







## Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities

Virtual Meeting October 11, 2024 (10 AM – 11 AM)

## <u>Agenda</u>

- 10:00 am Welcome
- 10:05 am Roll Call
- 10:10 am Approval of Minutes
- 10:15 am Chairman's Discussion
- 10:20 am Review of Draft Report
- 10:55 am Closing Remarks
- 11:00 am Adjourn

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#### **DRAFT MINUTES**

Task Force on Transparency in Publicly Funded Animal Testing Facilities Patrick Henry Building 1111 E Broad St. Richmond, Virginia

September 20, 2024

The third meeting of the Task Force on Transparency in Publicly Funded Animal Testing Facilities (Task Force) convened at approximately 9:00 a.m. on September 20, 2024, at the James Monroe Building. Commissioner of Agriculture and Consumer Services Joseph Guthrie called the meeting to order.

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PRESENT	REPRESENTING
Joseph Guthrie	Chair, Virginia Department of Agriculture and Consumer Services (VDACS)
Dr. Paul Smith	Vice Chair, State Council of Higher Education in Virginia (SCHEV)
Suzanne Griffin	R1 University, Virginia Tech
Dr. Annette Hildabrand	R2 University, James Madison University
Dr. Robert Corley, III	Historically black colleges and universities replacing R3 University, Virginia State University
Daphna Nachminovitch	Animal Welfare, People for the Ethical Treatment of Animals
Sharon Adams	Animal Welfare, Virginia Alliance for Animal Shelters
Will Lowrey	Animal Welfare, Animal Partisan
Dr. D. Josh Cohen	Institutional Animal Care & Use Committee Member, Virginia Commonwealth University
Dr. Raphael Malbrue	American College of Laboratory Animal Testing Facility Veterinarian, University of Virginia
Steve Weddle	Virginia Press Association
Megan Rhyne	Virginia Coalition for Open Government
Corrine Louden	Virginia Freedom of Information Advisory Council
Hon. Jennifer Boysko	Senate of Virginia, Senate District 38
Hon. Hillary Pugh Kent	Virginia House of Delegates, House District 67
Hon. Shelly Simonds	Virginia House of Delegates, House District 70
Hon. William Stanley, Jr.	Senate of Virginia, Senate District 7 (by remote
non. million otanioy, or.	participation)

#### STAFF PRESENT

Kelly Altizer, Associate Director of Operations, Institute for Engagement & Negotiation (IEN) Mike Foreman, Special Projects Manager, IEN Meredith Keppel, Senior Associate, IEN Isaac Joseph, Policy Analyst, VDACS

#### INTRODUCTION

The meeting began by reviewing the minutes from the previous meeting. Dr. Cohen made a motion to adopt the minutes, and Dr. Corley seconded the motion. The Task Force voted unanimously to adopt the minutes.

The Task Force's next order of business was to review and approve an electronic meeting policy, which covered both remote participation and all-virtual meetings. Commissioner Guthrie explained that the purpose of adopting the policy was so that the Task Force could meet remotely in October if the Task Force felt the need to hold a fourth meeting and so that Senator Stanley could attend today's meeting electronically. Megan Rhyne made a motion to adopt the electronic meeting policy, and Dr. Hildabrand seconded the motion. The Task Force voted unanimously to approve the policy. Once the Task Force adopted the policy, Senator Stanley requested to attend the meeting electronically from a Senate retreat being held in Virginia Beach. As provided in Va. Code § 2.2-3708.3(B)(3), Senator Stanley participated through electronic communications means due to the distance between his principal residence and the meeting location. The Task Force approved Senator Stanley's request.

Commissioner Guthrie asked Justin Bell, Assistant Attorney General, to give a brief presentation on whether an Institutional Animal Care and Use Committee (IACUC) is a public body pursuant to the Virginia Freedom of Information Act (FOIA). This question had been raised during previous Task Force meetings. Mr. Bell provided a summary of relevant case law and answered questions from the task force members.

Commissioner Guthrie asked Dr. Charles Broadus, State Veterinarian and Director, Division of Animal and Food Industry Services, to provide a brief presentation on the potential costs and logistics of implementing a website or database repository for animal testing reports with VDACS. Dr Broaddus provided a summary of the duties of the Office of Veterinary Services, which currently does not include regulatory oversight of animal testing facilities. He also provided a cost estimate of that office providing and maintaining a web-based repository for animal testing reports and answered questions from members of the Task Force.

Ms. Nachminovitch and Mr. Lowrey provided the Task Force an overview of the presentation they had prepared regarding the current reporting requirements to which publicly funded animal testing facilities are subject. Copies of the presentation were distributed to the members of the Task Force.

#### **CONSENSUS TESTING**

At approximately 10:00 a.m., Kelly Altizer and Mike Foreman from IEN explained the process of consensus testing that the Task Force would be using to discuss potential proposals. IEN indicated it would present a list of proposals to the Task Force. These proposals were generated from ideas submitted by members of the Task Force prior to the meeting.

On each proposal, the members of the Task Force would anonymously indicate their level of support by writing a number 1, 2, or 3 on an index card. Level 3 support would indicate that the member fully supports the proposal. Level 2 would indicate that the member can accept with the proposal but has questions or concerns about it. Level 1 would indicate that the member does not support the proposal.

Consensus on a proposal would be achieved if all members voted either 3 or 2 and no member voted 1. After each proposal was introduced, the Task Force would take an initial vote of their level of support. After each vote, the Task Force would discuss their questions and concerns with the proposal.

The proposals and the vote tallies were as follows:

#### Proposal Step #1 - How to increase transparency

Proposal A: SCHEV's website will be used for additional information on animal testing.

- Level 3: 12
- Level 2: 3
- Level 1: 0

Proposal B: Universities will provide the U.S. Department of Agriculture - Animal and Plant Health Inspection Service (APHIS) inspection and annual reports to post on SCHEV's website.

- Level 3: 11
- Level 2: 2
- Level 1: 1

Proposal C: Universities will annually produce a report to document progress on the 3 Rs (refinement, reduction, replacement) for SCHEV's website.

- Level 3: 10
- Level 2: 2
- Level 1: 3

#### Proposal Step #2 – Information that could be included in a report by universities

Proposal D: Total number of laboratory animals (i.e., all vertebrates except fish) in the care of the institution, excluding agricultural animals.

- Level 3: 9
- Level 2: 4
- Level 1: 2

Proposal E: How the animals were acquired.

- Level 3: 11
- Level 2: 1
- Level 1: 3

Proposal F: Census of animals born at the facility in the last year, which also excludes agricultural animals.

- Level 3: 9
- Level 2: 3
- Level 1: 3

Proposal G: Disposition of all animals over the last year (i.e., euthanized, lost, adopted, transferred, traded, or sold).

- Proposal G was grouped with Proposal E and the combined proposal was voted on together.

Proposal H: Adverse events (i.e., unexpected incidents that lead to harm or endanger the wellbeing of animals and humans at a research university) during the last year.

- Level 3: 7
- Level 2: 5
- Level 1: 3

Proposal I: Money spent by the facility procure and maintain animals in the last year.

- Level 3: 9
- Level 2: 2
- Level 1: 4

After votes were tallied for each proposal, the Task Force discussed their questions and concerns for each proposal. The Task Force attempted to reach consensus and understanding by discussing specifics and logistics of implementing the proposals, tweaking the proposals to make them more amenable, and offering alternatives. Consensus was reached on proposal A.

#### **PUBLIC COMMENT**

At approximately 11:30 a.m., the Task Force received public comment from in-person attendees.

Charles Todd Woodson, from the Richmond Animal Advocacy Alliance, expressed concern over the difficulty of obtaining animal testing reports through FOIA. He also suggested that animal testing facilities should identify the specific species of animals they are using for testing in case that species is endangered.

Dr. James Bogenpohl, a member of his university's IACUC, expressed his concern that reporting on progress towards the 3 Rs could be problematic because an increase in federal funding could result in an overall increase in research programs and numbers of animals being tested but that this would not reflect the effort that universities take to implement the 3 Rs at the individual research protocol level.

#### CONTINUED CONSENSUS TESTING AND ADJOURNMENT

The Task Force resumed its discussion of proposals at approximately 11:40 a.m.

The Task Force's discussion continued past the scheduled end-time of 12:00 p.m. until the Task Force adjourned at approximately 1:00 p.m.

The Task Force will hold an all-virtual meeting on October 11 at 10:00 a.m. to review the draft Task Force report.

#### POLICY ON PARTICIPATION IN TASK FORCE ON TRANSPARENCY IN PUBLICLY FUNDED ANIMAL TESTING FACILITIES MEETINGS BY ELECTRONIC COMMUNICATIONS PURSUANT TO VA. CODE § 2.2-3708.3

It is the policy of the Task Force on Transparency in Publicly Funded Animal Testing Facilities (Task Force) that individual members of the Task Force may participate in meetings of the Task Force by electronic communications as permitted by § 2.2-3708.3 of the Code of Virginia. This policy shall apply to the entire membership and without regard to the identity of the member requesting remote participation or the matters that will be considered or voted on at the meeting.

Whenever an individual member wishes to participate from a remote location, the law requires a quorum of the Task Force to be physically assembled at the primary or central meeting location.

When such individual participation is due to a personal matter, such participation is limited by law to two meetings per calendar year or 25 percent of the meetings held per calendar year rounded up to the next whole number, whichever is greater.

Further, it is the policy of the Task Force that the Task Force may hold all-virtual public meetings pursuant to subsection C of § 2.2-3708.3. Such all-virtual public meetings are limited by law to two meetings per calendar year or 50 percent of the meetings held per calendar year rounded up to the next whole number, whichever is greater. Additionally, an all-virtual public meeting may not be held consecutively with another all-virtual public meeting.

Requests for remote participation or that the Task Force conduct an all-virtual public meeting shall be conveyed to the Commissioner of Agriculture and Consumer Services.

