Animal Care and Experimentation Committee (2017-2018)  
Executive Summary

This report provides an overview of committee activities. There are no action items.

Meetings: The Committee met September 26, 2017 in Bethesda and April 21, 2018 in San Diego.

Symposium: The ACE Committee sponsored a symposium at EB 2018 symposium on “Avoiding Common Pitfalls in Preclinical Animal Research Design.”

Legislative issues: The ACE Committee went to Capitol Hill in conjunction with its fall meeting. We met with the staff from 8 congressional committees and 10 members’ personal offices. During these meetings we expressed objections to one bill that would end most VA dog research and another that would establish an unreliable metric for measuring progress towards the adoption of non-animal alternatives.

In February and March, Ra’an an provided testimony to the Maryland legislature raising objections to legislation that would mandate post-research adoption of dogs and cats. She also provided a written statement to the New Jersey legislature on similar legislation.

Reducing regulatory burden: Kevin Kregel and J.R. Haywood—two past chairs of the ACE Committee who have gone on to leadership roles in FASEB—played a pivotal role in developing the Reforming Animal Research Regulations report that was published in October, 2017. The report was based upon an April 2017 workshop sponsored by FASEB, the AAMC, NABR, and COGR that Alice Ra’an an and I also attended. During the past year, the APS has offered suggestions to the USDA and NIH about ways to reduce regulatory burden associated with animal research. In May and June, the APS also submitted letters urging the House and Senate Agriculture Committees to remove the Animal Welfare Act requirement that research facilities be inspected annually.

Support for targeted investigator: Ra’an an and I provided support for an APS researcher targeted by PETA after his research was featured in an EB press release. I gave him advice, and Ra’an an drafted press releases for the APS and the institution. However, the institution wanted to keep a low profile so these materials were never used.

Alliances: APS works closely with a range of organizations that share our interests in animal research issues.

Chapter Advocacy Outreach program: No speakers were requested in 2017 or thus far in 2018.

Respectfully submitted,

Jeff Henegar, PhD, Chair
Attachments

- Minutes of the September 26, 2017 ACE meeting
- Minutes of the April 21, 2018 ACE meeting
- EB 2018 symposium: Avoiding Common Pitfalls in Preclinical Animal Research Design
- Overview of legislative issues
- Legislative brief on VA dog research (H.R. 3197 and Amendment 226 to H.R. 3219)
- Legislative brief on HR 816 (Federal Accountability in Chemical Testing Act)
- Update on post-research adoption legislation
- Statement on Maryland bill SB 675 as amended (April 2, 2018)
- Statement on New Jersey bill A.3274 (May 16, 2018)
- Reforming Animal Research Regulations (executive summary and major recommendations)
- Comments on USDA proposal to use third-party accreditation (March 20, 2018)
- Comments to NIH on regulatory burden reduction (June 11, 2018)
- Comments to NIH on regulatory coordination and harmonization (June 11, 2018)
- Advice for targeted investigators
- Alliances with other organizations FASEB NABR, FBR, SUBR, AALAS, ACLAM
- 2018 update on the Chapter Advocacy Outreach program
APS Animal Care and Experimentation Committee Meeting
September 26, 2017
Bethesda, MD

Call to order: The meeting was called to order at 8:40.

Announcements: APS Executive Director Martin Frank provided an update on society activities, including his impending retirement and the relocation of the offices to 6120 Executive Boulevard in Rockville. Both of these events will take place in June 2018. Frank also reported on changes that will be made to the format of the Experimental Biology meeting and the fact that the APS journals will be moving to a new online platform called Literatum by Atapon. Earlier this year, APS adopted a new strategic plan, which will be published in the September issue of The Physiologist, and the APS Council has organized 7 task forces to address implementation of its key findings.

Approval of minutes: The minutes of the ACE committee’s meeting at EB were reviewed and approved.

Committee charge: The committee then reviewed its charge and the responsibilities of committee members. Henegar noted that one of his duties as ACE chair is to resolve issues concerning the welfare of animals in research that is submitted for publication in APS journals. He indicated that an increasing number of submissions from researchers in Asia have been flagged for review when it was not evident how the protocol had been reviewed and how the procedures were conducted. In some cases, the ambiguities are due to language, but the ACE chair is charged with ensuring that procedures involving animals comply with relevant oversight authorities and the APS Guiding Principles for the Care and Use of Animals in Research, Teaching and Testing (confirm). Most European countries have a national rather than a local review process.

Duties of members: Committee members were asked for their input on the duties of individual members. The question was asked as to whether the committee is transferring enough information to membership so that they are aware of its existence and the fact that it may be able to help them. It was suggested that Henegar resume the practice of attending the Section Advisory Committee meeting at EB. The question was also raised as to how to disseminate information to trainees and get them involved in this and other APS committees.

Funding update: Osthus provided an update on FY 2018 funding. She emphasized the need for Congress to raise the statutory budget caps in order to provide increases for funding agencies.

Symposium: Michele and Uray provided an update on the EB 2018 symposium. Michele indicated that he has gotten commitments from two speakers: James Fox, Director of the Division of Comparative Medicine at MIT, and Valerie Hamilton, a veterinary pathologist at Merck. He is still working on getting a third speaker, ideally someone with recent experience in how study sections are addressing topics such as SABV, reproducibility, sample sizes, etc.

Sex as a Biological Variable: In July, APS President Dennis Brown sent the questions developed by the committee to ORWH Director Janine Clayton, but he has not yet heard back from her. Henegar noted that in a October 2016 discussion with the committee, NIH representatives said there would be consistency in how study sections would expect grant applicants to address Sex as a Biological Variable (SABV). However, committee members have observed differences in how various study sections have been addressing this in their reviews. One member said that the chair of his study section treats the inclusion of SABV in the design of the research as a “significant score-driving factor,” while in another case, the key
issues are sample sizes and the overall rigor of the study design. One possible explanation for these differences may be the nature of the research being reviewed.

Ra’an an indicated that before she attempts to follow-up on the letter, she would like to know whether NIH’s FAQ has been updated to address any of the issues that were raised. Ra’an an will send a copy of the APS letter and a link to the FAQ to the meeting attendees for their review, and Jonker volunteered to aggregate the responses.

**Trainee slot:** The Committee on Committees has asked all APS Committees to review the role of their trainee member and decide whether to make any changes in the composition of the committee and how the trainee position is defined. McCabe reported that the Science Policy Committee had decided to reserve its trainee slot for a graduate student and to open up regular membership in the committee to post-docs. The committee discussed whether ACE should follow suit. Familiarity with animal research regulations is considered essential for participating in discussions on the topics that ACE addresses, and PIs usually handle IACUC approvals so post-docs are unlikely to have this expertise. Although there are undoubtedly some exceptions, the general sense was that in terms of having this expertise, most post-docs would be at a disadvantage if they had to compete with established investigators for a slot on the committee. Therefore, the consensus was to continue to reserve the trainee slot for either a graduate student or a post-doc.

At the same time, there was strong sentiment within the committee for ensuring that the perspective of younger members is represented and to provide them with information about animal research issues. Stein indicated that the Endocrine Section is setting up a trainee subcommittee and asked whether it would be possible to invite a representative of that group to participate in the ACE Committee meeting at EB or to include them on the Animal Research Forum. It was also suggested that the committee explore ways to provide early career scientists an opportunity to do animal research advocacy on Capitol Hill. Henegar invited committee members to follow up with ideas about how to do this.

**INFORMATION ITEMS:**

**Regulatory reform:** Yang reported on the USDA’s ongoing request for information about ways to reduce regulatory burden and invited committee members to suggest specific Animal Welfare Act regulations that ought to be repealed, replaced or modified, and the rationale for doing so.

Deschamps indicated that the final report of the FASEB-AAMC-COGR workshop on reducing the administrative burden of animal research oversight should be released in October. She said that the goal of the workshop was to identify specific actions federal agencies can take that are in line with the legislative mandate of the 21st Century Cures to reduce regulatory burden at the NIH, USDA, and FDA.

**Targeting young investigators:** Ra’an an reported on the recent PETA campaign against Yale post-doctoral researcher Christine Lattin, noting that this is part of a pattern of targeting young investigators such as post-docs and junior faculty. Henegar reminded the committee of the importance of making sure that the key individuals at an institution are informed when a campaign like this is launched. He stressed the importance of institutions pro-actively posting any citations they receive from USDA along with a statement concerning how they intend to address the problems identified. Ra’an an said that Americans for Medical Progress had recently launched a new website entitled Come See Our World (https://www.comeseefourworld.org/) where they are posting images of “real animals in research settings” for the public and the media.

**Adjournment:** There being no further business, the meeting was adjourned at 10:05 a.m.
Participants

Committee members present:
Jeff Henegar, Chair
Gaylen Edwards, Past Chair
Richard Auten
Don Bolser
Ed Dzialowski
Laura McCabe
Ken McKeever
Dan Michele
Timo Rieg
Liz Simon
Lauren Stein
Karen Uray
Harold Schultz, Council Liaison

Ad hoc participants:
Anne Deschamps, FASEB
Sonnet Jonker, past committee member
Mark Knuepfer, incoming committee member
Corey Reynolds, incoming committee member
Kathy Ryan, incoming committee member

Staff:
Claire Edwards
Rebecca Osthus
Alice Ra’an
Linda Yang

ACE Committee follow-up

Enhancing communication with the membership: Henegar will arrange to meet with the Section Advisory Committee at EB to provide information on ACE Committee activities likely to be of interest to the membership.

SABV: Committee members are asked to review the current status of NIH’s guidance concerning the consideration of sex as a biological variable (SABV) in light of the questions raised by the ACE Committee. Ra’an will provide committee members a copy of the APS letter to Janine Clayton and a link to NIH’s FAQ on this topic. Jonker volunteered to aggregate the committee’s responses so send them to her at jonkers@ohsu.edu.

