FASEB
FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

REPRESENTING OVER 100,000 RESEARCHERS
6120 Executive Boulevard | Suite 230 | Rockville, MD 20852
faseb.org

November 25, 2026

Submitted electronically via the NIH Office of Laboratory Animal Welfare comment portal

Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Dr (RKL1), MSC 7983
Bethesda, MD 20892

RE: Comments of the Federation of American Societies for Experimental Biology (FASEB) in response to a request for information on Feasibility of Annual Reporting of Live Vertebrate Animal Numbers, NOT-OD-27-001

Dear NIH Office of Laboratory Animal Welfare:

On behalf of the Federation of American Societies for Experimental Biology (FASEB), representing 21 scientific societies and more than 100,000 researchers, we appreciate the opportunity to respond to NOT-OD-27-001, Request for Information on Feasibility of Annual Reporting of Live Vertebrate Animal Numbers. FASEB supports the humane and responsible use of animals in research and shares the National Institutes of Health (NIH) Office of Laboratory Animal Welfare's (OLAW) commitment to effective oversight and accountability. We also recognize the importance of transparency in communicating the scope and conduct of federally supported animal research.

However, FASEB has significant concerns about the feasibility, utility, and potential consequences of the proposed annual reporting requirement. Although standardized information on animal use could provide some additional insight into research activities, the proposed approach raises substantial questions about added administrative burden and the allocation of financial resources necessary for implementation, the ability of institutions to generate accurate and comparable data across all vertebrate species, and the interpretation of those data in regulatory oversight. FASEB is particularly concerned that collecting and publicly reporting cumulative animal counts, categorized using existing U.S. Department of Agriculture (USDA) pain and distress classifications, may not provide a meaningful assessment of animal welfare or research practices while creating considerable new obligations for research institutions.

FASEB recommends that OLAW not move forward with the proposed requirement in its current form. Before establishing additional reporting obligations, NIH should more clearly define the objectives and intended uses of the information, evaluate the limitations of existing reporting categories, and assess whether the proposed data collection would provide sufficient value to justify its costs. If NIH determines that additional reporting is warranted, substantial guidance, institutional consultation, and implementation safeguards will be necessary to ensure that the resulting information is reliable, useful, and appropriately contextualized. Any public reporting should be limited to appropriately contextualized national aggregate data.

1. Current Tracking and Reporting Practices

Institutions currently collect and maintain animal-use information for a variety of operational, husbandry, veterinary care, and regulatory purposes. However, the systems and processes used to manage this information vary considerably across institutions and research programs. Existing animal census and facility management systems are often designed to support daily husbandry operations, animal inventory management, and per diem billing rather than to generate cumulative annual counts of individual animals categorized by species and pain and distress classification.

For example, animal census systems may track cage or tank inventory, while IACUC protocol management systems maintain information about approved animal numbers, species, and procedures. Veterinary and husbandry records may contain additional information about individual animals, including health status, treatment, transfers, and disposition. Breeding colony records may be maintained separately from experimental animal records. Although these systems collectively provide information necessary for institutional animal care and use programs, they are not necessarily integrated or configured to produce the annual reporting proposed by OLAW.

The distinction between maintaining information for operational purposes and compiling it for institutional reporting is important. Information may be available within an institution without being readily accessible in a format that supports cumulative annual counts. For example, cage counting is particularly common in rodent care and husbandry programs, which represent approximately 95 percent of animal research programs across the U.S. Many institutions thus have established inventory protocols and equipment designed to facilitate cage counts rather than individual counts. Meeting the proposed requirement could therefore necessitate the integration of multiple databases, development of new data interfaces, and establishment of additional procedures to reconcile and validate information across facilities and research programs, which would pose substantial added administrative burden.

Existing federal reporting requirements also differ in their scope and purpose. Institutions with Domestic Animal Welfare Assurances report average daily animal inventory by species and facility as part of their Assurances. USDA-registered research facilities separately report animals covered by the Animal Welfare Act (AWA), including applicable pain and distress categories. OLAW Annual Reports currently focus on changes to institutional animal care and use programs, IACUC membership, and other required programmatic information. Foreign Assurances also differ from Domestic Assurances in their existing inventory reporting requirements.

Consequently, the proposed requirement would not simply involve transferring information from an existing annual reporting system. Many institutions would need to establish new processes to reconcile information collected for different purposes, apply consistent counting methodologies, and generate data that are not currently maintained in a standardized format.

