVE MEMBERS, AND  
SHALL INCLUDE AT LEAST:



ONE DOCTOR OF  
VETERINARY MEDICINE;



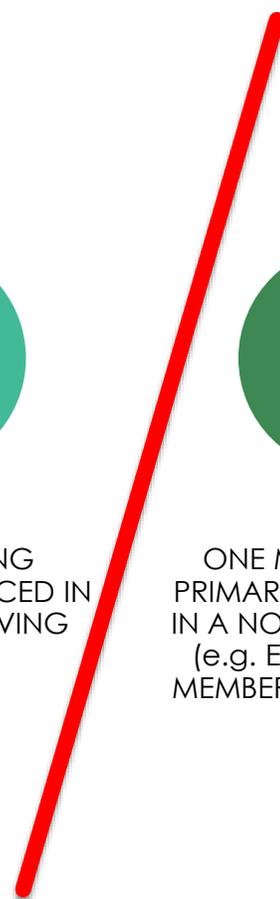
ONE PRACTICING  
SCIENTIST EXPERIENCED IN  
RESEARCH INVOLVING  
ANIMALS;



ONE MEMBER WHOSE  
PRIMARY CONCERNS ARE  
IN A NONSCIENTIFIC AREA  
(e.g. ETHICIST, LAWYER,  
MEMBER OF THE CLERGY);



ONE INDIVIDUAL WHO IS  
NOT AFFILIATED WITH THE  
INSTITUTION IN ANY WAY  
OTHER THAN AS A MEMBER  
OF THE IACUC



**Expectation is that these individuals should bring to IACUC activities a set of values that depart from those of the researchers and veterinary staff composing the remainder of the committee**