Trainees and early-career scientists on the ACE Committee: The ACE Committee wishes to continue to reserve its trainee slot for either a graduate student or a post-doc. However, the committee would also like to explore options to provide more early-career scientists with an opportunity to do animal research advocacy.

Regulatory burden: Yang will seek input from the committee to develop an APS response to the USDA’s request for information about ways to reduce regulatory burden.
CALL TO ORDER: The meeting was called to order at 8:30 and the minutes of the September 26, 2017 committee meeting were approved. Henegar reminded the committee of the symposium on “Avoiding Common Pitfalls in Preclinical Animal Research Design” scheduled for that afternoon and that the committee’s fall meeting will be held October 15-16 with travel information to be provided this summer. He also reported that on Friday he and Science Policy Committee Chair McCabe met with the Section Advisory Committee to explain the work of the ACE and SPC committees as well as to invite the sections to raise policy issues of concern with the committees. SAC members were encouraged to consult current committee rosters when deciding who to nominate for the committees because it is important for the committees to have diverse representation in terms of home states as well as APS sections membership. In addition, the ACE Committee needs members with scientific expertise working with various animal species.

DISCUSSION TOPICS: The committee discussed two possible topics to address during fall visits to Capitol Hill:

1. Regulatory reform through the farm bill
The farm bill has frequently been the legislative vehicle to amend the AWA. Since the farm bill is currently up for reauthorization, we have the opportunity to seek these changes to the law.

The 21st Century Cures Act that passed in 2016 called for NIH, FDA, and USDA to “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 the protection of research animals.” In April, 2017, several APS representatives participated in a workshop to identify specific legislative and regulatory changes to accomplish this objective. One recommendation was eliminating the Animal Welfare Act (AWA) requirement for the USDA to conduct annual inspections of research facilities. Removing this requirement would reduce regulatory burden for institutions with good records of compliance and permit the USDA to devote more inspection resources where they are needed. (Annual inspections are not required for
breeders or exhibitors, which are also regulated under the AWA.) The report also recommended that IACUCs only be required to conduct annual inspections of animal facilities. Because the current requirement for semi-annual inspections is part of the AWA regulations, it could be changed by revising the regulations, but it could also be changed through congressional action.

Both the House and Senate Agriculture are in the process of drafting their bills, and NABR has been working with research institutions to ask their members of Congress to put these changes into the farm bill. If they are added, however, it will undoubtedly provoke a negative reaction from animal rights groups, who have argued against any streamlining of regulatory oversight. However, we can make the counter argument that we are trying to fulfill the 21st Century Cures mandate to reduce regulatory burden.

It was suggested that in developing our positions, we incorporate arguments reflecting the concerns of members of Congress, i.e., finding ways to help people in their districts. Saving the government money is also a popular position, but we should avoid suggesting that the budget for AWA inspections can be reduced since that might jeopardize animal welfare.

2. **Support for VA research with dogs**

Last year the White Coat Waste Project (WCWP) tried to prohibit VA from conducting Category D or E surgical research with dogs. The provision was then expanded to prohibit any research with dogs. In the end, Congress endorsed changes the VA had already made to its oversight procedures for dog studies, permitting the research to go forward. However, the convoluted wording of the final appropriations language enabled WCWP to claim victory, and it has since redoubled its efforts to include a prohibition on dog research in this year’s VA funding bill.

While the current provision applies only to the VA, if the effort succeeds, it will lead to efforts to prohibit research with dogs sponsored by other agencies. In some of our Hill meetings last fall, it was evident that congressional staff doesn’t understand how IACUCs work so that information should be included in our advocacy. Our talking points should explain that the USDA pain categories indicate potential pain, but they do not mean that animals will actually experience any pain. Rather, the Category D and E designations trigger additional oversight and protections, including greater scrutiny of the research protocol; requiring the use of analgesics and anesthetics unless there is strong scientific justification to withhold them; and defining humane endpoints. The talking points should also note spay and neuter surgeries that pets routinely undergo would be classified as Category D procedures.

The Committee felt that both topics would be worthwhile to address.

- **Action item:** As we move through the summer, the staff will determine whether these topics remain relevant.

**REGULATORY ISSUES**

1. **SCAW conference**

Simon provided an overview of the winter 2017 conference of the Scientists Center for Animal Welfare. One area of controversy in the meeting was a recommendation by Randy Nelson that IACUCs conduct a full committee review of all protocol amendments. She noted that many in the audience objected to having this be considered a best practice for IACUCs. The USDA representative to the conference reviewed recent activities that included updating its inspection guide, redefining categories of non-compliant items, implementing a new policy on “teachable moments,” and changes to the USDA process for appealing inspection findings. The OLAW representative reviewed the list of most commonly-cited issues, which were subsequently described in *Lab Animal*. Haywood noted that according to the statistics
in that article, the incidence of noncompliance amount to .65 per Assured Institution. He has asked Lab Animal for the raw data to confirm this and plans to share his analysis of the article once he has the data. This led to a discussion about the fact that OLAW uses the term “noncompliance” to describe all issues regardless of whether they involve animal welfare or recordkeeping.

⇒ Action item: The committee would like to recommend that OLAW adopt new terminology that differentiates between administrative issues and ones that have an impact on animal welfare. Hansen and Uray agreed to work on this.

2. NIH RFI on regulatory coordination
Yang reviewed NIH’s recent RFI on regulatory coordination, which was developed as a response to Section 2034 of the 21st Century Cures legislation. She also reviewed the suggestions mentioned in an earlier email discussion. The committee suggested also addressing the following issues:

Requirements for continuing review of protocols should follow a risk-based methodology: The recently revised Common Rule governing human subjects research that takes effect July 19, 2018, states that protocols involving minimal risk may not require annual continuing review. Therefore, a similar approach should be applied to animal research protocols. For example, studies that involve minimal risk to animals such as breeding protocols and observational studies should not require continuing review.

Annual reporting to OLAW and USDA on a single reporting schedule and/or as a single report: Committee members support the idea of synchronizing the schedule for annual reports, but a single report form is acceptable only if it differentiates information according to the agency. That is, institutions can enter their information on one form, but the report that goes to the USDA will only include species covered by the AWA. A question was also raised about what are the statutory requirements for reporting animal numbers.

Harmonize USDA and OLAW guidance to reduce duplicative consideration of alternatives to painful/distressing procedures: There should be unified guidance for how investigators are expected to address consideration of alternatives to these procedures. Database searches frequently fail to provide useful information. At the same time, researchers already spend time learning how to reduce pain and distress in ways that are consistent with the requirements of specific animal models as part of their training in research study design. Therefore, the USDA’s current emphasis on providing documentation for two database searches should be replaced with an emphasis on this kind of reflective approach.

Institute a minimum 60-day comment period for new OLAW policy guidance: The committee strongly supports increasing the comment period to 90 days. Moreover, rather than making policy pronouncements in the Protocol Review column of Lab Animal, all new OLAW statements of policy should be subject to review. This could be provided through the Research Policy Board that was authorized under the 21st Century Cures Act. The Board has not yet been created, but one of its roles is to review regulations regarding animals, biosafety, radiation safety, etc.

Other approaches not previously mentioned: In its comments, the APS should endorse the FASEB-AAMC-COGR-NABR report, Reforming Animal Research Regulations, and should cite the NIH recommendations listed in the table on pages 26-27 of the report.

Other resources:

AAALAC Program Descriptions: It is not helpful to suggest that institutions use sections of AAALAC program description in their OLAW Assurances. In any case, OLAW should not require detailed program
descriptions in the Assurance. Rather, institutions should simply be asked to state that they will follow the applicable regulations, and they should also simply indicate that they are accredited by AAALAC.

**Encourage use of the PDP Compliance Unit Standard Procedures as a repository of best practices:** This resource is not available to all institutions. Moreover, simply adopting best practices that were developed at one institution can create compliance problems if there are different circumstances at another institution.

**IACUC Administrators Association Repository:** This resource is not accessible to all institutions.

**Designated Member Review and Veterinary Verification and Consultation:** These are good tools that institutions should be encouraged to adopt.

**Expand ongoing IACUC training activities:** This activity does not address the emphasis of Section 2034 of 21st Century Cures, which is to reduce regulatory burden imposed by federal agencies

⇒ **Action item:** Yang will draft the APS response.

**SELF-REPORTING TO USDA:** Henegar reviewed the recent USDA Tech Note concerning self-reporting. According to the Note, self-reporting certain instances of non-compliance will not result in AWA citations. However, USDA will retain the information, and it may still be subject to disclosure under FOIA. Self-reporting is not mandatory so for the time being it makes sense to monitor the experiences of those who choose to do so to see what their experience is.

**OTHER ISSUES**

**Update on post-research animal adoption bills:** Henegar and Ra’an anan provided an update on legislation in several states requiring research institutions to make dogs and cats available for adoption at the conclusion of research studies.

**NEW BUSINESS**

**Call for greater openness in animal research:** Ra’an anan will circulate Speaking of Research’s call for greater openness regarding animal research. This is a document that individual scientists can sign, urging greater transparency as a way to regain public support for animal research.

**Sex as a biological variable:** A question was raised about how NIH is implementing its new requirement for consideration of sex as a biological variable. Anecdotal reports indicate that implementation varies significantly between and within study sections. This may be a topic for the committee to revisit.

**ADJOURNMENT:** There being no further business, the meeting was adjourned.
Avoiding Common Pitfalls in Preclinical Animal Research Design

The ACE committee organized a symposium at EB 2018 on optimizing preclinical animal research design. The topic was selected because of concerns that the findings of such studies may not be reproducible and relevant to human medicine. The speakers addressed the following aspects of preclinical experimental design:

**James Fox** of the Massachusetts Institute of Technology discussed what factors to consider in selecting the appropriate animal model, including the species, age, genetic background, and pathogen status of the animals.

**Valerie Hamilton** of Merck pointed out the FDA’s requirements for moving new pharmaceuticals from the initial discovery stage to clinical testing.