FASEB encourages NIH to consider these differences when evaluating institutional readiness. The availability of animal management software or existing compliance records should not be interpreted as

evidence that institutions can readily produce accurate annual counts across all species and pain and distress categories.

2. Feasibility and Data Consistency

FASEB recognizes that annual institutional reporting may be feasible for some species and research programs using existing inventory systems. However, the feasibility of consistently reporting cumulative annual numbers across all live vertebrate species covered by the PHS Policy is substantially more complicated. Clear definitions and standardized methodologies will be necessary before institutions can reasonably assess the scope of the proposed requirement.

Defining What Constitutes an Animal Count

The PHS Policy defines animals broadly to include live vertebrate animals used or intended for use in research, research training, experimentation, biological testing, or related purposes. Applying this definition to cumulative annual counts raises questions about when an animal should be counted and which activities should be included.

Breeding colonies present a particularly significant challenge. Institutions may maintain large colonies to support research programs, including animals used for breeding, colony maintenance, genetic characterization, and development of research models. Many animals produced through these programs may never be used in an experimental procedure. Others may be genotyped, determined to be unsuitable for a particular study, or euthanized before experimental use.

NIH should clarify whether and when these animals must be included in annual totals. For example, should an animal be counted when it is born, when it is entered into an institutional inventory, when it is assigned to an approved protocol, or when it undergoes an experimental procedure? How should institutions account for animals bred but not used, including those euthanized as part of routine colony management? For animals purchased from vendors, at what point in their ownership transfer should they be included in the count? Without clear definitions, institutions may adopt different accounting practices, limiting the comparability of reported numbers.

Additional questions arise when animals are used in multiple research activities. An individual animal may be transferred between investigators, assigned to multiple protocols, or participate in sequential research procedures. Institutions will need to know whether the reporting metric represents unique individual animals or cumulative animal uses. These are fundamentally different measures, and failure to distinguish between them could result in duplicate counting or inconsistent reporting.

FASEB recommends that NIH establish explicit definitions for animals included in annual totals, including breeding animals, offspring, genotyped but unused animals, animals used for multiple purposes, and animals transferred between facilities or research programs.

Species-Specific Considerations and Estimation

The proposed requirement encompasses a broad range of vertebrate species, including rodents, fish, amphibians, reptiles, and birds. Institutional practices for managing and tracking these animals differ substantially, and methodologies appropriate for one species or research setting may not be suitable for another.

For example, individual-level tracking may be practical for some mammalian research models but less feasible for aquatic species maintained in large populations or breeding systems. Fish and amphibians may be produced, housed, and managed in ways that make precise individual counts difficult, particularly during early developmental stages or in large breeding populations. NIH acknowledges that estimates may be permitted in select circumstances, but additional guidance will be necessary to ensure that institutions apply estimation methods consistently.

OLAW should clarify which species and circumstances would qualify for estimated reporting, what methodologies would be considered acceptable, and what level of precision would be expected. Institutions should not be required to establish resource-intensive individual tracking systems where a validated population estimate would provide sufficiently reliable information for the intended purpose.

Guidance should also address how institutions document estimation methodologies, account for uncertainty, and report changes in estimation practices over time. Without such guidance, differences in reported totals may reflect methodological differences rather than actual changes in animal use.

Pain and Distress Categorization

FASEB has additional concerns about applying USDA pain and distress categories across all vertebrate species covered by the PHS Policy. These categories were developed within the regulatory framework of the AWA and are used for reporting animals covered by that statute. Extending their application to species outside the AWA raises questions about the availability and appropriateness of existing guidance.

Pain and distress are evaluated within the context of species-specific physiology, behavior, and responses to experimental procedures. The methods used to assess and alleviate pain and distress in rodents may not translate directly to fish, amphibians, reptiles, or other vertebrate species. NIH should not assume that existing USDA guidance can be applied uniformly across all species and research activities without additional interpretation and guidance.

There is also an important distinction between anticipated and actual animal experiences. Protocol-level review provides an assessment of the expected effects of proposed procedures, but individual animals may experience different outcomes depending on their physiological condition, response to treatment, and other circumstances. Analgesia, anesthesia, supportive care, and other interventions may also substantially affect the experience of an animal undergoing a procedure.

A reporting system based primarily on prospective protocol-level categorization may therefore not accurately reflect the actual experience of individual animals. Conversely, unexpected complications or adverse events may result in experiences that differ from those anticipated during protocol review.

