

August 10, 2023

The NABR Update is a news summary of federal and state government affairs, animal rights activities, and other issues related to animal research that may have a direct effect on your organization or its constituents. It's an exclusive service available for NABR members only. If your organization is interested in joining NABR or if you have any questions or suggestions, please email us at info@nabr.org.

NHP Update

Science Magazine Highlights NABR's Challenge to the IUCN Listing Long-Tailed Macaques as Endangered

On Aug. 1, National Association for Biomedical Research (NABR) President Matthew Bailey was featured in an article by Science Magazine on NABR's petition to reverse a Red-List by the International Union for Conservation of Nature (IUCN) to list the long-tailed macaque as endangered.

In the article, Bailey explains that the IUCN decision was not based on fact, stating that the petition "contains numerous errors and misstatements, and does not provide actual evidence of species declines."

What is not stated in the article is that NABR has completed the informal petition process and now moves on to the formal petition process at IUCN.

The full Science article is available here.

FEDERAL

Senate Appropriations Committee Approves Labor, Health and Human Services, Education, and Related Agencies Fiscal Year 2024 (LHHS) Appropriations Bill

On July 27, the Senate Appropriations Committee favorably voted all 12 fiscal year 2024 spending bills out of committee. This included the FY24 LHHS bill, which funds the Department of Health and Human Services and includes language directing the agencies how Congress would like to see the funds allocated. The House is expected to continue work on its version of the FY24 LHHS bill in September.

Below is the report language impacting biomedical research.

National Primate Research Centers (pg. 127) — The Committee includes \$30,000,000 in funding to expand, remodel, renovate, or alter existing research facilities or construct new research facilities for nonhuman primate resource infrastructure, as authorized under 42 U.S.C. section 283k.

Research with Non-Human Primates (pg. 132) —The Committee recognizes the critical role of non-human primate [NHP] research in virtually all areas of biomedical research. Research with unique animal models makes irreplaceable contributions to understanding the biological processes that cause disease, which is necessary for the development, safety and efficacy testing of new therapeutics before clinical trials. NHP research will be vital to studying both the underlying mechanisms and potential cures for costly and emergent diseases. The Committee is concerned about the condition and availability of critical Federal research assets outlined in the 2023 National Academies report on the State of the Science and Future Needs for Nonhuman Primate Models in Biomedical Research. In particular, the Committee is alarmed that NIH has no central data management or reporting structure for tracking the number of NHPs required to meet current and future research needs. The Committee directs NIH to develop a strategic management plan for NHP research resources to bolster cooperative efforts, data sharing, purposeful planning, and data-driven care and management methods. The Committee urges NIH to award funding to meritorious research proposals using NHPs to study neurological diseases as well as research into preventing the next pandemic. NIH is also encouraged to continue the development and validation of new approach methodologies that reduce the need for, enhance the utility of, and mitigate shortages and costs of NHP models in the future.

Hepatitis B (pg. 97) —The Committee applauds NIAID for leading the effort to update the Strategic Plan for Trans-NIH Research to Cure Hepatitis B, so it remains a robust road map to find a cure. The Committee is aware of the widely held view in the scientific community that finding a cure for hepatitis B, as has now been achieved for hepatitis C, is a winnable goal and is within reach in the near-term. For these reasons, the Committee urges that research, based on the needs as identified in the updated Plan, be funded in fiscal year 2024 and beyond. The Committee urges NIAID to expand the use of Program Projects, R01 and U01 Cooperative Research Agreements, as was successfully used to discover cures for hepatitis C, as well as cooperative research programs modeled after the Martin Delaney Collaborations and applauds the success of the point of Care Technologies Research Network

[POCTRN] and Rapid Acceleration of Diagnostics [RADx] programs and urges more use of these programs for development of point of care tests for HBV, HDV and the cancers caused by these viruses. Finally, the Committee understands that research to enhance the human immune system to control and cure hepatitis B is promising and the continued use of animal models is a research tool that needs to be continued.