**Tom Cheever** of the National Institute of Arthritis and Musculoskeletal and Skin Diseases addressed biological variables to consider when writing an NIH grant.

The symposium was organized and chaired by ACE Committee members **Daniel Michele** of the University of Michigan and **Karen Uray** of the University of Debrecen. The presentations are available online at [http://www.the-aps.org/ResearchDesignSymposium2018](http://www.the-aps.org/ResearchDesignSymposium2018).
Overview of 2017-2018 ACE legislative issues

As part of the ACE Committee’s fall meeting, we met with staff from 8 congressional committees and 10 members’ personal offices. During these meetings, the committee addressed two issues:

**The Federal Accountability in Animal Testing (FACT) Act (H.R. 816):** This bill would require federal agencies to report how many animal tests they conducted, supported, or required. The stated purpose of the bill is to encourage federal agencies to adopt non-animal toxicity tests for drugs and chemicals. This legislation would affect not only the FDA and EPA but also NIH-sponsored research. Our concern is that the reporting would be used by anti-research groups as a measure of progress towards the adoption of alternatives. Our legislative brief underscored the unreliability of this measure because a variety of factors drive the number and kinds of animal and non-animal tests required. To date no action has been taken on this legislation See the APS legislative brief on the FACT Act.

**Restrictions on VA dog research (H.R. 3197 and Amendment 226 to H.R. 3219):** These measures would prohibit the VA from conducting any research with dogs that falls under USDA pain categories D or E, effectively prohibiting any cardiovascular or other studies that require surgery. Rep. Dave Brat (R-VA) introduced H.R. 3197 on July 12, designating it as the “Preventing Painful Procedures and Experiments on Respected Species” or PUPPERS Act. Two weeks later Brat succeeded in attaching the identical language in the form of an amendment 226 to the House’s FY 2018 Military Construction and Veterans Affairs appropriations bill. Amendment 226 was approved by voice vote on July 26. This meant that the Senate would have to take the lead in stripping the amendment from the final legislation, and the House would have to agree. The APS submitted letters opposing this measure to the Chairs of the House and Senate Appropriations Subcommittees responsible for VA research funding. The ACE Committee then met with the Majority (Republican) and Minority (Democratic) staff of the House and Senate Veterans Affairs authorizing committees, urging them to bring their influence and expertise to bear. See the APS legislative brief on the VA dog research.

The final FY 2018 omnibus funding bill included this language nullifying the Brat amendment:

> “The agreement includes section 254 prohibiting the use of canines in VA research unless: the scientific objectives of the study can only be met by using canines; the study has been directly approved by the Secretary; and the study is consistent with the revised VA canine research policy document released in December 2017.”

Although this language actually allows the VA to continue the research under new approval procedures, anti-research groups such as the White Coat Waste Project (WCWP) declared it a victory and renewed their efforts to force the VA to halt virtually all research with dogs.
FACT Act won’t measure progress towards the adoption of alternatives

The stated purpose of H.R. 816 (Federal Accountability in Chemical Testing or FACT Act) is to encourage federal agencies to adopt non-animal tests for the toxic effects of drugs and chemicals. It would do this by requiring government agencies to submit biannual progress reports on the number of animal and non-animal toxicology tests they conduct, support, or require industry to conduct for regulatory purposes. This would apply to all agencies that are part of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). It would require extensive information gathering and reporting by the FDA for pharmaceutical companies it regulates and by the EPA for chemical companies it regulates. It would also require the NIH, CDC, VA, and DOD to report not only on work done in government labs but also on research the agencies support through grants and contracts with academic and industry researchers.

The American Physiological Society opposes H.R. 816 for these reasons:

Tallying the numbers of animal and non-animal tests will not measure progress towards the adoption of alternatives because other factors drive the number and kinds of tests needed:

- What are the research priorities of federal agencies such as the NIH and of pharmaceutical companies, and how much money is being invested in research in a given year?
- Are there non-animal alternatives to test the safety of the specific kinds of drugs in question?
- Are government agencies trying to determine how to protect the public in the face of threats such as the Zika virus, lead contamination of a city’s water supply, or the widespread environmental effects of natural disasters such as Hurricane Harvey?
- Are animal tests needed to determine whether a disease or treatment affects men and women differently?

Collecting the number of animal and non-animal tests is an unwarranted burden on government agencies, industry and academia:

The reports required under H.R. 816 will not measure progress towards adopting alternatives so the time and money spent to collect this information constitutes regulatory burden.

This is the kind of unnecessary requirement that Congress sought to reduce through the provision of the 21st Century Cures Act calling for a “complete review of applicable regulations and policies for the care and use of laboratory animals.”
Congress should not restrict life-saving research at the VA

H.R. 3197 and the Brat amendment to the VA’s FY 2018 appropriation would halt research involving surgery on dogs—even when the animals receive the same kind of anesthesia, analgesia, and post-operative care provided to pets and human patients undergoing surgery. This legislation is a response to problems that occurred at the Richmond VA Medical Center in 2015-2016. However, those problems were promptly identified and corrected, and the VA has since moved to further enhance its animal welfare oversight program. VA research with dogs is subject to the ethical standards of the Animal Welfare Act and the Public Health Service Policy on Humane Care and Use of Animals. Thus, the restrictions proposed in this legislation are unwarranted, and they would hamper vital research.

In an op-ed in USA Today, Veterans Affairs Secretary David Shulkin said that the Brat amendment would interfere with the VA’s mission to “push the envelope constantly in search of medical advancements that will help improve the lives of disabled veterans.” Shulkin called upon Congress to “preserve humane and carefully supervised canine research at VA.”

Veteran service organizations opposing this legislation include the Paralyzed Veterans of America and the American Legion. Other opponents include the Friends of VA Medical Care and Health Research Coalition and the American Veterinary Medical Association.

Research is critical to improving healthcare, and animal studies are a critical part of health research. In order to develop and test new treatments for disease, researchers need to know what effect these interventions would have in a living organism. Over 99% of VA-sponsored animal research involves rats or mice. Only 0.05% involves dogs. Nevertheless, dogs are an important research model because their hearts, lungs, and circulatory systems are more similar to humans than rodents or even other large animals such as pigs. Dogs are also more similar to humans in terms of how diseases such as diabetes affect them. In addition, we cannot test the safety and effectiveness of new medical devices and surgical techniques intended for human patients in small animals such as rodents. Research with dogs is needed to improve treatments for heart disease and diabetes. It is also needed to find treatments for a life-threatening condition that affects people who are paralyzed—the inability to clear the lungs by coughing.

In an interview in Stars and Stripes, Paralyzed Veterans of America Executive Director Sherman Gillums, Jr. pointed out that there was no mention of how research with dogs helps veterans when the Brat amendment was debated on the House floor. “The catastrophically disabled veteran population, I think, might give balance to this discussion that they had without us in the room,” Gillums said. In an op-ed in The Hill, Gillums noted that the lives of paralyzed veterans “will never be the same as our lives before service, but advances in research will help us experience lives with less pain—and more hope.”

Other veteran service organizations that oppose this legislation include: Association of the US Navy; National Defense Committee; Square Deal for Veterans; Vietnam Veterans of America; and Iraq and Afghanistan Veterans of America.
Update on post-research adoption legislation

Animal rights opponents of research are engaged in a long-term campaign to pass state laws mandating the post-research adoption of dogs and cats through animal “rescue” groups. Arguments for this legislation are clearly meant to stoke anti-research sentiments. Supporters say the legislation is needed because dogs and cats are mistreated in research, living in barren cages, and subjected to cruelty by researchers and indifference from caretakers. Supporters also point out that while research is federally regulated, what happens to animals afterwards is not.

Some research facilities have dog and cat adoption policies, but others do not. The push for mandatory adoptions should be a wake-up call for institutions to put robust adoption policies into place and to defend them rigorously to their legislators. Research facilities should also put more effort into explaining to legislators why animal research is necessary and what they are doing to provide compassionate care to animals. In 2018, the APS submitted the attached statements concerning bills pending in Maryland and New Jersey. In fact, bills have also been introduced in at least half a dozen other states, but the bills are not identical so nuanced messaging is essential. The Office of Science Policy is not equipped to follow state legislation that closely.

Mandatory adoption is a project of the Beagle Freedom Project (BFP), an anti-research group that recently changed its name to the Rescue + Freedom Project. No explanation for the change was given, but the group may be trying to evade its own notoriety. BFP was founded by Kevin Chase and Shannon Keith. Chase, also known as Kevin Kjonaas or Kevin Jonas, has been an anti-research activist since his student days at the University of Minnesota. At U. of M, he was a leader of Student Organization for Animal Rights (SOAR) and interned with the Animal Liberation Front. He then went to the U.K. and worked for the Stop Huntingdon Animal Cruelty campaign against Huntingdon Life Sciences (HLS). Later he then brought that campaign to the U.S. and in 2006 he was convicted under the Animal Enterprise Terrorism Act for inciting harassment against HLS. BFP co-founder Keith was one of his attorneys. Jonas, as he was then known, spent 6 years in federal prison. Afterwards he changed his name to Chase and founded BFP, presumably so they could pursue an anti-research agenda without running afoul of the law.

BFP (now Rescue + Freedom) advances the arguments in favor of mandatory adoption laws, but the bills in each state are sponsored by local legislators. Many of these legislators repeatedly support legislation that is pro-animal and/or anti-research. However, denouncing them as extremists because they are working with BFP—as NABR has done—can backfire. For that reason, the APS statements on the Maryland and New Jersey bills provide a broad rationale for the research itself and address the specific flaws of the bills.