FASEB recommends that NIH provide detailed guidance on assigning pain and distress categories across species, including how to account for veterinary interventions, analgesia, unexpected adverse events, and differences between prospective protocol assessments and actual animal experiences. Institutions should not be expected to develop independent interpretations of USDA categories without a consistent framework.

3. Implementation Timeline

The time required to implement the proposed reporting would depend on institutional infrastructure, the number and types of species used, the organization of animal care and research programs, and the extent to which relevant information is already captured in a form that can be used for annual reporting.

For institutions with integrated animal-management and research-administration systems, implementation may be more straightforward. Other institutions may need to modify existing software, establish new procedures for collecting and reconciling information, or develop manual processes to compile and validate annual totals. Institutions may also need time to train personnel and coordinate across animal facilities, veterinary staff, IACUC offices, and research groups.

A realistic timeline cannot be established until NIH has clarified the reporting definitions, counting methodology, and data requirements. FASEB recommends that NIH first develop and solicit feedback on detailed reporting guidance, followed by a voluntary pilot involving institutions with different sizes, research portfolios, and animal-use practices. The pilot should assess the time and resources needed to produce the requested information, identify inconsistencies in how institutions interpret the requirements, and determine whether the resulting data are sufficiently reliable and comparable to justify a broader mandate.

Any subsequent implementation timeline should account for the findings of this process and provide sufficient lead time for institutions to make necessary changes. A uniform implementation date that does not account for differences in institutional capacity could create disproportionate burdens, particularly for institutions that lack integrated systems or dedicated personnel to support this work.

4. Institutional Resources and Costs of Implementation

Implementing annual reporting would likely require both one-time investments in institutional infrastructure and recurring administrative resources. The extent of these costs would depend on the size and complexity of an institution's animal care and use program, the species involved, and the capabilities of its existing information systems.

Potential implementation activities include modifying or replacing animal census software, integrating information from multiple institutional databases, establishing individual animal tracking or

reconciliation procedures, developing standardized reporting methodologies, and training personnel responsible for maintaining and submitting the data.

Recurring responsibilities would include collecting and reconciling information throughout the reporting year, reviewing and validating annual totals, resolving discrepancies, and preparing institutional reports for certification and submission. These activities would require time from investigators, animal care and veterinary personnel, IACUC administrators, information technology staff, and institutional compliance offices.

The burden is likely to vary substantially across institutions. Large research universities may have dedicated animal program administrators, established information technology infrastructure, and centralized animal facilities. Smaller institutions or those with more limited research portfolios may lack these resources and would need to develop new capabilities to meet the proposed requirement. Institutions with extensive breeding colonies or aquatic research programs may face additional challenges because of the scale and nature of their animal management activities.

FASEB is particularly concerned that the proposed requirement could divert personnel and financial resources from activities that directly support animal welfare and research. Time spent reconciling databases, preparing annual reports, and validating cumulative counts is time that cannot be devoted to veterinary care, husbandry, investigator support, or other essential program activities.

Costs associated with implementation and ongoing compliance may also be reflected in institutional animal care expenses, including per diem rates and other charges to research programs. These expenses could ultimately be borne by federal research awards and other research funding sources.

This proposed requirement should also be considered in the context of Section 2034(d) of the 21st Century Cures Act, which directs NIH, in collaboration with USDA and FDA, to review policies and regulations governing animal care and use and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protecting research animals. Adding a new reporting requirement that necessitates substantial institutional investment and recurring administrative effort should be carefully evaluated against this statutory objective.

Before implementing a new requirement, NIH should conduct a more comprehensive assessment of the resources institutions would need to comply. This assessment should distinguish between initial software and infrastructure investments, recurring personnel costs, and indirect costs associated with institutional oversight and certification. NIH should also clarify that reasonable costs associated with compliance are allowable research expenses and ensure that Institutes and Centers appropriately consider these costs in grant budgets.

5. Potential Benefits and Limitations of Annual Reporting

Annual reporting of animal numbers could provide NIH with additional information about animal use across institutions and support analysis of national trends. Depending on the quality and consistency of

the data, this information might help identify broad patterns in research involving particular species or categories of procedures. It could also contribute to discussions about the responsible use of animals in research and efforts to advance replacement, reduction, and refinement (the 3Rs).

However, the potential value of these data depends on their accuracy, comparability, and intended use. NIH should clearly articulate what information it seeks to obtain and how that information will inform oversight, policy development, or public understanding.

The Relationship Between Animal Counts and Animal Welfare

Animal counts alone are not a measure of animal welfare. The number of animals used by an institution does not convey the scientific purpose of the research, the quality of animal care, the veterinary oversight provided, or the measures taken to prevent or alleviate pain and distress.