Individual participation from a remote location shall be approved unless such participation would violate this policy or the provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia). If a member's participation from a remote location is challenged, then the Task Force shall vote whether to allow such participation.

The request for remote participation or that the Task Force conduct an all-virtual public meeting shall be recorded in the minutes of the meeting. If the Task Force votes to disapprove of the member's participation because such participation would violate this policy, such disapproval shall be recorded in the minutes with specificity. The minutes shall include other information as required by §§ 2.2-3707 and 2.2-3708.3 depending on the type of remote participation or all-virtual public meeting.

This policy applies to all committees and subcommittees of the Task Force.

Version History			
Version	Date	Change Summary	
1	9/20/2024	Original	



VIRGINIA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES







## Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities

Patrick Henry Building September 20, 2024

#### Introduction

The third meeting of the Commonwealth Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities was held on September 20, 2024, at the Patrick Henry Building in Richmond, Virginia. The session was attended by all seventeen (17) appointed members or their designees as well as facilitators from the Institute for Engagement & Negotiation (IEN) and members of the public. The following members were present:

Commissioner, Joseph Guthrie (Chair) Virginia Department of Agriculture and Consumer Services (VDACS) Dr. Paul Smith (Vice Chair) State Council of Higher Education for Virginia (SCHEV) Delegate Shelly Simonds (D, VA-70) Delegate Hillary Pugh Kent (R, VA-67) Senator Jennifer Boysko (D, VA-38) Senator William Stanley (D, VA-20) - remote Corrine Louden, Freedom of Information Advisory Council (FOIA Council) Daphna Nachminovitch, People for the Ethical Treatment of Animals (PETA) Dr. Robert Corely, III, Virginia State University Steve Weddle, Virginia Press Association (VPA) Sharon Adams, Virginia Alliance for Animal Shelters (VAAS) Dr. Annette Hildabrand, James Madison University (JMU) Dr. Raphael Malbrue, University of Virginia (UVA) Will Lowrey, Animal Partisan Dr. D. Josh Cohen, Virginia Commonwealth University (VCU) Megan Rhyne, Virginia Coalition for Open Government (VCOG) Suzanne Griffin, Virginia Polytechnic Institute and State University (VT)

#### Welcome, Introductions, and Approval of Minutes

Commissioner of Agriculture and Consumer Services Guthrie introduced himself and Dr. Paul Smith (SCHEV), Vice Chair. Members introduced themselves, and minutes from the August meeting were passed. A remote meeting policy offered by the Chair and was passed by the Task Force. This will allow for remote participation for members with a planned October virtual meeting to review the draft report prior to submission to the General Assembly.

Chair Guthrie asked Senator Stanley to introduce himself and share his response to the initial prompt asking what success in the Task Force would look like, in his view. He explained that Envigo was within his district, and he feels very passionately about this issue. He believes that more steps are needed to protect all animals—not just companion animals which have become better protected following the Envigo incident.

#### **Review Reports for Task Force Members**

Mr. Justin Bell, Office of the Attorney General, was asked to share information about Institutional Animal Care and Use Committees (IACUCs). Specifically, the Task Force wanted to know if IACUCs have a responsibility to public disclosure and whether they are public bodies under the Freedom of Information Act (FOIA). Mr. Bell reviewed a circuit court decision from the 1980s that points to IACUCs not being public bodies. Additionally, an attorney general's opinion from 2001 explains that Institutional Review Boards (IRBs) are not public bodies under Virginia law, and Mr. Bell feels that IRBs are analogous to IACUCs. There was discussion about whether an amendment to that section of the law was reviewed as part of the 2001 opinion.

The group agreed there is significant confusion on this topic and suggested that perhaps legislators may consider clarification in the future. A point was made that if legislators wanted to clarify IACUCs under FOIA, it would be important to note that IACUC records fall under public record, not that they are a public body under FOIA, as that would trigger public meeting notice requirements.

After Mr. Bell, Dr. Charles Broaddus, State Veterinarian, spoke about the Office of Veterinary Services (OVS) which is part of VDACS. He noted that OVS does not interact with universities currently; rather, they primarily prepare for, respond to, and mitigate the outbreak of agricultural animal disease in livestock and poultry. Their main mission is to investigate and contain the spread of agricultural disease. Dr. Broaddus also shared that OVS is happy to take on more duties as the General Assembly sees fit, but they estimated they would need at least one more full-time employee (FTE) as well as over \$250,000 in the first year to establish a database. It is estimated that an additional \$110,000 would be needed to keep the software running on an annual basis. There was a request for more information on how the cost was derived. The Commissioner agreed that Dr. Broaddus would provide the quote from VDACS IT.

Megan Rhyne (VCOG) provided information about a bill she had seen referenced several times in public comment and by the Task Force. This information was provided in the packet given to each Task Force member

Daphna Nachminovitch (PETA) provided an overview of the presentation she created with Will Lowery (Animal Partisan). She highlighted that the impetus for the legislation that precipitated the Task Force was the high number of APHIS violations by Virginia institutions. Ms. Nachminovitch also pointed out that the Animal Welfare Act is the only federal regulation which protects some of the animals tested on (again, reminding members that rats, mice, and some birds are excluded). She also wanted to bring to the Task Force's attention that there is a difference between designated member review (DMR) vs. full committee review (FCR) which changes the IACUC process. There was a question about self-reporting of adverse events to NIH's Office of Laboratory Animal Welfare (OLAW) and whether this information is publicly available. Ms. Nachminovitch confirmed that the information in their presentation was obtained through FOIA. There was a follow-up question about whether the majority of research at the universities is federally funded and, therefore, required to self-report to OLAW. The universities said that it varies by institution but that a significant amount of their research is federally funded.

#### **Review of Agenda and Meeting Summary**

Mike Foreman (IEN) reviewed the agenda for the day and reintroduced the group requests/ground rules that guide engagement for the Task Force.

#### **Review Consensus Testing Process**

Kelly Altizer (IEN) reviewed the process for consensus testing and how members would indicate their level of support for a proposal using a 3, 2, or 1. which corresponds to the following:

- (3) Full support for the proposal
- (2) Has some questions or concerns, but can accept the proposal
- (1) Cannot support the proposal as written

Ms. Altizer explained to the group that index cards would be used to allow for anonymous testing for consensus, but that discussion would follow to allow concerns to surface and adjustments to be made to the proposal where needed. Questions were answered about other logistics related to testing for consensus.

Commissioner Guthrie had invited Task Force members to submit their ideas for draft proposals prior to the meeting. Draft proposals were submitted by Dr. Raphael Malbrue, Delegate Shelly Simonds, Daphna Nachminovitch & Will Lowrey, and Sharon Adams, and all are included in Appendix A.

#### **Proposal Review and Evaluation**

Mr. Foreman and Ms. Altizer shared that the IEN team had identified some areas of common ground between the draft proposals submitted, and were offering a combination of those ideas as a start point for testing for consensus. The Commissioner shared that he and Dr. Smith (SCHEV) would abstain from participating in the tests for consensus.

Midway through the consensus testing process, the Commissioner identified that more time was needed, and participants agreed to extend the meeting time until 1:00 p.m. in order to ensure more material could be covered by the group.

#### **Proposal Evaluation: Part One**

Proposals considered in the first round of testing for consensus included:

- A) The SCHEV website will be used for additional information on animal testing [note: this is in response to concerns raised by members that information can be difficult to find and located in many different places, so it would be helpful if there one location where information could be found]
- B) The universities will provide APHIS annual and inspection reports to be posted on the SCHEV web site.
- C) The universities will annually produce a report to document their progress on the 3 Rs to be posted on the SCHEV website.

	Proposal	Proposal	Proposal
	Α	В	С
No Support	0	1	3
Support with Concerns	3	2	2
Full Support	12	11	10
ABSTAIN		1	
TOTAL	15	15	15
% of NO SUPPORT	0%	7%	20%
% of SUPPORT with concerns	20%	13%	13%
% of FULL SUPPORT	80%	73%	67%

#### Table 1. Consensus Tabulation for Proposals A, B, and C

# Discussion of Proposal A: The SCHEV website will be used for additional information on animal testing

Ms. Altizer noted that this point was raised in the Task Force's first meeting, and at the time members thought that the VDACS website might be an appropriate venue for this information. However, after that meeting, SCHEV was identified as a better fit. Dr. Smith reminded the group that this was because they already have mechanisms in place to receive and post other information from the Universities, while VDACS does not.

Some members expressed concerns about whether the public would know to look at SCHEV's site for this information but were not opposed to it being posted there.

This proposal achieved consensus (3-12, 2-3, 1-0).

## **Discussion of Proposal B -** The Universities will provide APHIS annual and inspection reports to be posted on the SCHEV web site.

Some members expressed concerns that this does not advance transparency since the universities already have to post the reports on their website. In general, group members were supportive of measures that make it easier for people to access information.

This proposal received strong support but did not achieve consensus (3-11, 2-2, 1-1, 1 abstention).

# Discussion from Proposal C - The universities will annually produce a report to document their progress on the 3 Rs to be posted on the SCHEV website.

Group members were generally supportive of more information being shared by the universities, but some members did not want to support this proposal without the inclusion of specific components which were evaluated by the group in the next section below.

One member noted a concern about creating additional reporting burden for researchers.

This proposal received strong support but did not achieve consensus (3-10, 2-2, 1-3).

#### Proposal Evaluation: Part Two

In the second portion of proposal evaluation, group members considered six proposed indicators to be included in an annual report by the universities. They are as follows:

- D) The total number of laboratory animals held in the care of research institutions (excludes agriculture)
- E) How animals were acquired by research institutions (purchased or adopted)
- F) Census Number<sup>1</sup> of animals born at research institutions in last year
- G) The disposition of all animals at research institutions over the last year (euthanized, lost, adopted, transferred, traded, or sold to other facilities).
- H) Adverse events at research institutions during the preceding year (identified by species, as defined by NIH)
- I) The money spent by each research facility in the preceding calendar year for the use of animals in research to procure and maintain the animal.