In 2014, Minnesota—where Chase/Jonas/Kjonaas spent his student days—became the first state to enact a mandatory post-research adoption law. The law applies to dogs or cats in research conducted by or in collaboration with an institution of higher education. It requires the animals to be offered to an animal rescue organization for adoption at the end of the study unless they must be euthanized for scientific, educational, or other research purposes. Many state legislatures have considered similar bills since then, and some of the bills are more problematic than others. Six states now have mandatory post-research adoption laws: California, Connecticut, Illinois, Maryland, Nevada, and New York. Other bills are currently under consideration in Delaware, Massachusetts, New Jersey, Pennsylvania, and Rhode Island. Hawaii, Iowa, Maine, North Dakota, Texas, and Indiana have thus far rejected post-research adoption bills, but the legislation is expected to be re-introduced.
It should be noted that in response to a controversy over toxoplasmosis research at USDA, the Senate Appropriations Committee included language in the report that accompanies USDA’s FY 2019 funding legislation instructing the agency to “develop a program to adopt out cats no longer needed in research.” Report language is not binding, but this is the first time that Congress has weighed in on post-research adoptions.
American Physiological Society Statement on SB 675 as amended

Submitted to the Maryland House Appropriations Committee
April 2, 2018

The American Physiological Society (APS) supports SB 675 as amended because the amendments have addressed the concerns raised in our prior testimony.

1. **SB 675 no longer disrupts research institutions’ existing adoption programs.** The amended bill allows institutions the option of continuing to place dogs and cats with their own staff rather than having to send animals to an outside organization even when a staff member wants to adopt them. If the institution has more animals than it can place, it can continue to work with outside groups to place those animals in new homes.

2. **SB 675 no longer includes reporting requirements that would create a misleading scorecard of research institutions’ commitment to animal welfare.** The amended bill eliminates annual reports on the number of dogs and cats needed for research and the number released for adoption. What these numbers actually reflect is how much research funding is available and what kinds of diseases are being studied. It was important to strike the reporting requirements because otherwise the numbers could easily be misinterpreted as measuring how well animals are treated. This would have created a deceptive scorecard in which changes in the numbers might have been interpreted—incorrectly—as a reflection of changes to researchers’ commitment to animal welfare. Consequently, such a scorecard could foster a hostile climate for biomedical research and testing in Maryland. In addition, as Johns Hopkins and the University of Maryland have pointed out, no other state has passed legislation with such reporting requirements.

**BACKGROUND:** This additional information is provided to explain why the proposed reporting requirements would be harmful.

**To cure a disease, we need to know what causes it and what it does to the body:** Animal studies are one part of the effort to answer these questions. Researchers try to find answers using many different approaches. These include biochemical, molecular, and genetic analyses; cell cultures; computer models; and technologies such as organs-on-a-chip. In fact, federal laws such as the Animal Welfare Act and agency rules such as the Public Health Service Policy on Humane Care and Use of Laboratory Animals do not permit researchers to study animals until they have tried non-animal alternatives. However, many serious diseases—and potential treatments for them—affect different parts of the body all at once. Studying animals with a condition similar to a human disease lets researchers watch a disease process in action and look for ways to halt or reverse it.

**Research depends upon funding:** If research funding—including the NIH budget—rises, there will be more research, and the number of animals needed may increase. On the other hand, if funding decreases, animal numbers may fall simply because there is less research.
Researchers work with the animals that provide the best “model” of a disease: If there is a focus on health problems where dogs or cats provide the closest representation of the disease, the number of dogs and cats needed will go up. On the other hand, if there is a focus on health problems that can be studied using non-animal techniques or other animal models, the number of dogs and cats needed will go down.

Whether animals can be adopted depends upon whether they have to be euthanized: Some of the controversy surrounding this legislation revolves around why some dogs and cats can be adopted while others cannot. Simply put, some animals have to be euthanized so researchers can examine their tissues and organs because that may be the only way to find out how a disease affects the body or whether a new drug works and whether it has dangerous side effects.

In conclusion, the APS supports SB 675 as amended and would oppose any efforts to restore language that has been stricken from the bill.
American Physiological Society Statement on Assembly Bill 3274

The American Physiological Society opposes Assembly Bill 3274. Despite the good intentions of those sponsoring the legislation, A3274 would seriously disrupt medical research and drug testing in New Jersey.

New Jersey is home to many leading biomedical research institutions. Many cutting-edge vaccines, treatments, and cures for serious diseases and debilitating conditions afflicting both humans and animals were developed in this state. Research involving animals is an essential component of both basic research and drug development. Moreover, those who do this work have a strong commitment to the welfare of research animals. Unfortunately, A3274 would undermine these efforts.

Stepping back to provide some context, before researchers can prevent, treat, or cure a disease, they need to know its causes and how the disease affects the body. Researchers first try to answer these questions through clinical observation, epidemiological studies, genetic analysis, cell cultures, computer models, and technologies such as organs-on-a-chip. However, many serious diseases—and potential treatments for them—affect different parts of the body all at once. Fortunately, biological processes are similar in people and animals so researchers can learn about a disease that afflicts humans or other animals by studying research animals. This enables researchers to observe the disease process in action, look for ways to halt or reverse it, and determine whether a potential treatment is likely to be effective and safe.

The American Physiological Society wishes to draw your attention to the following concerns:

- The adoption mandate in A3274 only exempts dogs or cats that must be euthanized for health or safety reasons. This is a glaring deficiency because the primary reason why research animals cannot be adopted at the end of a study is scientific: To understand a disease, researchers need to find out how that disease affects an animal’s body. Similarly, if they are trying to develop a new treatment, they need to find out whether it is likely to work or if it has dangerous side effects. This often means that animals have to be euthanized so researchers can examine their organs and tissues.

- A3274 would disrupt existing adoption programs by requiring research institutions to offer adoptable animals to animal rescue organizations. Facilities, including those in New Jersey currently place unneeded research animals with their own veterinarians, animal caretakers, and researchers who have already formed attachments with them.
Organizations seeking to re-home research animals should be required to distance themselves from individuals who have engaged in violence, threats of violence, and other acts of intimidation against biomedical research. The definition of an animal rescue organization under New Jersey law does not preclude the participation of individuals who have been convicted of violating federal statutes such as Animal Enterprise Protection Act of 1992 (Pub.L. 102–346), the federal Animal Enterprise Terrorism Act (Pub.L. 109–374) or similar laws passed by the states. Failure to address this issue is a serious defect of A3274.

For the foregoing reasons, the American Physiological Society urges the Assembly Agriculture Committee to reject A3274.

The American Physiological Society is a scholarly association founded in 1887 to advance understanding of how living systems function. The APS has more than 11,000 members throughout the U.S. and around the world. APS members are involved in research and education in colleges, universities, medical and veterinary schools, industry, and government. The APS has a long-standing interest in animal welfare and is proud of the continuing leadership role it plays in fostering high standards of animal care.
Reforming Animal Research Regulations:
Workshop Recommendations to Reduce Regulatory Burden

Report of an April 17, 2017 workshop organized by FASEB, AAMC, and COGR, with assistance from NABR
Participant List
Workshop on Reforming Animal Research Regulations, April 17, 2017

Nancy Ator, PhD
Professor, Behavioral Biology
Chair, Animal Care and Use Committee
Johns Hopkins School of Medicine

Matthew Bailey
President
National Association for Biomedical Research

Kathryn Bayne, MS, PhD, DVM, DACLAM, DACAW, CAAB
Chief Executive Officer
AAALAC International

Taylor Bennett, DVM, PhD, DACLAM, DACAW
Senior Scientific Advisor
National Association for Biomedical Research

Richard Bookman, PhD
Senior Advisor, Program Development & Science Policy
University of Miami Miller School of Medicine

Lizbet Boroughs, MSPH
Associate Vice President, Federal Relations
Association of American Universities

Cindy Buckmaster, PhD, CMAR, RLATG
Director, Center for Comparative Medicine
Baylor College of Medicine
Chair, Board of Directors
Americans for Medical Progress

Kevin Cain
Director, Governmental Affairs
Association of American Veterinary Medical Colleges

Anne Deschamps, PhD
Associate Director, Science Policy
Federation of American Societies for Experimental Biology

Anurupa Dev, PhD
Senior Science Policy Analyst
Association of American Medical Colleges

J. Crawford Downs, PhD
Vice Chair of Research, Department of Ophthalmology
University of Alabama at Birmingham School of Medicine
Chair, ARVO Animals in Research Committee

Richard Eckert, PhD
Chair, Department of Biochemistry and Molecular Biology
University of Maryland School of Medicine

Howard Garrison, PhD
Director, Office of Public Affairs
Federation of American Societies for Experimental Biology

Molly Greene, BA, CPIA
Advisor, Institutional Animal Care and Use Committee
Michigan State University

F. Claire Hankerson, DVM, MS, DACLAM
Director and Attending Veterinarian
Michigan State University

Joseph H. Haywood, PhD
Assistant Vice President, Regulatory Affairs
Michigan State University

Steve Heising
Director, Science Policy
Association of American Medical Colleges

Michael Heintz, MS, JD
Director, Advocacy & Training
Society for Neuroscience

Anurupa Dev, PhD
Director, Animal Care and Quality Assurance
University of Missouri
Chair, APS Animal Care and Experimentation Committee

Kevin Kregel, PhD
Associate Provost
University of Iowa
Chair, FASEB Animals in Research and Education Subcommittee

Ross McKinney, MD
Chief Scientific Officer
Association of American Medical Colleges

Lisa Nichols, PhD
Director, Research and Regulatory Reform
Council on Governmental Relations

Alexander Ommaya, DSc
Senior Director, Clinical Effectiveness and Implementation Research
Association of American Medical Colleges

Sangeeta Panicker, PhD
Director, Research Ethics
American Psychological Association

Stacy Pritt, DVM, MS, MBA, CPIA, DACAW
Director, Institutional Animal Care and Use Committee
University of Texas Southwestern Medical Center
Vice President, AVMA

Alice Ra’an’an
Director, Governmental Relations and Science Policy
American Physiological Society