Institutions with different research portfolios may report substantially different animal numbers without those differences indicating differences in their commitment to animal welfare. For example, institutions conducting research involving genetically altered models or maintaining extensive breeding colonies may report higher numbers than institutions conducting research with other models or species. These differences may reflect the nature and scope of scientific activities rather than differences in welfare standards.

Similarly, pain and distress categories provide a regulatory classification of animal use but do not constitute a comprehensive assessment of animal welfare. They do not capture all aspects of an animal's experience, including housing conditions, environmental enrichment, monitoring, veterinary care, or the effectiveness of interventions.

FASEB recommends that NIH clearly communicate the limitations of animal counts and pain and distress categories as indicators of animal welfare. These data should not be used as stand-alone measures of institutional performance or as the basis for comparisons that do not account for differences in research activities and institutional programs.

Relationship to the Principles of Replacement, Reduction, and Refinement

FASEB supports the continued advancement of the principles of replacement, reduction, and refinement (the 3Rs) in biomedical and biological research. However, the number of animals reported annually should not be treated as an independent measure of progress toward these principles.

Reduction must be considered in the context of scientific validity, rigor, and reproducibility. Appropriate sample sizes are necessary to achieve statistically meaningful results, and reducing animal numbers below those needed to answer a scientific question can undermine research quality. Underpowered studies may produce inconclusive results, waste research resources, and necessitate additional experiments that would increase the overall number of animals used compared to the original study if it was appropriately powered. Many of the best practices in rigor and reproducibility, including NIH's policy on consideration of sex as a biological variable (NOT-OD-15-102), may increase animal use numbers but

lead to stronger scientific output in line with NIH expectations. Responsible application of the reduction principle requires minimizing animal use while maintaining scientifically rigorous experimental design.

Likewise, refinement may involve changes in research methods, housing, monitoring, or interventions that do not necessarily result in lower animal counts. The development and validation of improved research models may also require additional animals in the short term while supporting more refined approaches over time.

Annual animal counts may provide useful information about broad trends, but they cannot independently establish whether institutions or research programs are making meaningful progress toward the 3Rs. NIH should avoid interpreting increases or decreases in reported numbers without considering the scientific and operational context.

Defining the Intended Use and Value of the Data

Before implementing annual reporting, NIH should identify the specific questions the proposed data are intended to answer. For example, will the information be used to evaluate national trends in animal use, inform policy decisions, identify opportunities for refinement, or provide the public with a more complete picture of federally supported research?

These objectives may require different types of information and different levels of reporting detail. Institutional aggregate counts may be sufficient for evaluating broad trends, while more detailed information may be necessary to address specific research or oversight questions. The latter, however, could create substantially greater administrative burden and raise additional privacy and security concerns.

NIH should also establish a process for evaluating whether the information collected is achieving its intended objectives. Without a clear understanding of how the data will be used, institutions may be required to devote substantial resources to producing information that has limited practical utility.

FASEB encourages NIH to define the intended uses of annual reporting and establish criteria for evaluating its effectiveness before creating a new reporting obligation.

6. Direct and Indirect Burdens

The proposed reporting would create additional direct and indirect burdens for institutions. The direct burden would include the staff time and resources required to identify relevant records, reconcile information across systems, apply consistent counting and categorization methods, validate data, and prepare annual reports. The degree of burden would vary among institutions, but existing reporting processes should not be assumed to accommodate the proposed requirement without additional work.

These administrative responsibilities may also affect individual researchers. Investigators and research staff may be asked to provide or verify information about animal use, clarify discrepancies between protocol records and facility records, or assist with the classification of animals. Such activities would add

to existing administrative responsibilities and could divert time from research and other activities that directly support animal care and scientific work.

The proposed reporting could also create indirect burdens. FASEB is particularly concerned about the public release of animal-use data at the individual institution level. Institution-level reporting would make it possible to identify and compare institutions based on annual animal numbers and pain and distress categories, even though those figures would not provide sufficient context to assess the nature, purpose, or welfare implications of the research. Differences in research portfolios, species, breeding practices, and institutional operations could be overlooked, creating a risk that the data would be misinterpreted by the public or used to make unsupported comparisons.

Publicly identifying institutions and their animal-use numbers could also create security and reputational concerns. Institutions conducting animal research may face heightened scrutiny, unwanted attention, or targeted harassment. Public reporting that allows animal-use information to be attributed to individual institutions could increase these risks without providing a corresponding benefit to animal welfare or public understanding.