Cephalopod Research (pg. 120) — The Committee recognizes that there are no federally required welfare standards for the use of cephalopods in federally-funded research because all invertebrate animals are excluded from the Public Health Service [PHS] Policy on the Humane Care and Use of Laboratory Animals, which provides certain welfare standards for vertebrate animals. The Committee acknowledges that other countries have established oversight requirements for cephalopods when used in government-funded research. Due to cephalopods' current exclusion in Federal regulations, there is limited oversight of their involvement in research. The Committee recognizes that researchers must still justify their use and numbers when proposing research seeking NIH funding. As interest in the welfare of these animals in research is increasing, the Committee encourages the NIH to consider developing guidance for the humane care and use of cephalopods in NIH-supported research, including possibly expanding the current definition of "animal" in the PHS Policy.

Research Transparency (pg. 132) —As demonstrated over the past several years, the Committee remains committed to funding NIH research and ensuring that our Nation's researchers, particularly our early career scientists, have the support to make the scientific breakthroughs that may transform healthcare. However, it is critical that NIH can ensure funds are used for the best possible research that fulfill the core research mission of NIH. NIH is encouraged to justify, in writing made available on a publicly accessible website, that each grant or agreement promotes efforts to seek fundamental knowledge about the nature and behavior of living systems and/or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

The Senate Appropriations Committee press release is available here.

Full bill text is available <u>here</u>. The LHHS report can be seen <u>here</u>.

Office of Laboratory Animal Welfare (OLAW) 21st Century Cures Act Survey

As mandated by the 21st Century Cures Act, the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) and United States Department of Agriculture (USDA) have taken steps to identify and reduce inconsistent, overlapping, and unnecessarily duplicative regulations and improve coordination of regulations and policies, while maintaining the integrity and credibility of research findings and the protection of research animals. We are requesting feedback from IACUC administrators, coordinators, and others involved directly in the oversight of animal care and use programs by completing a 15–20-minute voluntary online survey.

The results of the IACUC administrator survey will help in the development of a final survey geared towards investigators. The survey will inform the NIH OLAW and USDA on the effectiveness of the flexibilities and updates on reducing administrative workload, allowing investigators more time to focus on their research. It will also provide insight on any additional measures that may be taken by the federal agencies to assist institutions.

A survey link has been distributed to IACUC administrators, coordinators, and other contacts from Domestic Assured institutions and USDA Registered research facilities via email on June 1st, 2023, from <u>noreply@qemailserver.com</u>.

- Only one survey response per institution will be permitted and accepted (per assurance number and/or registration).
- The survey will close on August 31st, 2023.
- This survey is completely voluntary. There are no negative consequences from the participating federal agencies for taking part or choosing not to complete the survey.

If your institution would like to participate, but your IACUC administrator or coordinator has not received a survey link please contact <u>olaw@nih.gov</u>. Thank you for your consideration in helping with this important survey.

The survey will close on Aug. 31, 2023.

Lawmakers Introduce Bills That Would Impact Biomedical Research at Foreign Labs

On Aug. 1, Sen. Joni Ernst (R-IA) introduced the Accountability in Foreign Animal Research (AFAR) Act to defund animal research conducted at foreign labs.

The AFAR Act:

- Prohibits the secretary of Health and Human Services, acting through the director of the National Institutes of Health from conducting or supporting research on animals in certain foreign countries.
- These countries include:
 - The People's Republic of China, including the Hong Kong Special Administrative Region (China)
 - The Republic of Cuba (Cuba)
 - The Islamic Republic of Iran (Iran)
 - The Democratic People's Republic of Korea (North Korea)
 - The Russian Federation (Russia)
 - Venezuelan politician Nicolas Maduro (Maduro Regime)

- Such other foreign country that the secretary of Health and Human Services, in consultation with the secretary of state and the secretary of defense, determines is a foreign adversary.
- The AFAR Act is supported by the White Coat Waste Project.

More information is available here.