### Intended IACUC Composition

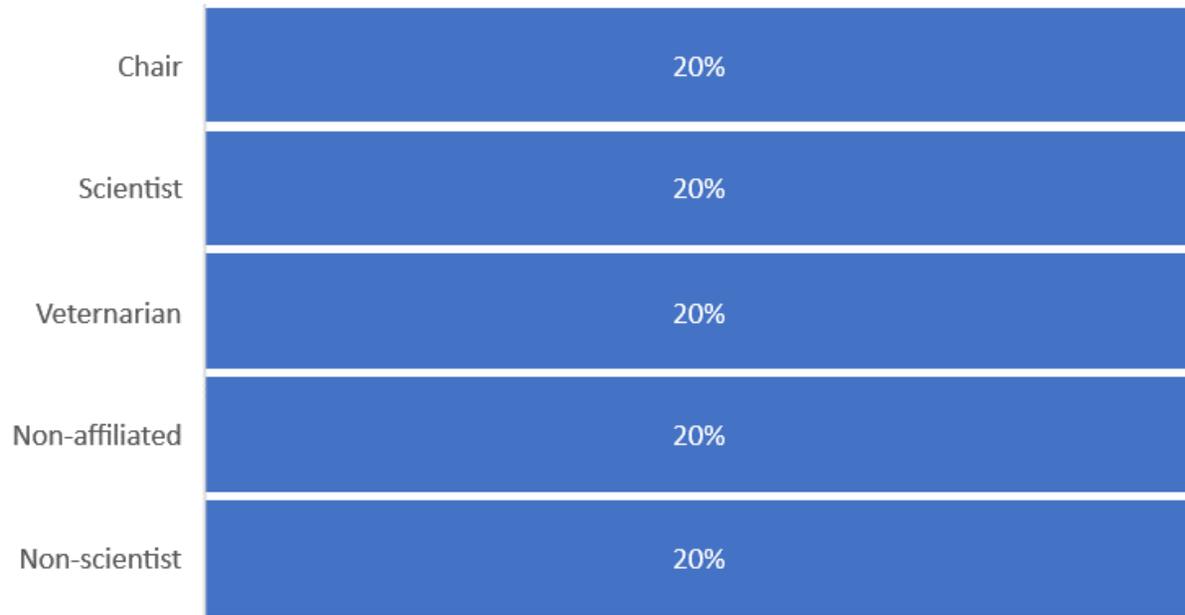
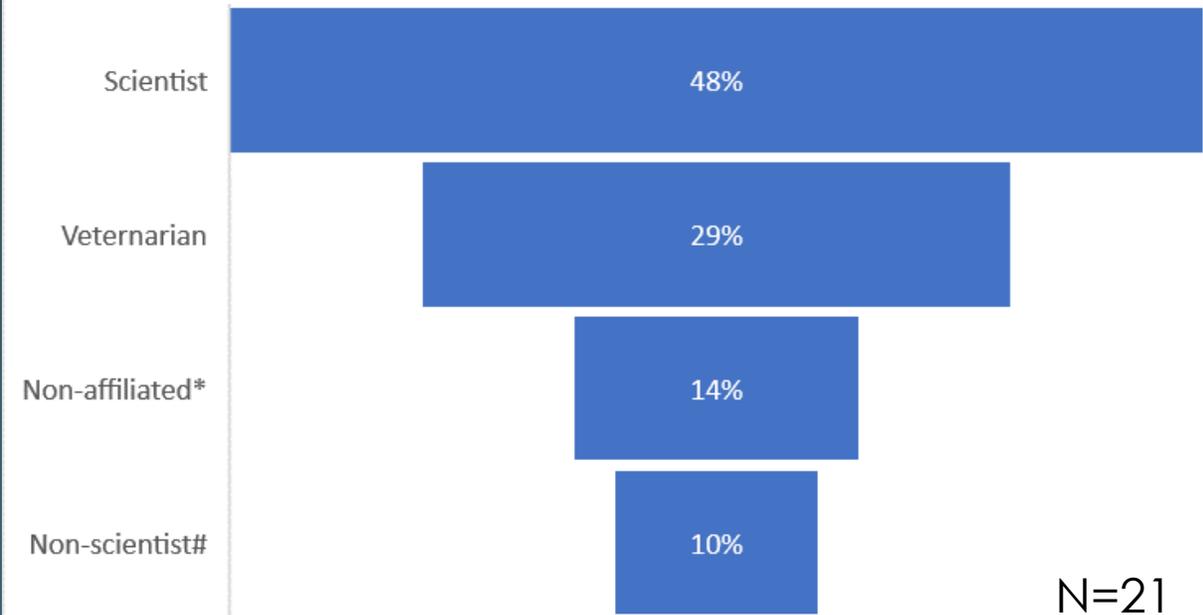


Exhibit 2

### UW IACUC Composition



# Our Non-scientist members include the Executive Director of a Pacific Northwest organization whose mission is to promote the public's trust in biomedical research and its ethical conduct. UW is a Platinum Member of his organization. Our other non-scientist member is the Assistant Director of one of the Animal Research Divisions in HSB.

# Lack of Balanced Diversity/Balanced Representation

▶ UW IACUC is certainly not meeting the intent of the 1985 AWA Amendment

▶ Impacts reproducibility and translatability

Institution	Critical Citation Rate
Washington	0.56
Wisconsin	0.12
UC-Davis	0.28
Minnesota	0.00
Oregon HSU	0.33
Tulane	0.00
Emory	0.16
Texas	0.12

**Focus on Reproducibility**

**REVIEW**

**The role of the IACUC in ensuring research reproducibility**  
Arnold Silverman<sup>1</sup>, James Macy<sup>2</sup> & Patricia A. Pretege<sup>3</sup>

There is a "village" of people impacting research reproducibility, such as funding panels, the IACUC and its support staff, institutional leaders, investigators, veterinarians, animal facilities, and professional journals. IACUCs can contribute to research reproducibility by ensuring that reviews of animal use requests, program self-assessments and post-approval monitoring programs are sufficiently thorough, the animal model is appropriate for testing the hypothesis, animal care and use is conducted in a manner that is compliant with external and institutional requirements, and extraneous variables are minimized. The persons comprising the village also must have a shared vision that guards against reproducibility problems while simultaneously avoiding...  
...been observed... a barrier to research... This...  
...variables and strengthen research reproducibility.