Sarah Rovito, PE
Assistant Director, Research Policy
Association for Research in Vision and Ophthalmology

Jeffrey Henegar, PhD
Professor, Department of Psychiatry & Human Behavior
University of Mississippi Medical Center
Chair, APA Committee on Animal Research and Ethics

Mar Sanchez, PhD
Associate Professor, Psychiatry and Behavioral Sciences
Emory University School of Medicine
Chair, SIN Committee on Animals in Research

Yvette Seger, PhD
Director, Science Policy
Federation of American Societies for Experimental Biology

Scott Simon, PhD
Professor, Biomedical Engineering
Vice Chair, Institutional Animal Care and Use Committee
University of California, Davis

Lauren Stump, DVM
Assistant Director, Government Relations
American Veterinary Medical Association

Ara Tahmassian, PhD
Chief Research Compliance Officer
Harvard University

Sally Thompson-Iritani, DVM, PhD
Director, Office of Animal Welfare
University of Washington

James Tomasek, PhD
Vice President for Research
University of Oklahoma Research Park

Matt Windsor, PhD
Senior Manager, Science Communications
Association for Research in Vision and Ophthalmology

Report Reviewer
Reginald W. Miller, DVM, DACLAM
Dean, Research-Operations and Infrastructure
Icahn School of Medicine at Mount Sinai
Executive Summary

The Federation of American Societies for Experimental Biology (FASEB), the Association of American Medical Colleges (AAMC), and the Council on Governmental Relations (COGR), with the assistance of the National Association for Biomedical Research (NABR), convened a workshop on reforming animal research regulations on April 17, 2017. The goal of the workshop was to provide actionable recommendations for promoting regulatory efficiency, animal welfare, and sound science. These recommendations are directed to federal agencies involved in the oversight of federally funded animal research, in particular the National Institutes of Health (NIH) and the United States Department of Agriculture (USDA).

The use of animals in research continues to be vital to our understanding of human and animal disease and the development of treatments and cures. Researchers take their commitment to the humane care and use of research animals very seriously, but there are numerous conflicting, outdated, or ineffective regulations that do not improve animal welfare. The proposed changes to regulations, policies, and guidelines outlined in this report would make research and researchers far more efficient while maintaining standards of care.

The vast amount of administrative effort necessary to comply with oversight requirements for federally funded animal research has been highlighted in a number of reports. To date, however, the majority of recommendations to reduce ineffective or redundant requirements by modifying and harmonizing federal regulations and policies have not been implemented. The focus of the April 2017 workshop was to identify requirements that demand significant administrative effort but do not enhance animal welfare. Workshop participants sought to prioritize steps that agencies and Congress can take to reduce these inefficiencies.

Highlights of the major recommendations developed by workshop participants are listed here. Additional recommendations on related topics are included in the body of the report. Many of these recommendations echo those made in previous reports from other organizations. Workshop participants strongly believe that these issues can and should be addressed without delay.

1 Participants’ names are listed on Page 1. Their affiliations are provided for identification purposes only and do not represent an endorsement of these recommendations by their respective organizations.
Major Recommendations

Executive Office of the President and Congress

• The Executive Office of the President (EOP) and the Office of Management and Budget (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. A committee of experts engaged in animal research from entities that receive federal research awards should be invited to assist with this effort. The group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, Institutional Animal Care and Use (IACUC) members, veterinarians, and investigators engaged in animal research.

  ○ Harmonize existing federal requirements for those species currently covered by USDA and those covered by the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) to conform to the least burdensome standard while maintaining animal welfare.

  ○ Pilot new models and structures through the Federal Demonstration Partnership, as appropriate.

• 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 (FAQs), or interpretive rules before they are issued. Final policies and guidance should include material changes that reflect germane comments received from the regulated community.

  ○ Near-final documents should be reviewed by an external advisory committee of experts engaged in animal research from the regulated community before they are disseminated for public comment or final agency review. This would help ensure that policies and guidance meet their intended objectives while maintaining or improving animal welfare without creating unnecessary administrative work and cost.

  ○ All guidance documents should state clearly that they do not carry legal or regulatory force.

  ○ Guidance documents should not be accompanied by a requirement to obtain agency approval for alternative methods and/or processes.

• Congress should amend §2143(b)(3) of the Animal Welfare Act (AWA) and §495(b)(3) of the Health Research Extension Act (HREA) to require only annual inspection by the IACUC. This will eliminate significant administrative work for investigators and IACUC members and allow staff to better focus their efforts on the daily oversight and welfare of animals. Such a change is neither intended to negate or minimize the expectation for IACUCs to assess and assure compliance with federal requirements regarding the welfare of animals used in research, teaching, and testing.
• Congress should amend §2146 of the AWA to remove the requirement for annual USDA inspection of research facilities and allow for an inspection frequency based on compliance history, as part of the agency’s Risk Based Inspection System process.

NIH and USDA

• NIH and other federal agencies involved in the review of regulations and policies for the care and use of laboratory animals mandated by the 21st Century Cures Act (Cures) should appoint an external advisory group of experts engaged in animal research from entities that receive federal research awards to serve as advisors. The advisory group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, IACUC members, veterinarians, and investigators engaged in animal research. This will foster progress and impartiality in the conduct of this review, which should take into account relevant regulations, policies, and guidance, along with the recommendations of this and other reports that have addressed regulatory burden associated with animal research.

  o The committee could be designated an “expert subcommittee” of the Research Policy Board mandated by Cures. Agencies might also consider a permanent animal research advisory group modeled after the Department of Health and Human Services Secretary’s Advisory Committee on Human Research Protections.

• As part of the review mandated by Cures, all current Public Health Service (PHS) and USDA regulations, policies, guidance documents, FAQs, 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. This group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, IACUC members, veterinarians, and investigators engaged in animal research. The purpose of this review should be to ensure that these documents emphasize matters of core importance to animal welfare identified in HREA and AWA statutory language and are consistent with current scientific and technological knowledge and approaches.

• NIH and USDA should establish a risk-based process for review of animal research protocols similar to that for human subjects research under 45 CFR 46; §46.110. Through issuance of a Notice in the Federal Register similar to the NIH Notice issued in 2014 regarding Significant Changes (NOT-OD-14-126), USDA and the NIH Office of Laboratory Animal Welfare (OLAW) could amend the protocol review requirement to define types of studies involving low-risk, noninvasive, or minimally invasive procedures. These studies could then be deemed exempt from full IACUC consideration or eligible for administrative or single member (expedited) review, without concurrence by the full IACUC.
NIH

• The Guide for the Care and Use of Laboratory Animals (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. This would be consistent with OMB’s Agency Good Guidance Practices Bulletin and would significantly reduce administrative burden without compromising animal welfare.

• Eliminate the requirement for verification of protocol and grant congruency in NIH Grants Policy 4.1.1.2 to allow for reasonable advances, discoveries, and other developments in the overall research objectives.

• Revise the NIH guidance in NOT-OD-05-034 regarding prompt reporting to include only those incidents that jeopardized 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.

USDA

• Revise §2.31(d)(5) of the AWA Regulations (AWR) 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 §2.31(d)(1-4) at least once every three years” (emphasis added). This would make review frequency consistent with the PHS Policy.

• Revise USDA Animal Care Policy #14 to reflect the language in 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 for scientific and animal welfare reasons. This will enhance the community’s efforts to reduce the number of animals involved in research.

• Amend the language in USDA Animal Care Policy #12 with respect to literature searches to be consistent with 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…”
March 20, 2018

Ms. Bernadette Juarez, Deputy Administrator, Animal Care Program
APHIS
4700 River Road
Riverdale, MD 20737

Submitted electronically

RE: Docket No. APHIS-2017-0102

Dear Ms. Juarez:

Numerous reports in recent years have documented the extent to which overlapping oversight requirements by different agencies result in duplicative and unnecessary work on the part of research institutions and individual investigators. Congress responded to this concern by including a mandate in Section 2034 (d) of the 21st Century Cures Act\(^1\), calling upon USDA, NIH, and FDA to “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.” The American Physiological Society appreciates this effort on the part of USDA to reduce administrative burden by addressing how Animal Welfare Act (AWA) inspections are conducted.

§2146 of the Animal Welfare Act (AWA) requires the Secretary of Agriculture to “inspect each research facility at least once a year and, in the case of deficiencies or deviations from the standards promulgated under this chapter. . .conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected.”\(^2\) In the 33 years since annual inspections were mandated under the Food Security Act of 1985, the evidence of the research community’s compliance with the AWA as well as a broad commitment to animal welfare itself continues to mount.

According to an analysis by the National Association for Biomedical Research (NABR), in Fiscal Year (FY) 2017, the Animal and Plant Health Inspection Service (APHIS) conducted 1,288 inspections of the 959 registered research facilities in the U.S. Significantly, APHIS inspectors issued citations in only 238 of those inspections for a total of 380 noncompliant items (NCIs). This continues the downward trend from 561 NCIs in FY 2015 to 470 NCIs in FY 2016. Examining the data further, NABR determined that the 380 NCIs found in FY 2017 included:

\(^1\) P.L. 114 – 255. URL: https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf
• 329 noncritical NCIs (items that do not pose a direct risk to animal welfare)
• 47 other critical NCIs (items that have the potential to affect animal welfare)
• 4 direct NCIs (items that pose a risk to animal welfare now or in the near future)

NABR noted that 82% of the FY 2017 inspection reports contained no NCIs, and only 227 active research facilities—less than 24%—were cited for noncompliance. Of this group, about 60% had only one citation. Thus, the majority of NCIs were found in a relatively small number of institutions, and these institutions were subject to repeat inspections to confirm that they had made the necessary corrections.

This continuing trend towards compliance speaks to the validity of the risk-based inspections the Animal Care program initiated in 1988. According to the APHIS website, the risk-based inspection program was meant to allow the agency to “support its focused inspection strategy, allowing more frequent and in-depth inspections at facilities with a higher risk of animal welfare concerns, and fewer at those that are consistently in compliance.” This approach is an efficient way to increase compliance, particularly when resources are limited.