<sup>1</sup> The word "census" was changed to "number" by the Task Force during the discussion to increase clarity of the statement

The following general discussion points came out during the initial Task Force dialogue:

- Animal as defined by this proposal is "all animals except for fish."
- This would be reported by animal research facilities—which specifically excludes agriculture per Virginia Code
- Reporting these numbers does not preclude the universities from reporting additional context or information with it.
- Adverse event definition from OLAW: "unexpected incidents that lead to harm or endanger the well-being of animals and humans at a research facility."
- Suggestion to change animals "born" to "animals who make it past weaning" as with many rodents there are often issues with interacting with just born animals (puts undue stress on dames) and the fact that many rodent dames eat their young
  - Rebuttal: would not want to change to only animals weaned for primates or dogs / cats / etc. when there are several issues with babies of these species

	Proposal D	Proposal E	Proposal F	Proposal G	Proposal H	Proposal I
No Support	2	3	3	3	3	4
Support with Concerns	4	1	3	1	5	2
Full Support	9	11	9	11	7	9
TOTAL	15	15	15	15	15	15
% of NO SUPPORT	13%	20%	20%	20%	20%	27%
% of SUPPORT with concerns	27%	7%	20%	7%	33%	13%
% of FULL SUPPORT	60%	73%	60%	73%	47%	60%

Table 2. Consensus tabulation for Proposals D through I

Each proposal is reflected below along with the comments, ideas, and questions that were raised in the discussion:

## **Discussion of Proposal D:** Total number of laboratory animals held in the care of research institutions

Concerns about the economic cost, burden on researchers, and animal by animal count

- Change could be to make it an approximation or capacity at the research or a range of animals at an institution
- Difficulty around language and precision of counting. In order to make these counts, financial software needs to be acquired, and FTEs need to be hired.

- Question posed—if you know a general amount of food acquired, can you not aggregate to estimate the number of animals?
  - The food is not tracked centrally, it is still difficult to aggregate and takes time and resources
- Discussion about whether these numbers are already being tracked and whether they can just be shared with SCHEV?
  - Universities noted that the numbers submitted to their IACUCs reflect the *maximum* number of animals proposed.
- Universities are not opposed to providing a point in time count of animals; but it would still require financial support
  - 0

This proposal received strong support but did not achieve consensus (3-9, 2-4, 1-2).

## **Discussion From Proposal E:** How animals were acquired by research institutions (purchased or adopted)

- Question about whether animals are inspected when they are acquired
  - Attending vets inspect commercial facilities from which the institution acquires animals from
- With more explanation that animals would just be number of animals purchased vs adopted, etc., some opposition may become more likely to find common ground
- Clarified that information wanted is number of animals acquired through purchase or through adoption

#### Discussion From Proposal F- Number of animals born at research institutions in last year

- Reminded the group about the rodent example put forward before—trying to count rodents born during a year is incredibly difficult (do we count rodents who die via miscarriage or in birth or directly after birth?)
  - Many rodents are culled in biomedical research because they do not have the right genotype
- Suggestion that this would be particularly difficult for rodents (could be a category in G)

## <u>Discussion From Proposal G</u>- The disposition of all animals at research institutions over the last year

- Estimated animals within the categories of euthanized, lost, adopted, transferred, traded, or sold
- Discussion about how some of these datasets are not able to be done through point in time; they are ongoing which requires more resources
  - Universities made the point that this information is not something they are against; they just want to be responsible with taxpayer money given that there is an associated cost
- Clarification that the inclusion of this information would require yearlong tracking
  - $\circ$   $\;$  Accounting for every animal and where they came from / where they end up

- Much of the difficult capturing disposition and breeding numbers revolves around rodents' population colony

## Discussion From Proposal H- Adverse events at research institutions during the preceding year

No new comments raised

This proposal received some support but did not achieve consensus (3-7. 2-5, 1-3).

## **Discussion From Proposal I**- The money spent by each research facility in the preceding calendar year for the use of animals in research to procure and maintain the animal

- Financial data is very difficult to aggregate and is well protected. This may be incredibly burdensome to report.
- There is an assumption that money given by the federal government is reported and tracked, so the information is already available, however those reports do not give a granular budget breakdown.
  - This proposal received strong support but did not achieve consensus (3-9, 2-2, 1-4).

#### Summary of Consensus Results

Many of the proposals received strong overall support from the group. In general, animal and transparency advocates sought changes that would make specific data available and more readily accessible than it currently is. Most representatives from animal testing facilities were receptive to the different types of information being requested, and sought to help Task Force members understand some of the challenges inherent in procuring that information, as well as the burden it would represent from a financial and personnel perspective.

#### **Next Steps**

The Commissioner shared that VDACS would be working on the draft report, and that a virtual meeting would be held on October 11<sup>th</sup> so that Task Force members could share their comments on the document prior to its submission to the General Assembly.

#### **Chair Remarks and Public Comment Period**

Public comments were provided in-person by two people and those will be reflected in the final report.

The Task Force adjourned at 1 pm.

## **Appendix A: Submitted Proposals**

# <u>Proposal #1 - University Proposal (submitted by UVA on behalf of the partner institutions)</u>

#### Commissioner Guthrie,

I hope this message finds you well. I am writing on behalf of most, if not all, institutions represented on the task force on transparency in publicly funded animal testing facilities. Below is a list of recommendations that we believe will further enhance transparency in animal research conducted at public institutions within the Commonwealth.

At the heart of our institutions' mission is a deep commitment to responsible, ethical research and a genuine desire to address public concerns. We value the trust and investment the public has placed in our work, and it is our goal to ensure that our practices not only uphold the highest standards of care but also reflect the interests and concerns of the communities we serve.

With that in mind, we have carefully considered the following recommendations, which we feel will promote a clearer, more transparent relationship between public institutions and the public when it comes to animal research:

#### Goals:

- To provide greater transparency
- To facilitate public access to information compiled and required under existing regulatory schemes governing laboratory animal research
- To support the Commonwealth's ability to advance research that is vital for the advancement of both human and animal condition, and minimize burdens placed on researchers and institutions

#### Recommendations: On or before July 1 of each year

- Each institution that holds USDA registration shall provide its most recent annual report to the USDA APHIS on its required form that provides the number of animals by species
- Each institution that holds USDA registration shall provide a copy of each USDA APHIS inspection report (which includes the VMO findings from inspection potentially including citation) as well as the institution's response, if applicable
- Each institution shall generate a summary of all FOIA requests received over the preceding fiscal year related to animal research including requesting party

- Each institution shall provide a narrative report of the federal and state requirements applicable to the institution's animal research program as well as such institution's additional internal processes designed to strengthen its commitment for the ongoing improvement of animal care and welfare
- Include institution's philosophy and approach to advancing the 3Rs in animal research (Replacement, Reduction, and Refinement)
- Include general information about the professional qualifications of the institution's IACUC
- The State Council of Higher Education for Virginia (SCHEV) shall provide a landing page on its website directing to the above reports for ease of public access so interested parties can readily access the information in one location
- Institutions shall establish of an annual Higher Education Biomedical Research Day (at the Virginia General Assembly) that is organized by the institutions to provide awareness, outreach, and education about biomedical research activities in the Commonwealth and the opportunity for meaningful dialogue about the programs with the public

We believe that by implementing these steps, we can strengthen public trust and ensure that the research being conducted within the Commonwealth is both ethical and transparent.

Thank you for considering these recommendations. We would be happy to engage in further dialogue and provide additional details if needed at the upcoming task force meeting. Please don't hesitate to reach out with any questions or thoughts.

Respectfully,

Raphael A. Malbrue, DVM, MS, CertAqV, DACLAM Director & Attending Veterinarian Center for Comparative Medicine

#### Proposal #2 - Delegate Simonds

During our Task Force meetings, our university partners have expressed a sincere commitment to the ethical treatment of animals used in academic research and we have learned that universities do have rigorous in-house procedures to track the animals used in research as part of IACUC protocols.

At issue is that these research protocols and documentation are not available to the public, despite well-established public interest in animal testing. Therefore, we have a disconnect between the rigorous tracking happening inside the university and public access to this information.

I propose that our task force recommend a new requirement that all public universities doing research using animals publish an IACUC annual report summarizing data from current IACUC protocols and giving context for this research. Every report would be required to include the following data:

- The total number of animals used for research including birds, mice and rats with such animals identified according to species.
- How they were acquired or purchased or adopted.
- The number of animals born at the facility during the preceding calendar year.
- The disposition of the animals by group at the end of the calendar year; meaning the number of animals euthanized, lost, adopted, transferred, traded or sold to other facilities during the preceding calendar year.
- The number of animals who experienced adverse events during the preceding year identified by species, where adverse events means those unexpected incidents that lead to harm or endanger the well-being of animals or humans at a research facility.
- The dollar amount expended by each facility in the preceding calendar year for the use of animals in research to procure and maintain the animal.

The report would include data on animals used across the university so as to protect intellectual property in specific experiments. The report would also allow universities to provide context and organize the information the way they prefer, to include the narrative context of their research programs and how they are addressing the international principals of the "Three Rs" replacement reduction and refinement.

I hope we can discuss this idea at our upcoming meeting.

Sincerely,

Del. Shelly Simonds

#### Proposal #3 - Animal Partisan / PETA Proposal

Original legislation: <u>SB411</u> and <u>HB580</u>

An animal testing facility (as defined here) that uses an animal test method shall annually submit to the Virginia Department of Agriculture and Consumer Services (VDACS) or to the State Council of Higher Education for Virginia (SCHEV) in a format prescribed by the following information.