In recent years there has been increasing awareness and concern about the difficulty in obtaining reproducible data when the same experiment is repeated in a laboratory other than the laboratory where it was originally conducted. The extent of this problem...  
...the problem extends beyond biomedical experimentation to similar concerns have been raised for research conducted in psychology, ecology, nutrition, bioinformatics, human clinical medicine, and demographic distribution.

Improving reproducibility success takes the effort of an entire "village" that includes entities such as funding review panels, investigators, research institution leadership, laboratory animal facilities, IACUCs, and vendors. Using an example originating from an institutional animal program, the inability to reproduce experimental results may be due to a wide range of factors including experimental variables that might seem innocuous at first glance, such as temperature variations, responses to different individuals, surgical technique variations, fortuitously safety nets already set in place to guard against such seemingly innocuous variables, or when properly employed they can individually and collectively enhance the likelihood of a study's reproducibility. For instance, an organization's leadership can set an example for, and test upon, the highest level of research integrity, including institutions...

Department of Animal Medicine and Department of Pathology, University of Guelph, Guelph, Ontario, Canada; Department of Psychology, University of Guelph, Guelph, Ontario, Canada; Department of Psychology, University of Guelph, Guelph, Ontario, Canada

**Journal of the American Association for Laboratory Animal Science**  
Copyright 2018  
by the American Association for Laboratory Animal Science

Vol. 57, No. 2  
March 2018  
Pages 1-6

**Contribution of the Breadth and Depth of IACUC Membership to Experimental Design as a Factor in Research Reproducibility**

Swarna Mohan,<sup>1</sup> Robert W Barbee,<sup>2</sup> and Susan B Silk<sup>1</sup>

The IACUC comprises the key component of animal research oversight at any institution or facility and thus has the responsibility to review and approve proposed animal activities. As the primary oversight unit that ensures the quality of animal welfare and therefore contributes to overall research quality, the IACUC can support reproducibility in research by ensuring rigorous experimental design, standardization of care and management, and assessment of the validity of research. This Policy incorporates a wide range of experiences how each can help to enhance rigor and animal...

...scientific community as a whole, IACUC membership is a responsibility (along with the institution and research institutions) to enhance reproducibility. Recent publications have noted the role of IACUC in enhancing reproducibility. Factors such as optimization of animal numbers, analysis, and ethical considerations. This area is a range of expertise found among the membership process useful. One of the many functions of review and approve proposed animal activities, is the ability to require protocol modifications. Here we discuss ways in which the various members can contribute to this review and ensure rigorous animal design.

**Membership and Contribution to Research Success**

**Overall Percent of Protocols Receiving Full Review, by Institution**

Institution	Overall Percent With Full Review
Washington	2.4
Wisconsin	19.3
UC-Davis	20.4
Minnesota	16.0
Oregon HSU	22.5

The most basic of ethical consideration, the harms and benefits of a study need to be assessed as part of the approval process during IACUC deliberations