The American Physiological Society believes that Congress should amend §2146 so that APHIS Animal Care can conduct all inspections based upon the degree of risk, allowing the agency to use inspection resources where they are needed most. In the meantime, however, the agency should continue to work within existing law to maximize its resources. A record of institutional compliance with the AWA is one indicator of a commitment to animal welfare, while participation in a voluntary accreditation program such as AAALAC, International is another. The American Physiological Society recommends that APHIS take both of these factors into account in determining the frequency and intensity of its inspections. This will also provide the regulated community additional incentive to implement policies that ensure AWA compliance.

Sincerely,

/s/ Dennis Brown, PhD
President

The American Physiological Society is a scholarly association founded in 1887 to advance understanding of how living systems function. The APS has more than 11,000 members throughout the U.S. and around the world, including some 300 in Maryland. APS members are involved in research and education in colleges, universities, medical and veterinary schools, industry, and government. The APS has a long-standing interest in animal welfare and is proud of the continuing leadership role it plays in fostering high standards of animal care.

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June 11, 2018

Mr. Michael Poe
Office of Budget and Program Analysis
United States Department of Agriculture
Jamie L. Whitten Building, Room 101–A
1400 Independence Ave. SW
Washington, DC 20250

RE: Identifying Regulatory Reform Initiatives

Dear Mr. Poe,

The American Physiological Society (APS) is pleased to provide comments in response to the USDA’s July 17, 2017 Request For Information (RFI) on regulatory reform initiatives. The APS is a professional society of more than 10,000 members, many of whom use animals to understand how the body functions in a healthy or diseased state. Our members are involved in research and education in colleges, universities, medical and veterinary schools, industry, and government throughout the U.S. The APS supports the humane care and treatment of laboratory animals. At the same time, we also recognize that regulatory burden is a significant problem that must be addressed.

Since 2011, the USDA has conducted several reviews of its regulations to identify ones that are outdated, ineffective, or burdensome as mandated by Executive Orders 13563, 13610, and 13777. In 2016, Congress passed the 21st Century Cures Act directing the USDA, the NIH, and the FDA to review their regulations and policies for the care and use of laboratory animals with an eye to reducing administrative burden and to make appropriate revisions.

We appreciate USDA’s ongoing efforts to ease regulatory burden and have identified four areas where USDA’s regulations and policies exceed the requirements of the Animal Welfare Act (AWA) in ways that impose unnecessary burdens. These are areas where there is strong consensus in the research community1, 2 that current procedures can readily be modified to reduce the burden of compliance with the law while maintaining high levels of animal welfare.

We therefore urge you to reduce regulatory burden in these four ways:

1. Extend the review period for activities involving animals
2. Modify the emphasis of the alternatives search requirement
3. Establish a risk-based approach for protocol review
4. Permit multiple survival surgeries at the discretion of the IACUC

Below we have elaborated upon why and how these USDA regulations and policies should be modified.

1. **Extend the time between protocol reviews to match the PHS Policy**

The AWA gives the Secretary of Agriculture broad authority to promulgate standards governing the humane treatment of animals. **Section 2.31 (d)(5) of the Animal Welfare Regulations (AWR)** specifies that the IACUC should “conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC but not less than annually” (emphasis added). Federally-funded research facilities that are subject to the AWA are also subject to the PHS Policy on Humane Care and Use of Animals, which takes a different approach to the frequency of such reviews. According to Section IV.C.5 of the PHS Policy, “The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1-4 at least once every three years” (emphasis added).

Because the USDA’s requirement for an annual review of protocols does not align with the PHS Policy, facilities must keep track of different review timetables. Given that activities involving animals are already being reviewed on a continual basis, requiring annual reviews as well creates unnecessary work for IACUCs and investigators. We therefore urge the USDA to harmonize its review period with the PHS Policy by allowing reviews to be conducted at appropriate intervals as determined by the IACUC but no less than every three years.

2. **Modify the emphasis of the alternatives search requirement**

Section 2143(a)(3)(B) of the AWA states that researchers are required to consider “alternatives to any procedure likely to produce pain or distress in an experimental animal.”

Section 2.31(d)(1)(ii) of the AWR simply states that the IACUC must determine whether 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, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available.”

When USDA issued its final rule on this section of the regulations in 1989, the agency stated, “We have modified the requirement concerning consideration of alternative procedures to allow research facilities greater flexibility in devising internal procedures for their principal investigators to follow, which simplify their task of indicating what sources were consulted. The principal investigator must provide a written narrative of the sources consulted, such as biological abstracts, *Index Medicus*, the Current Research Information Service (CRIS), and the Animal Welfare Information Center that is operated by the National Agricultural Library. We believe that in fulfilling this requirement, Committee members will discuss these efforts with the principal investigator in reviewing the proposed activity. We also believe that consideration of alternatives will be discussed during Committee meetings where proposed activities are presented for approval, and made part of the meeting minutes. If the Committee 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.”

**USDA’s Animal Care Policy #12** goes significantly further, stating that “APHIS continues to recommend a database search as the most effective and efficient method for demonstrating

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compliance with the requirement to consider alternatives to painful/distressful procedures” (emphasis added). This is not consistent with the final rule on the consideration of alternative procedures: “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.”

Neither the AWA and AWR require a database search, yet the USDA recommends its use in Policy #12. To conduct a key word and literature search for every procedure in a protocol requires significant effort on the part of the investigator. At the same time, this is frequently cited as a waste of effort because such database searches rarely provide useful information regarding alternatives. We therefore recommend that the USDA revise Policy #12 to eliminate the emphasis on database searches. As we noted in our 2015 comments on reducing regulatory burden, many investigators believe that a brief written narrative concerning how reduction, refinement, and/or replacement were incorporated into the protocol “gives the review body (IACUC) much more insight into the consideration of alternatives, satisfies the regulatory objectives of the Animal Welfare Act, and reduces burden for researchers.”

3. Establish a risk-based approach for protocol review

Section 2.31(d)(2) of the AWR allows protocol reviews to be conducted through either full committee or through designated member review if no committee member objects to expedited review.

Protocols for human subjects’ research undergo a comparable process of review with an Institutional Review Board (IRB), a body that is comparable to the IACUC. Human subjects’ research is governed by the Common Rule, which exempts some types of noninvasive research from review or makes them eligible for expedited review by a single member of the IRB. The lack of categorical exemptions from review for animal research protocols is inefficient and burdensome compared to the approach used for human subjects’ research.

USDA should implement a risk-based protocol review system in which low-risk studies can be processed more expeditiously. This was one of the recommendations made by the Federation of American Societies for Experimental Biology, Council of Government Relations, the American Association of Medical Colleges, and the National Association for Biomedical Research in their 2017 report, *Reforming Animal Research Regulations.* This report recommends that “Studies deemed low-risk, noninvasive, or minimally invasive…be exempt from full IACUC review or eligible for administrative review without concurrence by the full IACUC.” This approach increases the efficiency of protocol reviews while still maintaining necessary protections for animal subjects.

4. Permit multiple survival surgeries

Section 2143(a)(6) of the AWA prohibits the Secretary from promulgating “rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such research facility” with certain exception as provided in subparagraphs (A), (C)(ii)-(v) and (7).

Section 2.31(d)(1)(x)(A-C) of the AWR permits the approval of multiple survival surgeries at the discretion of the IACUC if the request can be justified for scientific and animal welfare reasons.

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The AWR also includes a provision permitting the Secretary to approve multiple surgeries in other special circumstances.

**USDA Animal Care Policy #14** states “No animal is to be used in more than one major survival operative procedure except in cases of scientific necessity, veterinary care or other special circumstances as determined by APHIS.” This prohibits researchers from performing major multiple survival operative procedures on the same animal in an unrelated study, even when multiple years have elapsed between procedures or when multiple protocols are involved. This prohibition exceeds the statutory authority of the AWA and AWR. It also conflicts with efforts to replace, reduce, and refine animal research and can actually increase the number of animals used. We therefore urge the USDA to change Policy #14 to make it consistent with the AWA and AWR. That is, multiple survival surgeries should be permitted at the discretion of the IACUC as long as animal welfare takes priority.

We commend the USDA for evaluating current regulations and policies in an effort to ease regulatory burden and thank you for considering our recommendations to change several conflicting, outdated, and/or ineffective regulations that do not enhance animal welfare.

Please let us know if you need additional information on any of these topics.

Sincerely,

/s/ Jeff M. Sands, MD

APS President
APS response to NIH RFI on coordinating and harmonizing regulations and policies
(submitted June 11, 2018)

APS provided these comments on NIH’s March 14, 2018 RFI seeking input on the following proposals:

1. **Allow investigators to submit protocols for continuing review using a risk-based methodology.**

   The 2017 report “Reforming Animal Research Regulations” recommended using a risk-based methodology for protocol review: “Studies deemed low-risk, noninvasive, or minimally invasive could be exempt from full IACUC review or eligible for administrative review without concurrence by the full IACUC” (Recommendation #9 on page 16).

   - The American Physiological Society (APS) concurs with this and urges the NIH to implement risk-based reviews for all animal research protocols.

   Streamlining the review of new and continuing low-risk protocols will reduce burden both to those investigators whose protocols are being reviewed and to those who serve as IACUC members. A risk-based methodology will enhance animal welfare because by reducing the amount of time spent on reviewing low-risk protocols, IACUCs will be able to devote more time to overseeing research that may present a higher risk for pain and/or distress. This approach parallels the one used in the Common Rule governing Institutional Review Board (IRB) reviews of research with human subjects. The Common Rule already exempts some types of noninvasive research from review and makes other low-risk research protocols eligible for expedited review by a single member of the IRB. The updated Common Rule that takes effect July 19, 2018 takes additional steps to alleviate burden by eliminating the requirement for continuing review of studies that initially qualified for expedited review.