- 1. The total number of animals (on hand both at the beginning of the reporting period and at the end of the reporting period) used or held, for research, education, testing, or experimental, scientific, or biomedical purposes with such animals identified and grouped according to use and species.
- 2. The number of animals purchased and/or acquired from, including via transfer or trade with, other animal testing facilities or suppliers, during the preceding calendar year, with such animals identified and grouped according to species, and including the names and locations of the facilities supplying the animals, and identifying the numbers of each species supplied by each such facility.
- 3. The number of animals born at the facility during the preceding calendar year, with such animals identified and grouped according to species.
- 4. The number of animals euthanized, lost, adopted, transferred, traded or sold to other facilities during the preceding calendar year, with such animals identified and grouped according to disposition outcome and species.
- 5. The number of animals who died unassisted during the preceding calendar year, identified and grouped according to species.
- 6. The number of animals who experienced adverse events during the preceding calendar year, identified and grouped according to species; where the term "adverse events" means "those unexpected incidents that lead to harm, or endanger the well-being of animals or humans at a research facility."
- 7. The dollar amount expended by such facility during the preceding calendar year on activities that involved the use of animals in research, education, testing, experimental, scientific, or biomedical purposes where such dollar amount shall include amounts spent to procure and maintain the animals (including food, housing, veterinary care, administrative costs, animal care technicians, and other related costs) as well as amounts spent during the course of use of the animal.

#### Proposal #4- VA Alliance for Animal Shelters

Dear Commissioner Guthrie, co-Chair Smith and Members of the Task Force,

Please accept this proposal as the VAAS recommendation for approval by the Transparency Task Force to be forwarded for action by the Virginia Legislature. Virginia law requires that publicly funded entities provide an array of annual reports and public information to inform its citizenry, to encourage participation in democracy, and to ensure accountability. The purpose of requiring publicly available and comprehensive reports including the number of animals being held and used for experimental purposes in taxpayer-funded institutions is consistent with Virginia's requirements for other animal handling organizations and the responsibility associated with using tax dollars to support an organization's work.

The concerns presented to the Transparency Task Force regarding the publication of information regarding animals being held for and used for experimental purposed in Virginia seem to be the following:

#### It would be costly to produce animal counts or additional reports.

Inasmuch as Dr. Malbrue has presented documents reflecting where some information is already being collected, it doesn't appear that aggregating the information for a Virginia report would support the astronomical increased costs presented as an obstacle. All of the information that we believe should be reported is already being collected as part of any research protocol and the IACUC application process.

#### The information is either irrelevant or confusing without context.

The institutions can provide context by directing the interested parties to the websites of each institution where further explanations and information can be offered. Every institution believes that the research it is performing is valuable. Its researchers must make the case for conducting that research during the IACUC application process. Accordingly, the institutions would be the very best advocate for these activities and could provide context to their liking. The institution need not present information on ongoing research that would compromise it but can readily present information and make broader statements about the ongoing intent and perceived benefits of its research.

# Production of this information will negatively impact future research efforts in Virginia.

The institutions have provided no evidence supporting this assertion. In fact, many sources suggest that researchers may actually benefit from more transparency which could improve accountability, obtain valuable input for institutional decision making, and bolster public confidence.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7912879/

https://speakingofresearch.com/2018/02/20/basel-declaration-society-conference-callsfor-greater-transparency-in-animal-research/ https://news.uoguelph.ca/2022/08/howinstitutional-transparency-could-improve-animal-research/

#### 4. The information may not be of interest to the public.

The argument that it is unknown whether the public is interested in this topic is refuted by numerous studies and surveys. For example, a Pew Research article reflecting the opinions of the public relative to animal <u>research-https://www.pewresearch.org/short-reads/2018/08/16/americans-are-divided-over-the-use-of-animals-in-scientific-research/.</u> According to this survey, the public already has opinions regarding animal research and 52% oppose it. Those opinions would be enhanced by access to accurate and complete information. Notwithstanding that research, hundreds of organizations large and small are required to report annually on public websites including those not directly receiving taxpayer funds, indicating the General Assembly's recognition that the citizens of the Commonwealth value data on the workings of the government and other entities. For example, all nonprofit organizations must file an annual report with the State Corporation Commission.

It is a foundational expectation that organizations receiving taxpayer funds, as well as many others, are publicly accountable for the activities supported by those funds. In fact, higher education institutions have an obligation to publish an array of information, for example <a href="https://law.lis.virginia.gov/vacode/title23.1/chapter4/section23.1-409/">https://law.lis.virginia.gov/vacode/title23.1/chapter4/section23.1-409/</a>. Surely responsibly posting about the sentient animals being held and used for research at a publicly funded institution is at least as relevant to the public as "the average wage of undergraduate alumni within 20 years of graduation" which is currently required to be reported annually. (See above statute)

Therefore, the proposal outline below is recommended for adoption:

The APHIS Annual Report of Research Facility for each institution should be posted on the SCHEV website annually and be accompanied by the following additional information by species, to include all species used in research, including those currently excluded by the Animal Welfare Act: (See Attachment A below)

- Number of animals purchased by the research facility, transferred in or out of the research facility, or bred in the research facility.
- Number of animals euthanized or died unassisted.
- Number and description of Adverse Events as defined by the National Institutes of Health.

B. The addition of the aforementioned data for other species of currently excluded animals should accompany the annual report, including the count of such animals.

Finally, the inclusion of the amount of Virginia and federal taxpayer funding for animal research for each institution should be posted along with the above-mentioned report.

We believe that all of this information is already being collected as a consequence of the research itself or the management of the animals in the institutions' care. Counting the number of animals in the care of the institution once per year does not seem to be an onerous burden. The posting of each public institution's annual report will enable any interested party to follow the progress of that institution in achieving the 65-year-old goal of the 3Rs: <u>Reducing, Refining and Replacing the number of animals used for experimentation</u>. The report will also enable the institutions to provide further context for their research activities by linking each report to its website. Respectfully submitted,

Sharon Quillen Adams, MPA Chair, Virginia Alliance for Animal Shelters

(Attachment Annual Report of Research Facility)

# Task Force on Transparency in Publicly Funded Animal Testing Facilities Report

# Joseph W. Guthrie, Commissioner of Agriculture and Consumer Services

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Report of the Task Force on Transparency in Publicly Funded Animal Testing Facilities

#### **PUBLICATION YEAR 2024**

#### **Document Title**

Report of the Task Force on Transparency in Publicly Funded Animal Testing Facilities

#### Author

Joseph W. Guthrie, Commissioner of Agriculture and Consumer Services

#### Legislative Mandate

Chapters 675 and 693 of the 2024 Acts of Assembly

#### **Executive Summary**

As required by Chapters 675 and 693 of the 2024 Acts of Assembly (Acts), the Department of Agriculture and Consumer Services (VDACS), in collaboration with the State Council of Higher Education for Virginia (SCHEV), convened a Task Force on Transparency in Publicly Funded Animal Testing Facilities (Task Force) for the purpose of identifying potential deficiencies in publicly funded animal testing facilities, as that term is defined in § 3.2-6593.2 of the Code of Virginia, and recommending methods and context for making certain information about such animal testing facilities publicly available. The Task Force convened three separate meetings (July 26, 2024; August 30, 2024; and September 20, 2024) to discuss the existing framework for reporting animal testing statistics, the deficiencies in the existing framework, and ways to build upon or alter that framework to address the concerns of both the public and the publicly funded animal testing facilities. The Acts require the Task Force to report its findings and recommendations to the House Committees on Agriculture, Chesapeake, and Natural Resources; Finance; and Appropriations and the Senate Committees on Agriculture, Conservation, and Natural Resources and Finance and Appropriations by November 1, 2024.

The Task Force recommends that the General Assembly continue to explore the following areas when considering future legislation:

#### Utilizing SCHEV's website for information and reporting

The Task Force recommends that SCHEV use its website to host additional information about animal testing at publicly funded institutions. While some Task Force members were hesitant to lend their full support to this proposal without first discussing the potential content of new reporting requirements, the Task Force agreed that SCHEV should be the contact point for any new information or reporting requirements on animal testing.

#### Making existing reports accessible

Much of the Task Force's discussions revolved around what information and reports already exist and how the public can access them. The General Assembly may wish to consider options for making existing animal testing reports that publicly funded animal testing facilities already generate accessible to the public by means other than Freedom of Information Act requests, such as by collecting and posting these reports on SCHEV's website, and in a manner that minimizes the reporting requirements on publicly funded animal testing facilities.

#### Creating a Virginia-specific report

The area with the least amount of consensus from the Task Force concerned the creation of new reporting requirements. The main impediment for reaching consensus on this proposal is the uncertainty as to what specifically will be required in such report. While most members of the Task Force were supportive of a report that demonstrates progress towards the "3 Rs" (replacement, reduction, refinement), the Task Force was unable to achieve consensus on how to best measure that progress.

Elements of a Virginia-specific report that the General Assembly may wish to consider are:

- (i) Whether the report will be narrative or include quantifiable metrics
- (ii) The inclusion of all vertebrate animals, except for fish and agricultural animals
- (iii) Reporting a count of all animals in the care of the institution at the end of a reporting period
- (iv) Reporting on acquisitions and dispositions of animals throughout the reporting period
- (v) Considering whether the report would require research institutions to collect pointin-time data once during the reporting period or to collect data throughout the reporting period
- (vi) Providing certain allowances or exceptions for counting rats and mice (e.g., allowing rats and mice to be counted using cages or estimates or excluding rats and mice from counts of animals bred at the facility)
- (vii) The inclusion of other information that is already collected and reported to other organizations by the research facility

#### Introduction

Chapters 675 and 693 of the 2024 Acts of Assembly (Act) directed the Virginia Department of Agriculture and Consumer Services (VDACS), in collaboration with the State Council of Higher Education for Virginia (SCHEV), to convene a Task Force on transparency in publicly funded animal testing facilities (Task Force) (*Appendix A*). As stated in the Acts, the purpose of the Task Force is to identify potential deficiencies in publicly funded animal testing facilities and to recommend methods and context for making certain information about such animal testing facilities publicly available, including information pertaining to instances of noncompliance with federal animal welfare regulations, guidelines, or policies; as well as the care, use, and approximate numbers of animals used for research, education, testing, or other experimental, scientific, or medical purposes by each public institution of higher education in the Commonwealth, including animals not covered by the federal Animal Welfare Act (7 U.S.C. § 2131 *et seq.*).