For these reasons, FASEB strongly opposes public reporting of animal-use numbers at the individual institution level. If NIH proceeds with annual reporting, the information should be used for appropriate oversight and analysis, with any public release limited to national aggregate data that do not identify individual institutions. Aggregate reporting would allow NIH to communicate broad trends while reducing the risks of misleading institutional comparisons, reputational harm, and security concerns.

7. Additional Considerations and Recommendations

FASEB recommends that NIH reconsider whether the proposed annual reporting requirement is necessary and whether its anticipated benefits justify the additional burden on institutions and researchers. Before establishing a new reporting requirement, NIH should clearly define the policy objective, explain how the requested information would be used, and demonstrate why existing reporting and oversight mechanisms are insufficient to meet that objective.

If NIH determines that additional reporting is warranted, FASEB recommends the following considerations:

- **Develop clear, standardized counting definitions.** NIH should establish consistent definitions and working examples for counting animals across different research activities, including breeding colonies, genotyping, animals not ultimately used in research, transfers between facilities or protocols, and animals involved in multiple research activities. The guidance should clarify whether the reporting measure is intended to represent unique individual animals or cumulative uses.
- **Provide species-appropriate guidance for pain and distress categories.** NIH should clarify how USDA pain and distress categories should be applied to all species covered by the PHS Policy,

including species not covered by the AWA. Guidance should address how institutions should account for differences between prospective protocol classifications and actual animal experiences, including the use of anesthesia, analgesia, and other refinements.

- **Establish practical approaches for species and activities that are difficult to count.** Where direct counts are not feasible, NIH should define acceptable estimation methods and explain how institutions should document estimates and associated uncertainty. These methods should account for differences in animal management and research practices across species.
- **Minimize duplication with existing federal reporting requirements.** NIH should assess how the proposed reporting would interact with existing USDA reporting and PHS Policy requirements. Where information is already collected for another regulatory purpose, institutions should not be required to duplicate data collection unnecessarily. Any new requirement should be designed to complement, rather than add avoidable complexity to, existing reporting processes.
- **Pilot the reporting requirement before implementation.** NIH should work with institutions representing a range of sizes, research portfolios, and animal-use practices to test the proposed definitions, reporting methods, and data systems. A pilot would help identify feasibility concerns, estimate institutional costs, and determine whether the resulting data are sufficiently consistent and useful to justify mandatory reporting.
- **Provide sufficient implementation time and clarify allowable costs.** NIH should establish an implementation timeline based on the results of the pilot and provide institutions with adequate time to modify systems, develop procedures, and train personnel. NIH should also clarify whether the costs associated with data collection, system development, validation, and recurring reporting activities may be included in institutional and grant budgets.
- **Limit public reporting to national aggregate data.** FASEB strongly opposes the public release of animal-use data at the individual institution level. Publicly identifying institutions by their annual animal numbers and pain and distress categories could invite misleading comparisons, misinterpretation, and security concerns. Any public reporting should be limited to appropriately contextualized national aggregate information that does not identify individual institutions.

Ultimately, any new reporting requirement should be proportionate to its demonstrated value and should not compromise the resources available for animal care, research, or scientific oversight. The collection of additional numerical data should not be treated as an end in itself. NIH should ensure that the proposed reporting produces information that is accurate, comparable, and useful, while avoiding unnecessary administrative work for institutions and researchers.

FASEB
FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

REPRESENTING OVER 100,000 RESEARCHERS
6120 Executive Boulevard | Suite 230 | Rockville, MD 20852
faseb.org

Conclusion

FASEB appreciates OLAW's efforts to solicit input from the research community on this proposal. We encourage NIH to use this process to further assess the purpose, feasibility, and potential consequences of annual animal-number reporting before moving forward. In its current form, the proposed requirement raises substantial concerns about administrative burden, data consistency, and the interpretation and public release of institution-level information. FASEB therefore does not recommend implementation as proposed and strongly recommends that any public reporting be limited to national aggregate data.

FASEB welcomes continued engagement with OLAW and NIH on approaches that advance transparency and accountability while maintaining an effective, efficient, and scientifically sound framework for the oversight of research involving animals.

Respectfully,



Michael N. Lehman, PhD
President
Federation of American Societies for Experimental Biology

CC: Darla P. Henderson, PhD
Executive Director & Chief Executive Officer
Federation of American Societies for Experimental Biology
Contact: dhenderson@faseb.org | 301-634-7526