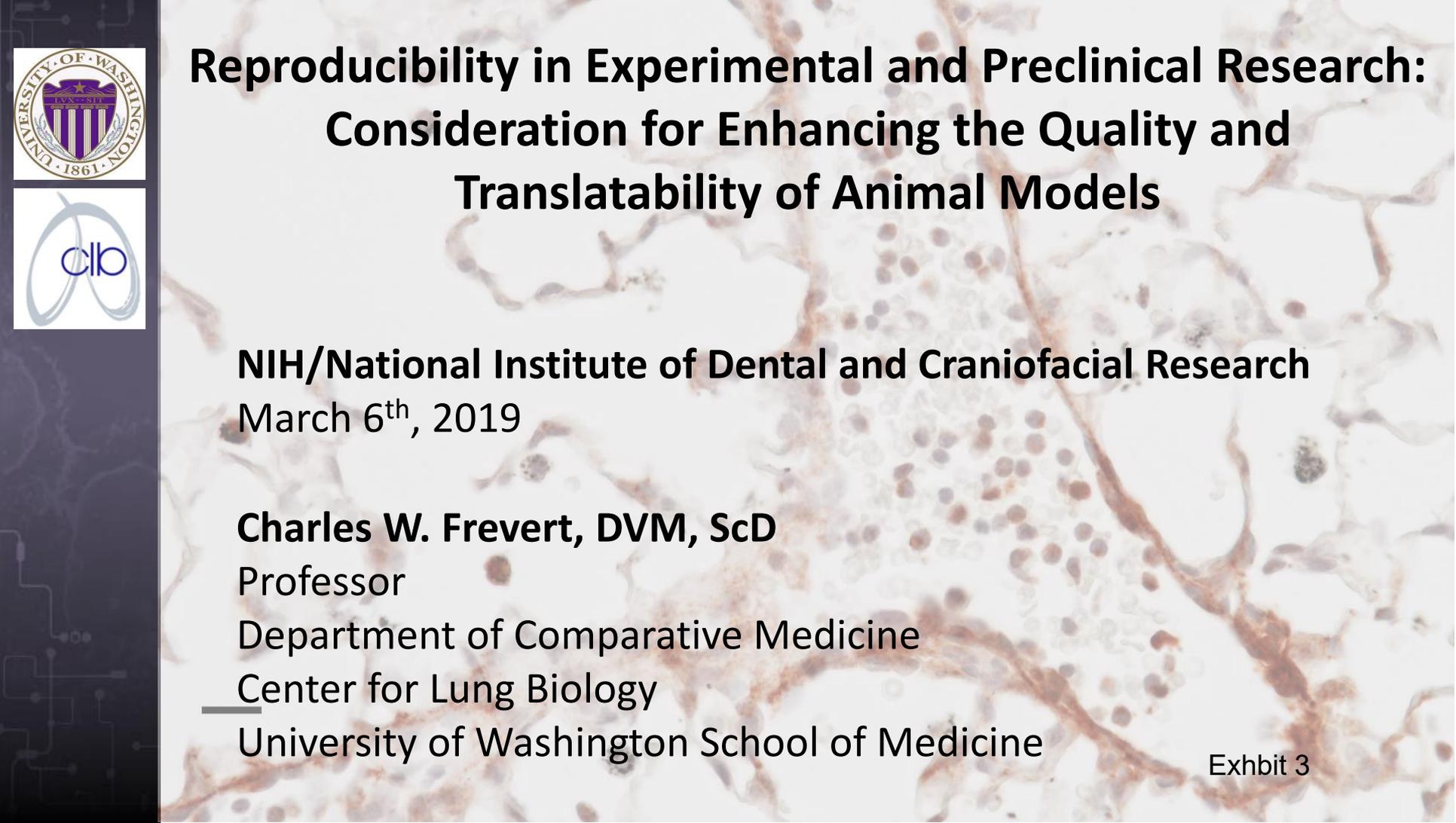
The responsibilities of the IACUC, which are articulated in the PHS policy, the Animal Welfare Act, USDA Regulations, and the *Guide*, are grounded in ethics. But we have no ethicists on the IACUC.

- ▶ Diversify and balance the IACUC membership
- ▶ Establish multiple IACUCs

Institution	Overall FCR Rate	New Protocol FCR Rate	USDA Covered Animals	Primates	Critical Citations	Critical Citation Rate/100 Primates	Percent of Animals Primates
Washington	2.4	7.7	2305	710	4	0.56	30.8
Wisconsin	19.3	48.0	4418	1659	2	0.12	37.6
UC-Davis	20.4	27.7	6494	2530	7	0.28	39.0
Minnesota	16.0	32.0	2156	107	0	0.00	5.0
Oregon HSU	22.5	52.4	2950	2132	7	0.33	72.3
Tulane			927	786	0	0.00	84.8
Emory			2663	1855	3	0.16	69.6
Texas			2547	2406	3	0.12	94.5