The Act requires that the Task Force consist of (i) representatives from one institution of higher education in the Commonwealth with Carnegie research classification R1, one institution of higher education in the Commonwealth with Carnegie research classification R2, and one institution of higher education in the Commonwealth with Carnegie research classification R3; (ii) representatives from three unaffiliated animal protection or animal welfare watchdog groups in the Commonwealth; (iii) an individual who serves as a member of an institutional animal care and use committee at one of the Commonwealth's publicly funded animal testing facilities; (iv) a Virginia-licensed American College of Laboratory Animal Medicine-certified veterinarian functioning in the role of attending veterinarian at one of the Commonwealth's publicly funded animal testing facilities; (v) a representative of the Virginia Press Association; (vi) a representative of the Virginia Coalition for Open Government; (vii) a member of the Virginia Freedom of Information Council; and (viii) two members of the Senate appointed by the Senate Committee on Rules and two members of the House of Delegates appointed by the Speaker of the House of Delegates. As VDACS was unable to identify an institution of higher education with Carnegie research classification R3, the agency chose a representative from a historically black university or college in the Commonwealth. As such, the Task Force consisted of the following members (Appendix B):

- Joseph Guthrie, Commissioner of Agriculture and Consumer Services (Chair)
- Dr. Paul Smith, State Council of Higher Education for Virginia (Vice Chair)
- Suzanne Griffin, Virginia Tech (R1 University)
- Dr. Annette Hildabrand, James Madison University (R2 University)
- Dr. Robert Corley, III, Viginia State University (Historically Black University)
- Daphna Nachminovitch, People for the Ethical Treatment of Animals (Animal Welfare)
- Sharon Adams, Virginia Alliance for Animal Shelters (Animal Welfare)
- Will Lowrey, Animal Partisan (Animal Welfare)
- Dr. D. Josh Cohen, Virginia Commonwealth University (Member of Institutional Animal Care & Use Committee)
- Dr. Raphael Malbrue, University of Virginia (American College of Laboratory Animal Testing Facility Veterinarian)
- Steve Weddle, Virginia Press Association
- Megan Rhyne, Virginia Coalition for Open Government

- Corrine Louden, Virginia Freedom of Information Council
- Hon. Jennifer Boysko, Senate of Virginia, Senate District 38
- Hon. William Stanley Jr., Senate of Virginia, Senate District 7
- Hon. Hillary Pugh Kent, Virginia House of Delegates, House District 67
- Hon. Shelly Simonds, Virginia House of Delegates, House District 70

#### Background

The Acts direct the Task Force to identify potential deficiencies in publicly funded animal testing facilities' informational reporting. Specifically, the Acts direct the Task Force to address certain areas of concern, such as instances of noncompliance with laws, regulations, or guidelines, as well as information on research animals not covered by the federal Animal Welfare Act. As such, much of the background of the Task Force's discussions revolved around the existing framework for reporting information on animal testing and whether that framework fell short of providing the public with the desired information.

This section will provide a brief overview of the most common types of animal testing reporting requirements that already exist for publicly funded animal testing facilities in Virginia in order to provide a landscape for the Task Force's discussions and proposals that follow in this report. Currently, informational reporting on animal testing in public universities is governed by a mix of federal laws and regulations, guidelines from federal agencies, and voluntary accreditation organizations.

The U. S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for overseeing the requirements of the federal Animal Welfare Act (AWA) and corresponding regulations. Under this regime, any animal testing facility that (i) purchases or transports covered animals in interstate commerce or (ii) receives federal funding is required to follow AWA reporting requirements. Importantly, covered animals under the AWA include only certain warm-blooded vertebrate animals but do not include rats, mice, birds, or cold-blooded animals that are often used in research. APHIS requires an annual report on the number of covered animals (i) held by the institution for research, (ii) used in research, (iii) experiencing pain or distress without the use analgesic, and (iv) experiencing pain or distress with the use of analgesic. These annual reports are accessible on USDA's website, and Chapters 532 and 533 of the 2023 Acts of Assembly added to the Comprehensive Animal Care Law a new section (Va. Code § 3.2-6593.2) that requires these reports and USDA inspection reports to be posted on the universities' websites as well.

The National Institutes of Health's (NIH) Office of Laboratory Animal Welfare (OLAW) is responsible for ensuring that research facilities that receive federal funding adhere to its guidelines set forth in the Public Health Service Policy (PHS Policy) as well as the Guide for the Care and Use of Laboratory Animals (Guide). These requirements cover all vertebrate animals used in research (including those not covered by the AWA) but only cover research funded by the NIH and other participating federal agencies (such as the Department of Veteran Affairs and the National Aeronautics and Space Administration). While testing facilities conducting federally funded research have annual and semiannual reporting requirements to OLAW, these reports do not include information about animals being used in research. These reports include broad-stroke information about changes in the institution's status, the members of its IACUC, and changes in

its program for the care and use of research animals. Instead, testing facilities include information about the number and type of animals – in additional to other information – that they plan to use for research in the "Vertebrate Animal Section" of applications and proposals for grants submitted to NIH. Additionally, violations of the PHS Policy are self-reported on a case basis by testing facilities to OLAW through the facilities' Institutional Animal Care and Use Committees (IACUC). Reports submitted to OLAW are accessible through use of the federal Freedom of Information Act (FOIA).

Both APHIS and OLAW require each covered research institution to maintain its own IACUC. While APHIS and OLAW each have separate requirements concerning the research institution's IACUC, such as the make-up of its membership, most research institutions maintain a single IACUC that meets both agencies' requirements. An IACUC is an independent body made up of scientists involved in animal research, veterinarians with experience in animal lab testing, and at least one member of the public not affiliated with the research institution, among others. An IACUC will review research protocols and proposals submitted by a research program from the institution and monitor the program's compliance with the protocol and applicable animal welfare laws, whether AWA, the PHS Policy, or the Guide. An IACUC is responsible for preparing the annual and semiannual reports to OLAW as well as reports of violations of the PHS Policy. Information on the animals that a research program plans to use for research, including the number and species of animal and the justification for their use, is submitted to an IACUC at the initial protocol/proposal stage or when the research program's protocol/proposal is modified. An IACUC has the authority to deny a protocol/proposal or request that it be modified.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) is a private, non-profit organization that offers voluntary accreditation to research facilities. Some federal grant programs, however, may require an institution to be AAALAC International accredited to apply for grants. While accredited research institutions submit annual reports of animals used in testing, this information is not publicly available because AAALAC International is a private organization.

References to these organizations, laws, and reports will be made throughout this report.

#### **Task Force Meetings**

The Task Force convened three separate meetings over the course of its legislative mandate during which the Task Force engaged in facilitated discussions about the current framework for reporting animal testing at public institutions of higher education and whether this framework is sufficient or may be expanded upon or improved. These meetings were held on July 26, 2024; August 30, 2024; and September 20, 2024. VDACS elected to hire a third-party mediator, the Institute for Engagement and Negotiation (IEN), to facilitate the discussions at each meeting. IEN is a public service organization of the University of Virginia.

The purpose of the discussions in the Task Force's first two meetings was to educate the members of the Task Force on the issues affecting this topic and to understand the different positions and perspectives of the members. These discussions helped narrow the focus of the proposals that were finally introduced and considered at the Task Force's third meeting.

#### July 26, 2024

At the beginning of the Task Force's first meeting, the members were given copies of the enacting legislation, a list of members, and a meeting agenda. The agenda is attached as *Appendix C*. Commissioner Guthrie opened the meeting and gave a presentation to the members of the Task Force outlining the Task Force's purpose (*Appendix D*). All members of the Task Force then introduced themselves, explained their connection or experience with the topic, and gave their aspirations for success for the Task Force.

IEN initiated the Task Force's discussion by prompting each member of the group with the same question: "In your view, what, if any, deficiencies exist in transparency around publicly funded animal testing facilities?" This promptly led to a discussion among the Task Force members about what reporting requirements already exist and what information is currently publicly accessible. Members of the Task Force who were familiar with the reporting requirements of animal testing facilities helped educate other members of the Task Force on the different reports and organizations, such as APHIS, OLAW, and IACUC. Much of this information is outlined in the Background section of this report.

Some members of the Task Force took this opportunity to point out the deficiencies of this existing framework in their view. For example, while annual APHIS reports and USDA inspection reports are easily accessible through the USDA's or universities' websites, these reports do not include information on all vertebrate species, such as mice or rats, and only report on violations of the AWA. Information on non-AWA-covered animals and violations of the PHS Policy are reported to OLAW, but this information is only accessible through FOIA. Many members of the Task Force, both representing universities and animal welfare organizations, expressed a common view that FOIA requests were burdensome, lengthy, and costly for all parties involved. A question was raised by members of the Task Force about whether IACUCs, which serve as a nexus for much of the information and reporting about animal testing generated by research institutions, are public bodies subject to Virginia's FOIA laws. At this time, other questions about FOIA were raised, such as whether exemptions from disclosure under FOIA apply to any of these records.

Thus, while some members of the Task Force found it difficult to access the type of information they desired from these multifarious records from different organizations, other members emphasized the amount of time and resources that are already expended by research institutions to prepare these reports.

During these discussions, the members of the Task Force considered the idea of collating all this information into one Virginia-specific report or centralizing all the records already generated by research institutions into one website or database hosted by VDACS or another state agency. Some members of the Task Force continued to emphasize that creating new reporting requirements would add to the regulatory burden of researchers. It was pointed out that Virginia research institutions would find it harder to attract and maintain important research programs if regulatory burdens were increased. Some members also expressed concern that reporting on pure numbers of animals without any context could be misleading or misinterpreted. For example, an increase in animals used for testing could be the result of increased funding and research programs, not a deviation from the research institution's commitment to reduce animal testing.

Other members argued that research institutions did not have a right to withhold information from the public simply because it may be misinterpreted, while others pointed out that reporting on numbers would not preclude a wider conversation about the context behind the numbers.

