

November 13, 2020

Dr. Kay Carter-Corker
Director, National Policy Staff, Animal Care
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
4700 River Road Suite 6D-03E
Riverdale, MD 20737
RE: Proposed Rule
[Docket No. APHIS-2019-0001] RIN 0579-AE54
Via: Federal Register Online Portal

Dear Dr. Carter-Corker,

Rise for Animals (Rise; formerly the New England Anti-Vivisection Society) is a national nonprofit animal protection organization on a mission to end animal experimentation in our lifetime. As such, we submit these public comments in dissent in the U.S. Department of Agriculture's Animal and Plant Health Inspection Service's (USDA-APHIS) proposed rule Docket No. APHIS-2019-0001.

I. IACUC Review of Activities Involving Animals

In its proposed rule, APHIS wants to "amend 9 C.F.R. § 2.31(d)(5) to remove the requirement for the IACUC [(Institutional Animal Care and Use Committee)] continuing reviews of activities covered by subchapter A, but not less than annually, and replace it with the requirement for the IACUC to conduct a complete review of approved activities at appropriate intervals as determined by the IACUC, but not less than every 3 years."¹ We would like to express our concern with this proposed change and recommend this change not be made.

As currently required by law, each research facility must have an IACUC. It is the responsibility of each IACUC to review animal-based research and to approve or withhold approval of activities regarding animal care and use or of modifications necessary to comply with IACUC

¹ *Proposed Rule*, U.S. Dep't of Ag. Animal & Plant Health Inspection Serv. 2020, https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-20512.pdf?utm_medium=email&utm_campaign=pi%20subscription%20mailing%20list&utm_source=federalregister.gov&fbclid=IwAR2E8IzINUUV35aEbicue0QVod7dhYGU91QkBMn5BEcqqgmte3tN1sXJ1Nhl (last visited Nov. 9, 2020).

requirements.² Additionally, each IACUC must conduct continuing reviews of each research program at least annually.³

a. Concerns with Allowing Individual IACUC Discretion to Determine Frequency of Protocol Review

As currently enacted, the Animal Welfare Act (AWA) allows IACUCs substantial discretion regarding the frequency of continuing reviews—IACUCs are in compliance so long as they conduct at least one continuing protocol review annually.⁴ This proposed rule, however, would broaden IACUC discretion, allowing them to choose the frequency of continuing reviews so long as one is conducted at least once every three years.

In our view, this is a dangerous precedent to set. IACUC's already have the power to choose to review protocols annually. Allowing IACUCs to diminish their oversight to once every three years instead of annually substantially reduces protocol review frequency and will likely result in exacerbating animal suffering resulting from unnecessary animal use, which these reviews guard against. We are concerned that the IACUCs will take this proposed rule as an opportunity to be less stringent about their unique and important role, and we strongly oppose this proposed rule in its current form given that it will reduce critically-needed IACUC review of protocols.

b. Requiring Continuing Review Only Every Three Years Violates the Intent of the Three R's

The widely accepted concept of Reduction, Refinement, and Replacement in animal-based research (Three R's) is implicit in the AWA since the 1985 amendment.⁵ The purpose of these principles are to evaluate animal research from an ethical standpoint—seeing each animal as an individual who can experience both pain and distress—and to prioritize reductions in animal both usage and animal suffering. Moreover, the Three R's also work toward eliminating animal-based research altogether. With these three goals in mind, research facilities are encouraged to consistently evaluate their animal use.

Limiting the frequency of protocol review will undermine efforts to follow the Three R's, because there will be less IACUC oversight and opportunity to ensure that these goals are implemented. Only conducting the review process once every three years will not allow IACUCs to make sure that research facilities are reducing, refining, and replacing animal-based models and research. It is necessary for IACUCs to review protocols annually to ensure that the Three R's are followed.

² Animal Welfare Act, 9 U.S.C. § 2143(b) (1966).

³ *Id.*

⁴ *Id.*

⁵ 3Rs Alternatives: Technologies & Approaches, U.S. Dep't of Ag., Nat'l Ag. Library, <https://www.nal.usda.gov/awic/3rs-alternatives-technologies-and-approaches> (last visited Nov. 9, 2020); 9 U.S.C. § 2143(e)(3)(A)–(B).

c. Infrequent Protocol Review Undermines the Spirit of Independent Policing

Each IACUC is an integral part of transparency and accountability at research facilities. The AWA was amended in 1985 specifically for the purpose of establishing IACUCs to oversee animal-based research with both animal welfare and research integrity in mind.⁶ IACUCs were designed to be self-policing bodies,

The current regulatory structure is designed to center the IACUC as a primary mechanism to ensure enforcement of the AWA. This change we are opposing would diminish the oversight capacity and role of the IACUC by limiting its role in reviewing research protocols. As such, this change to a less frequent review of research protocols undermines the spirit and intent of the independent policing that is inherent to the current AWA enforcement structure.

d. Changing the Frequency of Continuing Review Will Likely Result in Increased Number of Protocol Violations

One of the most important aspects of the annual continuing reviews is to ensure that protocols are not violated. It is imperative for IACUCs to annually review research protocols, to monitor what happens to animals in research.

Even with annual review, protocols are consistently violated across the U.S.⁷ and we are concerned that only requiring such review once every three years will add to this issue, not address it adequately. The validity of research depends on annual continuing review, to ensure the integrity of animal-based research is upheld, protocols are not violated, and animals are not unnecessarily used.

e. Delaying Performance Checks Affects Experiment Validity

During at least the last five to ten years, there has been a broad growing concern/crisis regarding the reproducibility of experimental outcomes in both animal and human research endeavors. To delay further checking with researchers about the performance of their approved activities and to reflect on their designs and the impact of their methods on animal data collection and well-being actively denies this major issue. The validity and usefulness of animal research in developing human biomedical understanding and therapeutic interventions is under question, reducing performance oversight is not the answer.

⁶ *Legislative History of the Animal Welfare Act: Introduction*, U.S. Dep't of Ag., Nat'l Ag. Library, <https://www.nal.usda.gov/awic/legislative-history-animal-welfare-act-introduction#:~:text=Amendments%20to%20the%20AWA%20enacted,teaching%2C%20testing%2C%20and%20research.&text=The%20articles%20stimulated%20such%20a,Animal%20Welfare%20Act%20in%201966> (last visited Nov. 5, 2020).

⁷ Rise has extensive evidence of protocol violations obtained through the Freedom of Information Act (FOIA); List of non-compliant items from 11/1/2018–10/8/2020 -- 8 Direct; 176 Non-Critical; 42 Critical; and 174 Teachable Moments.

f. Conclusion

We are concerned that diminishing the frequency with which IACUCs review research protocols will reduce IACUCs' abilities to ensure against wasteful and duplicative animal research, which will increase the likelihood of overly abundant animal suffering. Research involving animals requires regular IACUC oversight and accountability, not less. Therefore, we respectfully and sincerely dissent in the IACUC Review of Activities Involving Animals portion of APHIS's proposed rule.

Thank you for your consideration and attention to this important matter.

Sincerely,

A handwritten signature in cursive script that reads "Frances Chrzan".

Frances E. Chrzan, J.D.
Legislative & Public Policy Associate