Bivariate Correlation between Overall FCR Rate and Critical Citation Rate = -0.59

Bivariate Correlation between FCR Rate for New Protocols and Critical Citation Rate = -0.54



# Reproducibility in Experimental and Preclinical Research: Consideration for Enhancing the Quality and Translatability of Animal Models

NIH/National Institute of Dental and Craniofacial Research  
March 6<sup>th</sup>, 2019

**Charles W. Frevert, DVM, ScD**

Professor

Department of Comparative Medicine

Center for Lung Biology

University of Washington School of Medicine

Exhibit 3

# Improving Experimental Design to Enhance Reproducibility

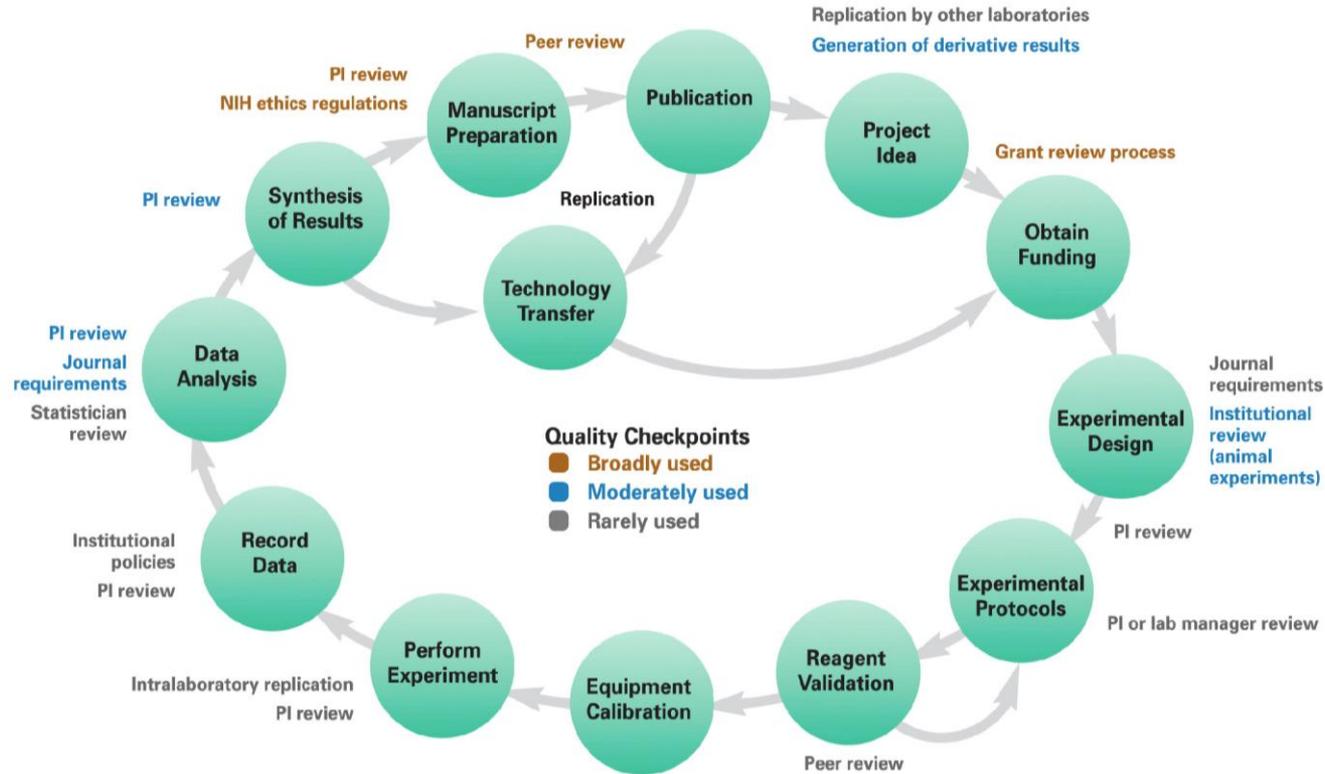


Exhibit 3