Before the conclusion of the Task Force's meeting, the Task Force received public comments from in-person attendees. Lisa Balance, Associate Vice President for Strategy and Regulatory Affairs, Virginia Commonwealth University, noted that the USDA website is searchable for every report from Virginia, including inspection reports. A member of the public would not need to go to each institution's website to find the reports.

The meeting summary for July 26 is attached as *Appendix E* and the meeting minutes are attached as *Appendix F*.

#### August 30, 2024

Prior to the Task Force's second meeting, Commissioner Guthrie tasked Dr. Malbrue as a subject matter expert to provide the Task Force with a factual report summarizing the current reporting requirements and defining the many acronyms that were used during the July meeting. This report was particularly intended for the benefit of the several task force members who are not experts in animal testing. Dr. Malbrue's presentation was provided to the Task Force members several days prior to the meeting, and Commissioner Guthrie asked Dr. Malbrue to give a brief synopsis of the report at the beginning of the August 30 meeting (*Appendices G and H*).

The agenda for the Task Force's second meeting is attached as *Appendix I*. IEN structured the meeting's discussion to revolve around three separate smaller group discussions. The members of the Task Force were split into one of these three smaller groups, and each group tackled a different topic of discussion that was facilitated by IEN. The Task Force then reconvened as one group, and each smaller group reported to the larger group the topics and proposals the smaller group had discussed. The discussion was opened to the full Task Force for anyone to add any ideas or comments to the report from each smaller group.

#### Group 1: Information Content

The first group consisted of Senator Boysko, Suzanne Griffin (Virginia Tech), Will Lowrey (Animal Partisan), and Aimee Seibert (designee for Steve Weddle, Virginia Press Association). This group was tasked with discussing the type of information desired by the public. Among the types of information discussed by the group that the public would want access to, and that may or may not already be accessible to the public, were:

- (i) animal counts by species, including non-AWA animals, in the custody of a research facility
- (ii) the status or disposition of the animals, such as whether any were euthanized or transferred
- (iii) any adverse events or violations of law that are required to be reported to APHIS or OLAW
- (iv) added context for the data reported to provide reasons for fluctuations in numbers
- (v) any other metrics that might demonstrate progress towards the "3 Rs" (replacement, reduction, refinement)

The 3 Rs are a guiding principle for the ethical use and treatment of animals used for research and part of an IACUC's philosophy when reviewing a research protocol, with the aspirational goal of reducing the number of animals used for research. The group identified the 3 Rs as a central reason why the public wants to collect this kind of information.

The group then discussed whether existing reports might already contain the information desired. Existing reports that the group considered were:

- (i) annual APHIS reports
- (ii) APHIS inspection reports
- (iii) reports to OLAW
- (iv) reports to AAALAC

The group discussed that some of the information desired by the public, listed above, is not included in these reports or otherwise publicly accessible, such as adverse events, non-AWA animals, and dispositions of animals. The group also debated whether the inclusion of this additional information would be a useful metric for demonstrating a research facility's progress towards the 3 Rs.

#### Group 2: Information Accessibility

The second group consisted of Delegate Kent, Dr. Annette Hildabrand (James Maddison University), Daphna Nachminovitch (PETA), Dr. Josh Cohen (Virginia Commonwealth University), and Megan Rhyne (Virginia Coalition for Open Government). This group was tasked with discussing the methods for accessing the information desired by the public.

The group discussed the current role of Virginia FOIA in accessing information on animal testing. Some group members pointed out that current accessible reports, such as APHIS inspection reports, often leave out necessary details, leading to FOIA being used as the main vehicle for accessing additional information. Some issues with the FOIA process that the group noted were:

- (i) excessive costliness and lengthiness for requesters
- (ii) incompleteness of the information produced for a request
- (iii) the only enforcement mechanism being a lawsuit in court
- (iv) the burden placed on research facilities to process requests

The group also discussed the possibility of websites or repositories where existing reports can be accessed and whether the burden of reporting could be shifted from researchers to other staff members of the research institutions or third parties.

#### Group 3: Information Tracking

The third group consisted of Delegate Simonds, Dr. Robert Corley (Virginia State University), Corrine Louden (Virginia FOIA Council), Dr. Raphael Malbrue (University of Virginia), and Sharon Adams (Virginia Alliance for Animal Shelters). This group was tasked with discussing the timing or frequency of information tracking. The group discussed the possibility of providing for a Virginia-specific report or a Virginiaspecific database or repository for collecting reported information, possibly hosted by VDACS or another state agency. This hypothetical report or repository could provide information on funding used towards animal research, cumulative counts of animals, or links to currently existing reports. The group considered whether the information desired by the public is already in the possession of the IACUCs and whether it would make sense for the IACUCs to report this data to VDACS or the agency in charge of the hypothetical repository. Some concerns were raised by members of the group that some universities in Virginia may not have the resources or infrastructure to generate a Virginia-specific report because these universities do not receive federal funding or do not maintain AAALAC accreditation and, therefore, do not regularly generate animal testing reports. The group also discussed and generally agreed to the sufficiency of a yearly reporting frequency.

After the Task Force reconvened to discuss these topics as a single group, the Task Force received public comment from in-person attendees:

- Naomi Charalambakis spoke on behalf of Americans for Medical Progress. Ms. Charalambakis expressed concern that requiring research institutions to report only numbers without context may result in misinterpretation and misuse of that data.
- R. Wayne Barbee, a retired biomedical researcher and animal welfare consultant, expressed his opinion that current reporting requirements are sufficient to meet the public's demand for information about animal testing and that he is concerned about the cost-benefit ratio for any new requirements.
- Dave Schabdach, from the Office of Research and Innovation at Virginia Tech, expressed concern over the quantity of FOIA requests that public research institutions already receive from the public.

The meeting summary for August 30 is attached as *Appendix J* and the meeting minutes are attached as *Appendix K*.

#### September 20, 2024

The Task Force convened its third meeting on September 20, 2024. The meeting agenda is attached as *Appendix L*. Prior to the meeting, Commissioner Guthrie tasked Justin Bell, Assistant Attorney General, to prepare and deliver a brief presentation on whether an IACUC is a public body subject to FOIA, as this question had been raised in previous Task Force meetings. Mr. Bell provided this report near the beginning of the meeting. He explained that current law does not provide a conclusive answer to this question. He answered questions from Task Force members and suggested that the Task Force was empowered by its mandate to explore and consider more effective and definitive ways of making this information accessible.

Prior to the meeting, Commissioner Guthrie had tasked Dr. Charles Broadus, Virginia State Veterinarian, to provide a brief report on the work of the Office of Veterinary Services and what,

if any, regulatory authority it has regarding animal testing facilities. Dr Broaddus provided a summary of the duties of the Office of Veterinary Services, which currently does not include regulatory oversight of animal testing facilities. He also provided a cost estimate of that office providing and maintaining a web-based repository for animal testing reports (*Appendix M*) and answered questions from members of the Task Force.

Prior to the meeting, a few members of the Task Force had sent presentations to Commissioner Guthrie's office to provide information to the members of the Task Force. Those presentations were made available to the Task Force members several days prior to the meeting. Commissioner Guthrie provided the authors of the reports an opportunity to deliver a brief summary. Those presentations included one from Daphna Nachminovitch and Will Lowrey concerning current animal research reporting (*Appendix N*) and one from Megan Rhyne and Daphna Nachminovitch pertaining to transparency in animal testing in other states (*Appendix O*).

Prior to the third meeting, Commissioner Guthrie requested that members of the Task Force prepare and submit proposals for increasing transparency in publicly funded animal testing facilities. The submitted proposals are attached as *Appendices P-1* through *P-4*.

IEN facilitated the Task Force's discussion of these proposals through the process of consensus testing. IEN created a list of proposals, labeled A through I, generated from the ideas in the proposals submitted by Task Force members. These proposals were divided into two categories, or "steps." The first step consisted of proposals A, B, and C and focused on *how* to increase transparency. The second step consisted of proposals D through I and focused on *what* information could be included in a report by research facilities. On each proposal, the members of the Task Force would anonymously indicate their level of support by writing a number 1, 2, or 3 on an index card. Level 3 support would indicate that the member fully supports the proposal. Level 2 would indicate that the member can accept the proposal but has questions or concerns about it. Level 1 would indicate that the member does not support the proposal. Consensus on a proposal was introduced, the Task Force would take an initial vote of their level of support. After each vote, the Task Force would discuss their questions and concerns with the proposal.

*Proposal Step #1: How to increase transparency* 

#### Proposal A: SCHEV's website will be used for additional information on animal testing.

The vote tally on this proposal was:

- Level 3: 12
- Level 2: 3
- Level 1:0

This was the Task Force's only proposal to achieve full consensus, with no member voting level 1. The premise behind this proposal, and the following two proposals, was that SCHEV could serve as a better host than VDACS for collecting reports on animal testing from universities in Virginia because it has an established reporting relationship with Virginia universities. One concern noted with the proposal was that the public might not be aware that SCHEV would be collecting this kind of information and would not think to look on SCHEV's website.

# *Proposal B: Universities will provide APHIS inspection and annual reports to post on SCHEV's website.*

The vote tally on this proposal was:

- Level 3: 11
- Level 2: 2
- Level 1: 1

This proposal achieved strong support but did not achieve consensus. The main concern behind this proposal from some members of the Task Force was that universities are already required to make their APHIS annual and inspection reports available on their own websites pursuant to Va. Code § 3.2-6593.2. Therefore, this proposal alone would not be considered to do enough to move the needle towards more transparency. Other members of the Task Force pointed out that the advantage of this proposal over existing requirements in the Virginia Code is that it would collect and centralize all these reports in one location, increasing transparency for the public.