   - The APS recommends both taking a risk-based approach to initial protocol review and eliminating continuing review of low risk protocols. This approach is more administratively efficient and still maintains necessary animal protection.

   The APS further recommends that the USDA harmonize its protocol review schedule with that of the PHS Policy. Section 2.31 (d)(5) of the Animal Welfare Regulations (AWR) requires IACUCs to “conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC but not less than annually.” In contrast, Section IV.C.5 of the PHS Policy on Humane Care and Use of Animals requires IACUCs to conduct continuing reviews of protocols and other ongoing activities at appropriate intervals as determined by the IACUC as long as such reviews are completed once every three years.

   Memoranda of Understanding between OLAW and many federal granting agencies require institutions receiving extramural funding from these agencies to hold PHS Assurances and comply with the PHS Policy. This includes virtually all U.S. academic research institutions. Given that research involving AWA-covered species is already subject to continuing review under the PHS Policy, the USDA’s requirement for annual reviews is unnecessary.

   - The APS urges the USDA to harmonize its protocol review requirements for institutions with OLAW Assurances by allowing them to conduct such reviews at appropriate intervals as determined by the IACUC but no less than every three years.

2. **Allow annual reporting to the OLAW and USDA on the same reporting schedule and as a single report through a shared portal.**
The American Physiological Society (APS) agrees that harmonizing the schedule for annual reporting would reduce administrative burden by allowing facilities to gather information to report to both agencies at one time. However, since the reporting requirements between the agencies differ, if a single form is used for data entry, the reports it generates should convey to each agency only the information pertinent to its reporting requirements.

- The APS also urges OLAW to make its annual report less burdensome by implementing checkboxes to indicate compliance.

In place of entering the dates of an institution’s semi-annual facility inspections, there should be a checkbox where Assured institutions can indicate that the inspections took place. A checkbox should also be provided for institutions to verify that their IACUCs are appropriately constituted.

Section 2.36(a) (5-8) of the AWR lists extensive reporting requirements for animal numbers. This is an administrative requirement with no basis in the AWA. Of all these subsections, the requirement to report the number of animals being bred, conditioned, or held by the institution but not yet assigned to a study is particularly burdensome.

- The APS recommends that USDA eliminate the requirement to report the number of animals being bred, conditioned, or held by the institution prior to assignment to a study.

- The APS further recommends that wherever animal numbers must be reported, both USDA and OLAW should allow institutions to report ranges of animals instead of exact numbers.

3. **Harmonize the guidance from NIH and USDA to reduce duplicative considerations of alternatives to painful and distressful procedures.**

   The American Physiological Society (APS) supports the idea of unified guidance on the consideration of alternatives to painful or distressful procedures as long as this guidance eliminates the emphasis on key word literature searches in USDA’s Animal Care Policy #12. Policy #12 recommends “a database search as the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures.” However, this is not consistent with the language in AWA Section 2143(a)(3)(B), which simply states that researchers are required to consider “alternatives to any procedure likely to produce pain or distress in an experimental animal.” The language of Policy #12 also exceeds what is written in Section 2.31(d)(1)(ii) of the AWR, which tasks the IACUC with determining whether 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, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available.” In other words, the regulations do not place any special emphasis on database searches.

Because conducting a key word search of the literature for every procedure in a protocol is time-consuming, and such searches rarely yield useful information, it has frequently been cited as a waste of effort. In our response to the USDA’s 2015 RFI on reducing regulatory burden, the APS pointed out the conviction of investigators that a brief written narrative concerning how reduction, refinement, and/or replacement were incorporated into the protocol “gives the review body (IACUC) much more insight into the consideration of alternatives, satisfies the regulatory objectives of the Animal Welfare Act, and reduces burden for researchers.”

- The APS therefore urges the NIH and USDA to harmonize their guidance on consideration of alternatives by eliminating the emphasis on database searches.
4. **Provide a minimum 60-day comment period for new OLAW policy guidance.**

As an organization that takes policy development seriously, the American Physiological Society (APS) believes that agencies need to allow individual scientists and organizations sufficient time to learn about new policy proposals, engage in thoughtful discussion, and develop meaningful responses. A 60-day comment period is insufficient to do this.

- The APS therefore recommends that OLAW implement a 90-day comment period on all new policy guidance.

It has previously been noted by many people on many occasions that materials such as interpretive notes, procedure manuals, webinars, and journal articles have increasingly come to be considered as de facto statements of OLAW policy. Because research institutions are risk averse, the belief that institutions must comply with all the suggestions in these materials has become a significant source of regulatory burden. While this can be seen as self-imposed burden, OLAW also bears responsibility because it has encouraged the view that these materials represent agency policy.

- For this reason, the APS strongly recommends that agency guidance materials that have been developed without the opportunity for input from the regulated community should be labeled clearly to state that they do not carry legal or regulatory force.

- The APS also encourages both the NIH and the USDA to solicit public comments on any current guidance documents that were implemented without public comment since this will help identify additional ways to reduce regulatory burden as mandated under 21st Century Cures.

The Cures Act also called for the establishment of a Research Policy Board to conduct assessments of regulations concerning various areas of research including the oversight of laboratory animals.

- The APS urges that this Board be constituted as soon as possible and that any new policy guidance be submitted to this Board for review.

5. **Other approaches not previously mentioned.**

The American Physiological Society (APS) endorses the recommendations of Reforming Animal Research Regulations and wishes to highlight the following recommendations to the NIH from page 27:

The Guide for the Care and Use of Laboratory Animals was not intended to be a regulatory document. Rather, it was intended “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 of the IACUC.

- OLAW is strongly urged to stop using the Guide as a quasi-regulatory document.

- In keeping with the above, OLAW should stop considering IACUC-approved strategies that differ from “should” statements in the Guide as departures or deviations.

- Furthermore, IACUCs should not be required to include such alternative strategies in their semiannual reports to the Institutional Official. This is in line with OMB’s January 25, 2017
Agency Good Guidance Practices Bulletin (72 FR 3432) and would significantly reduce administrative burden without compromising animal welfare.

- NIH should eliminate the requirement in Grants Policy 4.1.1.2 for verification of protocol and grant congruency. Grants are not contracts. Research objectives can be expected to change due to ongoing discoveries and other developments that occur between grant submission and actual receipt of funding. Furthermore, advances made during each phase of the research may well lead to alternative strategies in subsequent phases.

- Revise the NIH guidance in NOT-OD-05-034 regarding prompt reporting to cover only those incidents that have jeopardized the health or well-being of animals.

With respect to semi-annual inspections and program reviews, we recommend the following:

- The APS supports Recommendation #15 on page 21 of Reforming Animal Regulations, which calls for USDA to revise §2.31(c)(3) of the AWR as follows: “The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution’s programs and facilities that includes all members wishing to participate in the process. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.”

- The APS recommends that USDA require program reviews annually rather than semi-annually. Section 2143(b)(3) of the AWA requires only a semiannual inspection of animal study areas and facilities, but Section 2.31(c)(1-3) of the AWR requires both semiannual inspections and program reviews. These program reviews have frequently been cited as wasted effort since IACUCs typically review programmatic issues on an ongoing basis. Requiring only annual program reviews will reduce burden to IACUCs without diminishing animal welfare.

**Input is sought on the following tools and resources:**

1. Encourage the use of sections of the AAALAC International program description in applicable parts of the OLAW Animal Welfare Assurance for institutions accredited by AAALAC International.

   Using the AAALAC program description in the OLAW Assurance would not significantly reduce administrative burden because the real problem is that current Assurance requirements for these institutions are excessive. The APS instead recommends that the NIH reduce the level of detail required in Animal Welfare Assurances for AAALAC-accredited facilities. According to a 2016 survey conducted by the IACUC-Admin listserv, Assurances run an average of 24 pages. In contrast, the average Assurance to conduct research with human subjects is less than 5 pages.

   - The APS recommends that AAALAC-accredited facilities be permitted to submit an abbreviated Assurance that addresses only those aspects of the PHS Policy that are not addressed in their AAALAC, International program description.

2. **Encourage the use of the FDP Compliance Unit Standard Procedures as a repository of best practices for standard procedures used for research with animals.**

   - The APS agrees that the use of the FDP Compliance Unit Standard Procedures (CUSP) could reduce burden for PIs developing animal use protocols. However, we caution against allowing these best practices to become *de facto* regulations.
3. Encourage the use of the IACUC Administrators Association repository of best practices by IACUCs.

Because the IACUC Administrators Association repository is only available to subscribers, the APS is unsure how promoting this resource would reduce regulatory burden.

4. Encourage the use of new or existing tools to streamline protocol review through use of designated member review (DMR), DMR subsequent to full committee review, and/or Veterinary Verification and Consultation.

OLAW should encourage the use of tools such as VVC and DMR to streamline protocol review and reduce administrative burden on IACUCs and investigators. However, some IACUCs have been hesitant to use VVC due to confusion over how it should be implemented.

- The APS urges OLAW to provide additional guidance on this. Moreover, rather than requiring each IACUC to develop an exhaustive set of VVC procedures, the VVC policy should state that veterinarians are encouraged to use professional judgement in approving changes to ongoing protocols.

- Explicitly authorizing veterinarians to exercise their professional judgment would improve animal welfare while also reducing unnecessary burden.

5. Expanded IACUC training activities that focus on reducing burden on investigators.

Since IACUC training activities are implemented on an institutional level, this recommendation does not address the emphasis of the 21st Century Cures Act, which is to reduce regulatory burden imposed on a federal level.

- Having the NIH and the USDA explicitly state what is and is not required on guidance and policy documents and other materials would have a greater impact on reducing burden. The APS concurs with this sample language suggested by NABR: “[Agency’s] guidance documents, including this one, do not establish legally enforceable responsibilities. Guidance documents simply describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.”
May 15, 2018

The Honorable David Rouzer
424 Cannon House Office Building
Washington, DC 20515

Dear Representative Rouzer:

The American Physiological Society urges you to amend §2146 of the Animal Welfare Act (AWA) to remove the requirement that research facilities be inspected at least annually.