Lawmakers Introduce the Better Collaboration, Accountability, and Regulatory Enforcement (CARE) for Animals Act

On July 27, Congressman Guy Reschenthaler (R-PA-14) and colleagues in the House and Senate introduced the CARE Act (H.R.5041). According to the sponsors, this bill "aims to strengthen the U.S. Department of Justice's (DOJ) enforcement power against animal abusers."

This bill would amend the Animal Welfare Act (AWA) to expand and improve the enforcement capabilities of the attorney general. Specifically, the legislation provides DOJ with the same enforcement authority as the U.S. Department of Agriculture under the Animal Welfare Act and further gives the DOJ authority to seize and remove animals that are suffering mistreatment.

This bill is supported by the Humane Society Legislative Fund.

The CARE Act now awaits further action by the House Committee on Agriculture.

Bill text can be found <u>here</u>. The Senate companion bill is available <u>here</u>.

The press release is available <u>here</u>.

NIH Seeks Input on Challenges and Opportunities for the Further Development and Use of Novel Alternative Methods

As previously reported the National Institutes of Health (NIH) is <u>seeking public</u> <u>input</u> on challenges and opportunities for the further development and use of novel alternative methods (NAMs) in biomedical research. Input received from this request will inform the NIH and the development of the Advisory Committee to the NIH Director (ACD)'s recommendations on high-priority areas for future investment in NAMs.

The NIH is requesting information in three specific areas:

- The use of novel alternative methods to study human biology, circuits, systems, and disease states.
- Approaches for catalyzing the development and validation of novel alternative method technologies.
- Strategies for maximizing the research of novel alternative method technologies.

NABR encourages those with specific knowledge in these three areas or other areas involving the use of NAMS in biomedical research to provide feedback to the ACD working group.

Comments on the Request for Information **must be submitted by Aug. 16**, **2023**, through the online comment portal found <u>here</u>. The ACD Working Group on Novel Alternative Methods will also be hosting an expert workshop on Aug. 21, 2023.

For additional context on the NAMs issue, please see the latest Under the Poliscope blog <u>here</u>.

Questions may be sent to <u>SciencePolicy@od.nih.gov</u>.

Interagency Coordinating Committee on the Validation of Alternative Methods: Request for Comment on Draft Report on Validation, Qualification, and Acceptance of New Approach Methodologies

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces availability of the draft document, "Validation,

Qualification, and Regulatory Acceptance of New Approach Methodologies."

ICCVAM is accepting public comments on the document through **September 5**, **2023**; **5:00 p.m. EDT.** Please send comments to Amber Daniel at <u>amber.daniel@inotivco.com</u>.

The official notice can be accessed <u>here</u>.

Additional information including the draft document can be found here.

ABROAD

European Union Commission Rejects the European Citizens' Initiative (ECI) to Phase Out Animal Testing

As previously reported by the European Animal Research Association (EARA), the European Commission has rejected a petition by (ECI) to phase out all animal research in the EU.

The commission responded to the petition by stating, "Considerable advances have been made in developing (non-animal) alternatives, but animal models remain unavoidable at the moment to understand some more complex biological or physiological processes involved in health, disease and biodiversity."

In addition, the commission agreed to continue working on validated alternative scientific methods and support ways to expand and accelerate non-animal methods (their development, validation, and implementation), where possible.

EARA's press release can be read <u>here</u>.

ANNOUNCEMENTS

OLAW Fall Webinar to be Held on Sept. 14, 2023

OLAW will be hosting a fall webinar to explore the NC3Rs Experimental Design Assistant (EDA).

The EDA helps users build a diagram representing an experimental plan, provides customized feedback, and can make suggestions on statistical methods, randomization, blinding, sample sizes, and other critical design aspects. Dr. Esther Pearl, NC3Rs Programme Manager for Experimental Design, will discuss how the EDA can assist research staff, how it can simplify protocol review for IACUCs, and will demonstrate features of this free resource.

This webinar will be held on Sept. 14, 2023, from 1-2 p.m.

More information and registration for the webinar can be found here.

NABR | 1909 K Street, NW, Suite 300 | Washington, DC 20006 | Tel 202.857.0540 | Fax 202.659.1902 | info@nabr.org