#### <u>Proposal C: Universities will annually produce a report to document progress on the 3 Rs for</u> <u>SCHEV's website.</u>

The vote tally on this proposal was:

- Level 3: 10
- Level 2: 2
- Level 1: 3

This proposal achieved strong support but did not achieve consensus. While the concept of an annual report was generally supported, some members of the Task Force expressed that they could not support this proposal without first deciding what reporting requirements will be included in these reports. Some group members suggested that any metric for demonstrating progress on the 3 Rs would need to be quantifiable while other members expressed concern that new reporting requirements would place additional burdens on researchers and suggested that the report should be more narrative.

#### Proposal Step #2: Information that could be included in a report by universities

Before the Task Force began voting on the following set of proposals, the Task Force discussed which definition of "animal" should be used in the proposals. The Task Force settled on using the definition of "animal" in the Virginia Code, which includes all vertebrates except for fish. A concern was raised by some Task Force members that this definition could inadvertently include non-laboratory animals, such as agricultural animals, that a university might keep for educational purposes. Thus, the following proposals include the caveat that agricultural animals are not intended to be included in scope of the proposals.

<u>Proposal D: Total number of laboratory animals (i.e., all vertebrates except fish) in the care of the institution, excluding agricultural animals.</u>

The vote tally on this proposal was:

- Level 3:9

- Level 2: 4
- Level 1: 2

This proposal achieved strong support but did not achieve consensus. Members of the Task Force pointed out the following questions and concerns with the proposal:

- Increased cost to the universities and burdens on researchers
- Whether the money to cover the costs of additional reporting would come from tuition or from taxpayers
- Generating counts of non-AWA covered animals, specifically rats and mice, is difficult because there are much larger numbers of rats and mice and because their population can fluctuate for number of reasons that are hard to track
- Keeping track of daily changes in animal populations would impose an unreasonable burden on researchers
- Universities that are not AAALAC accredited or do not regularly report to USDA or OLAW do not have the resources or infrastructure to conduct this kind of reporting

Members of the Task Force discussed possible changes to the proposal to address some of these concerns. Some members suggested that counting rats and mice by using cages, an estimated range of numbers, or other type of approximation would be easier than counting the total number of individual laboratory rats and mice in the care of each institution. Some members also suggested that the research institutions would not have to keep track of daily changes in animal population, but, instead, that it would be sufficient to produce one annual report that was a snapshot of the number of animals in the care of the institution at the end of each reporting cycle. With an annual snapshot, the public could see changes in the animal population by comparing the numbers at the beginning and end of the reporting cycle. Some members again raised the concern that context would need to be added to explain any changes in the number of animals at the end of each reporting cycle.

#### Proposal E: How the animals were acquired

The vote tally on this proposal was:

- Level 3: 11
- Level 2: 1
- Level 1: 3

This proposal was combined and voted on together with Proposal G. The premise behind combining both proposals was that the public would be interested in accessing a report that resembled an accounting structure. In this hypothetical report, research institutions would report how animals were coming into the institution (i.e., purchased, transferred, bred, etc.) and how the animals were leaving the institution (i.e., transferred, euthanized, sold, etc.).

One of the concerns with this proposal was that research institutions do not have a reliable paper trail on purchases, transfers, or breeding on which to base this report. Individual researchers or programs are responsible for acquiring their own animals, which may come from different venders and use different sources of funding. Thus, there is no centralized location already in place for this type of information. Some members pointed out that researchers must propose the animal vender from which they intend to acquire laboratory animals in their research protocols to

an IACUC and the IACUC can approve or disapprove the vender, which may be a reliable mechanism already in place for ensuring that animals are ethically sourced.

However, other members suggested that they would be more interested in a report that contained broad institution-wide numbers for each category of acquisition (purchased, transferred, or bred) rather than following a paper trail back to the specific venders or sources from which the institution acquired the animal, which would be less burdensome for research institutions. Due to the difficulty of keeping track of numbers of animals bred, especially for rats and mice, some members also suggested that they would support a proposal that included purchase and transfer numbers but not breeding numbers if that would be less burdensome for research institutions.

A final concern voiced for this proposal was that, despite the fact that such a report would only be required annually, reporting on the acquisitions and dispositions of animals would become a daily task for researchers because they would need to collect this information throughout the reporting cycle.

### <u>Proposal F: Census of animals born at the facility in the last year, which also excludes</u> <u>agricultural animals.</u>

The vote tally on this proposal was:

- Level 3:9
- Level 2: 3
- Level 1: 3

Members of the Task Force pointed out that this proposal focused on the breeding of animals at the research facilities, which is one of the methods of acquisition of animals. Thus, many of the same issues as in the previous proposal were discussed. The concerns of Task Force members focused primarily on the issue of conducting a census of rats or mice. Some issues pointed out with respect to counting rats and mice that are bred were:

- Not all rat or mice pups that are born survive to be weaned, in which case can or should they be counted in a census?
- Some rat or mice pups are eaten by their parents, and this may occur without the knowledge of the researchers
- Researchers may be looking for a specific gene in the rats and mice that they breed, in which case rats and mice that are bred but do not carry the gene are culled

To address some of these concerns, a member of the Task Force suggested changing the proposal to the number of animals weaned instead of the number of animals born. Other members suggested removing rats and mice from this proposal and, instead, only requiring a census of other animals that do not present these difficulties of counting. Daphna Nachminovitch provided additional information after the meeting regarding the impact of stress, crowding, and competition for resources on mortality rates in rodent populations (*Appendix Q*).

### <u>Proposal G: Disposition of all animals over the last year (i.e., euthanized, lost, adopted, transferred, traded, or sold).</u>

Proposal G was grouped with Proposal E and the combined proposal was voted on and discussed together.

<u>Proposal H: Adverse events (i.e., unexpected incidents that lead to harm or endanger the wellbeing of animals and humans at a research university) during the last year.</u>

The vote tally on this proposal was:

- Level 3: 7
- Level 2: 5
- Level 1: 3

This proposal achieved some support but did not achieve consensus. The term "adverse events" in this proposal is intended to mirror the term as it is used for OLAW adverse event reports. Some members of the Task Force echoed the same concerns as for previous proposals, such as increased costs and burdens of new reporting requirements and that some universities in Virginia may not have the resources to do this because they do not report regularly to OLAW. Other members pointed out that universities may already report adverse events to OLAW and it may be a simple matter to post those reports on their own website or SCHEV's website, which would eliminate the need to use FOIA to access such reports.

### <u>Proposal I: Money spent by the facility institution to procure and /maintain animals in the last year.</u>

The vote tally on this proposal was:

- Level 3: 9
- Level 2: 2
- Level 1:4

This proposal received strong support but did not achieve consensus. Some members of the Task Force questioned whether this would be a useful metric for demonstrating animal welfare or progress towards the 3 Rs. Other members pointed out that these kinds of financial records are diffuse and that it would be overly burdensome to attempt to collect or centralize this information for reporting. A member pointed out that financial reports are routinely sent to grant funders and suggested that these kinds of reports could be included with other animal testing reports that would be posted on SCHEV's website.

At the end of the Task Force's discussion of each of the proposals, despite some tweaks and concessions made to the proposals to make them more amenable, no member of the Task Force indicated that their level of support had changed for any of the proposals. Thus, no new votes were taken and consensus was not achieved on any of the proposals except for Proposal A.

During the Task Force's discussion, the Task Force took a short break to receive public comments from in-person attendees. Charles Woodson, from the Richmond Animal Advocacy Alliance, expressed his concern over the difficulty of using the FOIA process to get information and reports. He also suggested that research facilities report the particular species of the animals in their care in case the species is labeled as endangered. Dr. James Bogenpohl, an IACUC member for Chistopher Newport University, expressed his concern that reporting on progress towards the 3 Rs could be problematic because an increase in federal funding could result in an

overall increase in research programs and numbers of animals being tested but that this would not reflect the effort that universities take to implement the 3 Rs at the individual research protocol level.

The meeting summary for the Task Force's September 20 meeting is attached as *Appendix R* and the meeting minutes are attached as *Appendix S*.

### **Summary and Recommendations**

Over the course of the Task Force's three meetings, the members were able to bring to the table and discuss many of their questions and concerns about increasing the transparency of publicly funded animal testing facilities. Although only one of the Task Force's ultimate proposals achieved consensus, many of the proposals received strong support from the Task Force. The Task Force recommends that the General Assembly continue to explore the following areas when considering future legislation:

### Utilizing SCHEV's website for information and reporting

As agreed to in Proposal A, the Task Force recommends that SCHEV use its website to host additional information about animal testing at publicly funded institutions. Relatedly, Proposals B and C also considered using SCHEV's website as a repository for existing or new reports. These proposals received strong support but did not achieve consensus, with many Task Force members hesitant to lend their full support without first discussing the potential content of new reporting requirements. However, the Task Force agreed that SCHEV should be the contact point for information and reporting on animal testing.

### Making existing reports accessible

Much of the Task Force's discussions revolved around what information and reports already exist and how the public can access them. Although consensus on the issue was not officially tested, the Task Force's discussion throughout all three meetings revealed a general agreement that FOIA is burdensome and costly for both parties involved and that members of the Task Force were generally supportive of finding alternatives. The General Assembly may wish to consider options for making existing reports to OLAW, IACUCs, AAALAC, or other organizations accessible to the public by means other than FOIA, such as by collecting and posting these reports on SCHEV's website, in a manner that minimizes the reporting requirements on publicly funded animal testing facilities. Existing Virginia legislation already requires such facilities to post annual APHIS and USDA inspection reports on their own website (Va. Code § 3.2-6593.2). This could also include financial reports made to funders that describe how grant money is being spent on animal testing.

### Creating a Virginia-specific report

The area with the least amount of consensus from the Task Force concerned the creation of new reporting requirements. However, as evidenced by the Task Force's vote on Proposal C, the Task Force demonstrated strong support for a report that documents progress on the 3 Rs (replacement, reduction, refinement). The main impediment for reaching consensus on this proposal is the uncertainty as to what specifically will be required in such report. While most members of the Task Force were supportive of a report that demonstrates progress towards the 3 Rs, the Task Force was unable to achieve consensus on how to best measure that progress.