§2146 pertains to the inspections of all entities subject to the AWA. This includes not only research facilities, but also animal dealers, exhibitors, intermediate handlers, carriers, and operators of auction sales. The first sentence of this section states that the Secretary of Agriculture “shall make such investigations or inspections as he deems necessary” to determine whether entities licensed or regulated under the AWA are in compliance with the law. It goes on to say that “in the case of deficiencies or deviations from the standards promulgated under this chapter, [the Secretary] shall conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected.” Nevertheless, the requirement for an annual inspection applies only to research facilities.

The USDA currently utilizes a Risk-Based Inspection System to the extent permitted by this provision of the AWA. The APS believes that it is in the best interest of research facilities and the government to amend AWA to remove the annual inspection requirement. This step will reduce the burden of compliance for research facilities while also permitting USDA to better allocate its resources.

Excessive regulatory requirements governing research have been highlighted in a number of reports in recent years. In 2016 Congress responded by including a mandate to reduce regulatory burden in the 21st Century Cures legislation. This bill, which authorizes new programs at the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), was approved with overwhelming bipartisan support. §2034 of 21st Century Cures calls upon the NIH, USDA, and FDA to “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.”

In April, 2017, a group of people with broad expertise in federal animal research oversight requirements participated in a workshop to identify specific ways for these agencies to comply with the 21st Century Cures mandate. The workshop was sponsored by the Federation of American Societies for Experimental Biology; Association of American Medical Colleges; Council on Government Relations; and the National Association for Biomedical Research. The workshop’s recommendations were published in October, 2017 in the report Reforming Animal Research
Regulations: Workshop Recommendations to Reduce Regulatory Burden. It included the recommendation\(^1\) that Congress should amend §2146 of the AWA to remove the requirement for annual USDA inspection of research facilities. The purpose of the change is to allow USDA to implement fully its Risk Based Inspection System so the agency can set the frequency of inspections based upon compliance history and other risk factors.

Research facilities have demonstrated a strong commitment to the AWA’s requirements for the humane treatment of research animals. According to the National Association for Biomedical Research (NABR), there were no instances of noncompliance with AWA standards in nearly 80% of USDA inspections of research facilities in FY 2016. This finding was based on an analysis of 1,339 annual inspection reports posted in USDA’s Animal Care Inspection Service database. While noncompliance was found in 21% of these inspections, in two-thirds of that group there was only a single citation, and sometimes only for paperwork issues.

It is worth noting that at large research facilities, USDA inspections may last several days, and they require veterinarians and other animal care staff to set aside their other duties while they accompany the inspectors and pull records for them. Consequently, mandatory annual inspections are an unjustified burden on the 80% of research facilities that have demonstrated full compliance with the AWA. Annual inspections of these facilities also prevent USDA personnel from making more visits to research facilities that are not in compliance, as well as to noncompliant animal dealers, exhibitors, intermediate handlers, carriers, and operators of auction sales.

The APS urges you to amend AWA §2146 to remove the requirement for annual inspections of research facilities. This will enable USDA to allocate its resources according to where they are needed most.

Sincerely

Jeff M. Sands, MD
President

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APS alliances with animal research advocacy organizations

The APS works closely with these organizations that have common interests in animal research issues:

**FASEB:** FASEB looks to APS for expertise on animal research issues. Kevin Kregel, the APS representative to the FASEB Board, is a former chair of the ACE Committee. Even before joining the Board, Kregel chaired FASEB’s Animals in Research and Education Subcommittee, which develops policy positions on animal issues for FASEB. It is a position he has held for 9 years. I am a member of that subcommittee, as are 4 other past ACE chairs: Gaylen Edwards, J.R. Haywood, Timothy Musch, and Bill Yates. Haywood was the first chair of the FASEB animal issues subcommittee and later represented APS on the FASEB Board. From that post he went on to serve as FASEB’s Vice President for Science Policy (2012-2013) and as FASEB President (2014-2015). Kregel and Haywood were instrumental in the development of the *Reforming Animal Research Regulations* report.

**National Association for Biomedical Research (NABR)/Foundation for Biomedical Research (FBR):** NABR’s mission is to provide a voice for the scientific community on legislative and regulatory issues that affect animal research. It provides regular information through its weekly newsletter. APS works closely with NABR, and former Executive Director Martin Frank has been a member of the NABR Board of Directors for several years. The APS also supports FBR, which promotes public understanding and support for biomedical research, most recently through a campaign called *Love Animals? Support Animal Research*.

**Americans for Medical Progress (AMP):** Americans for Medical Progress focuses on “public outreach that builds understanding and appreciation for necessary and humane animal research.” AMP’s programs include an advocacy campaign called *Raising Voices, Saving Lives; Come See our World*, which seeks to counter animal rights propaganda with stories and images of animals in research settings; and promoting April 19 as *Biomedical Research Awareness Day* to “honor, raise awareness of, and pledge support for animals needed for biomedical research. Director of Science Policy Alice Ra’an an and past ACE Chair Bill Yates are members of the AMP Board.

**States United for Biomedical Research (SUBR):** SUBR is a coalition of 11 state and regional organizations that offer programs and resources on the benefits of biomedical research and the crucial role laboratory animals play in the scientific process. APS began providing financial support to the individual state organizations. Starting in 2006, APS also began supporting the SUBR umbrella organization to support collaboration between the groups.

**American Association for Laboratory Animal Sciences (AALAS):** AALAS is a membership organization for those involved in laboratory animal science ranging from caretakers and facility managers to IACUC coordinators and veterinarians. The APS is an affiliate member of AALAS as a way to engage with others who are concerned with our issues. Being an affiliate entitles us to have an exhibit booth at the AALAS annual meeting, which provides opportunities to network with others involved in research policy issues. In addition, in 2017, the APS participated in an AALAS activity to encourage local high school students to learn about animal research and make them aware of careers in laboratory animal science. Using one of the career cards developed by the APS Education Office featuring APS members’ research and career paths, Science Policy staff formulated a question for these students about Stephen Secor’s work on digestion in boa constrictors. Those who answered the question correctly received materials including a set of career cards and a *New York Times* article, “*When the lab rat is a snake.*”
National Animal Interest Alliance (NAIA)/Homes for Animal Heroes: NAIA is a broad coalition that seeks to “promote the welfare of animals, to strengthen the human-animal bond, and safeguard the rights of responsible animal owners, enthusiasts and professionals through research, public information and sound public policy.” NAIA has partnered with AALAS to establish Homes for Animal Heroes which seeks to provide homes for retired research animals through a comprehensive adoption network.

American College of Laboratory Animal Medicine (ACLAM): ACLAM provides professional certification for laboratory animal veterinarians and engages in activities to promote and defend research. Ra’anana works closely with ACLAM on a number of issues.
Countering an Animal Rights Campaign

When you are named in an animal rights campaign, it is impossible to know how serious a threat you may face. Activists often comb through public records to identify projects they deem objectionable. Some campaigns are simply meant to “name and shame” those who work with animals. Nevertheless, once your work has been caricatured, it increases the likelihood that you may have to deal with harassment, threats, or worse. The American Physiological Society’s Office of Science Policy prepared this guide to help you take prudent steps to protect your safety, ensure your privacy, and defend your research.

Document the campaign

- Retain copies of any material that mentions you. Be sure to take screen shots of web pages—including comments—since these may later be changed or removed.
- Set a Google Alert with your name and key search terms so you can monitor future activity. (This is a prudent step for every researcher to take.)
- Log and report the time, date, and content of phone calls, emails, or any other communications from activists.

Inform your institution

- Contact your Attending Veterinarian and IACUC Chair about what needs to be done. (Most institutions have a plan for how to respond to this kind of situation.)
- Provide copies of key campaign materials plus a non-technical overview of your research. This will help your institution counteract the negativity that animal rights campaigns typically seek to generate. Make yourself available to work with the Attending Veterinarian, IACUC Coordinator, and University Relations Office to refine this overview and develop other explanations of your research.

Secure your personal information.

- Change the privacy settings on your social media accounts and online photo albums to limit access to them. Have family members do the same.
- Remove personal information such as your home address and phone number from the internet and social media websites. Have family members do the same.
- Ask the Information Technology department to remove or limit access to your lab and office phone numbers, addresses, and fax numbers.

Defending your research

- Work with your institution’s communications office to compose a statement about your research, the necessary role animal studies play, and the care provided to them.
- Identify scientists at other institutions who can explain the significance of your research, and provide them with your overview and/or the statement prepared by your institution.

For further information, contact Alice Ra’anana at the APS Office of Public Affairs at araanan@the-aps.org or 301-634-7105.
The APS Chapter Advocacy Outreach program was established in 2012 to help physiologists become more effective advocates for science. It is a joint project of the APS Science Policy and Animal Care and Experimentation Committees. The program provides support for a member of the APS Science Policy or Animal Care and Experimentation Committee or a member of the APS staff to speak at chapter meetings on a topic related to science policy and/or advocacy.

The Office of Science Policy provides information to the Chapter Advisory Committee each year about the program and invites them to request a speaker. A list of sample topics is also provided, which includes the following:

- Advocacy for Science: Making a Compelling and Understandable Case
- Research Advocacy: Why your voice matters
- Advocacy in Your Own Backyard
- Challenging Topics in Research Advocacy: Animals in Research
- Animal Data Reproducibility Issues
- Science Policy Careers

There were three requests for speakers in 2013; two in 2014; one in 2015; and three in 2016. There were no requests in 2017, and none to date in 2018.

Council allocated up to $6,000 per year for this program, which covers travel, food, and lodging, but not honoraria. The only additional cost is staff time, which is minimal, particularly in years when no speakers are requested.