Elements of a Virginia-specific report that the General Assembly may wish to consider are:

- (i) Whether the report will be narrative or include quantifiable metrics
- (ii) The inclusion of all vertebrate animals, except for fish and agricultural animals
- (iii) Reporting a count of all animals in the care of the institution at the end of a reporting period
- (iv) Reporting on acquisitions and dispositions of animals throughout the reporting period
- (v) Considering whether the report would require research institutions to collect pointin-time data once during the reporting period or to collect data throughout the reporting period
- (vi) Providing certain allowances or exceptions for counting rats and mice (e.g., allowing rats and mice to be counted using cages or estimates or excluding rats and mice from counts of animals bred at the facility)
- (vii) The inclusion of other information that is already collected and reported to other organizations by the research facility

### **Public Comments**

The Task Force received numerous written comments that were submitted in between the Task Force's three meetings. These comments are attached to this report as *Appendix T*.



### Appendix A

Appendix A-1: Chapter 675 of the 2024 Acts of Assembly Appendix A-2: Chapter 693 of the 2024 Acts of Assembly

### VIRGINIA ACTS OF ASSEMBLY -- 2024 SESSION

#### CHAPTER 675

An Act to direct the Department of Agriculture and Consumer Services to convene the Task Force on Transparency in Publicly Funded Animal Testing Facilities; report.

[S 411]

#### Approved April 8, 2024

### Be it enacted by the General Assembly of Virginia:

**1.** § 1. The Department of Agriculture and Consumer Services, in collaboration with the State Council of Higher Education for Virginia, shall convene the Task Force on Transparency in Publicly Funded Animal Testing Facilities (the Task Force) for the purpose of identifying potential deficiencies in publicly funded animal testing facilities, as that term is defined in § 3.2-6593.2 of the Code of Virginia, in the Commonwealth and recommending methods and context for making certain information about such animal testing facilities publicly available, including information pertaining to instances of noncompliance with federal animal welfare regulations, guidelines, or policies, as well as the care, use, and approximate numbers of animals used for research, education, testing, or other experimental, scientific, or medical purposes by each public institution of higher education in the Commonwealth, including animals not covered by the federal Animal Welfare Act (7 U.S.C. § 2131 et seq.).

The Task Force shall consist of legislators and stakeholders, including (i) representatives from one institution of higher education in the Commonwealth with Carnegie research classification R1, one institution of higher education in the Commonwealth with Carnegie research classification R2, and one institution of higher education in the Commonwealth with Carnegie research classification R3; (ii) representatives from three unaffiliated animal protection or animal welfare watchdog groups in the Commonwealth; (iii) an individual who serves as a member of an institutional animal care and use committee at one of the Commonwealth's publicly funded animal testing facilities; (iv) a Virginia-licensed American College of Laboratory Animal Medicine-certified veterinarian functioning in the role of attending veterinarian at one of the Commonwealth's publicly funded animal testing facilities; (v) a representative of the Virginia Press Association; (vi) a representative of the Virginia Coalition for Open Government; (vii) a member of the Virginia Freedom of Information Council; and (viii) two members of the Senate appointed by the Senate Committee on Rules and two members of the House of Delegates.

The Task Force shall report its findings and recommendations on how to improve transparency at publicly funded animal testing facilities in the Commonwealth to the House Committees on Agriculture, Chesapeake and Natural Resources, Finance, and Appropriations and the Senate Committees on Agriculture, Conservation and Natural Resources and Finance and Appropriations no later than November 1, 2024. Such report shall be submitted as a report document as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

### VIRGINIA ACTS OF ASSEMBLY -- 2024 SESSION

#### CHAPTER 693

An Act to direct the Department of Agriculture and Consumer Services to convene the Task Force on Transparency in Publicly Funded Animal Testing Facilities; report.

[H 580]

#### Approved April 8, 2024

### Be it enacted by the General Assembly of Virginia:

**1.** § 1. The Department of Agriculture and Consumer Services, in collaboration with the State Council of Higher Education for Virginia, shall convene the Task Force on Transparency in Publicly Funded Animal Testing Facilities (the Task Force) for the purpose of identifying potential deficiencies in publicly funded animal testing facilities, as that term is defined in § 3.2-6593.2 of the Code of Virginia, in the Commonwealth and recommending methods and context for making certain information about such animal testing facilities publicly available, including information pertaining to instances of noncompliance with federal animal welfare regulations, guidelines, or policies, as well as the care, use, and approximate numbers of animals used for research, education, testing, or other experimental, scientific, or medical purposes by each public institution of higher education in the Commonwealth, including animals not covered by the federal Animal Welfare Act (7 U.S.C. § 2131 et seq.).

The Task Force shall consist of legislators and stakeholders, including (i) representatives from one institution of higher education in the Commonwealth with Carnegie research classification R1, one institution of higher education in the Commonwealth with Carnegie research classification R2, and one institution of higher education in the Commonwealth with Carnegie research classification R3; (ii) representatives from three unaffiliated animal protection or animal welfare watchdog groups in the Commonwealth; (iii) an individual who serves as a member of an institutional animal care and use committee at one of the Commonwealth's publicly funded animal testing facilities; (iv) a Virginia-licensed American College of Laboratory Animal Medicine-certified veterinarian functioning in the role of attending veterinarian at one of the Commonwealth's publicly funded animal testing facilities; (v) a representative of the Virginia Press Association; (vi) a representative of the Virginia Coalition for Open Government; (vii) a member of the Virginia Freedom of Information Council; and (viii) two members of the Senate appointed by the Senate Committee on Rules and two members of the House of Delegates.

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### **APPENDIX B**

Members and Designees

### Task Force on Transparency in Publicly Funded Animal Testing Facilities <u>Chapter 675 [S 411]</u>

### **Task Force Members**

Fulfilling the	Task Force Member	Organization	
Representation of			
Chair	Joseph Guthrie,	Virginia Department of	
	Commissioner	Agriculture and Consumer	
		Services (VDACS)	
Vice Chair	Dr. Paul Smith,	State Council of Higher	
	Sr. Associate for Student Mobility Policy & Research	Education for Virginia (SCHEV)	
R1 Classification	Suzanne Griffin	Virginia Tech	
R2 Classification	Dr. Annette Hildabrand	James Madison University	
HBCU replacing the R3 Classification	Dr. Dean Corely, III	Virginia State University	
Animal Protection or Animal Welfare	Daphna Nachminovitch	People for the Ethical Treatment of Animals (PETA)	
Animal Protection or Animal Welfare	Sharon Adams	Virginia Alliance for Animal Shelters	
Animal Protection or Animal Welfare	Will Lowrey	Animal Partisan	
Institutional Animal Care & Use Committee Member	Dr. D. Josh Cohen	Virginia Commonwealth University	
American College of Laboratory Animal Testing Facility Veterinarian (VA Licensed)	Dr. Raphael Malbrue	University of Virginia	
Virginia Press Association	Steve Weddle	VPA	
Virginia Coalition for Open Government	Megan Rhyne	VCOG	
Virginia Freedom of Information Advisory Council	Corrine Louden	FOIA Council	
Senate of Virginia	Honorable Jennifer Boysko	Senator	
Senate of Virginia	Honorable William Stanley, Jr.	Senator	
Virginia House of Delegates	Honorable Hillary Pugh Kent	Delegate	
Virginia House of Delegates	Honorable Shelly Simonds	Delegate	

Each member of the task force can appoint a designee.

Representation Designee of	Task Force Designee	Organization
Vice Chair	Dr. Joe DeFillippo	State Council of Higher
		Education for Virginia
		(SCHEV)
R1 Classification	Dr. Milt Brown	Eastern Virginia
		Medical School
Institutional Animal Care & Use	Dr. James Bogenpohl	Christopher Newport
Committee Member		University
American College of Laboratory	Dr. Mark Bates	Virginia Commonwealth
Animal Testing Facility		University
Veterinarian (VA Licensed)		
Virginia Press Association	Betsy Wells Edward	VPA

### Appointed Designees (as of date)

### APPENDIX C

Meeting Agenda, July 26, 2024









### Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities

Patrick Henry Building, East Reading Room 1111 E. Broad St. Richmond

> July 26, 2024 9 AM – 12 PM

### **Participants Agenda**

### <u>Overview</u>

This Commonwealth Legislative Task Force was created during the 2023-24 General Assembly session. The actual legislative language is shown in the printed copies of the enacting legislation (VA Code Chapter 675 S 411). The main purpose is to identify potential deficiencies in publicly funded animal testing facilities, as that term is defined in §3.2-6593.2 of the Code of Virginia.

Furthermore, the Task Force is to recommend methods and context for making certain information about such animal testing facilities publicly available, including information pertaining to instances of noncompliance with federal animal welfare regulations, guidelines, or policies, as well as the care, use and approximate numbers of animals used for research, education, testing, or other experimental, scientific, or medical purposes by each public institution of higher education in the Commonwealth, including animals not covered by the federal Animal Welfare Act (7 U.S.C. §2131 et seq.).

### 8:45 Coffee

### 9:00 Welcome & Task Force Protocol

- Joe Guthrie, Commissioner, Virginia Department of Agriculture & Consumer Services
- Dr. Paul Smith, Senior Associate for Student Mobility Policy and Research State Council of Higher Education for Virginia (SCHEV)

### 9:30 IEN Overview and Agenda Review

Kelly Altizer, Associate Director of Operations, Institute for Engagement & Negotiation (IEN) Mike Foreman, Special Projects Manager, IEN Meredith Keppel, Senior Associate, IEN

### 9:40 Task Force Member Introductions

Kelly Altizer and Mike Foreman

- Name / Organization
- Connection to this topic
- What does success for this Task Force look like to you?

### 10:20 Break

### **10:30 Requests for Working Together** Kelly Altizer and Mike Foreman

### **10:40 Group Discussion**

Kelly Altizer and Mike Foreman

*In your view, what, if any, deficiencies are there in transparency around publicly funded animal testing facilities?* 

What is working well, or what are areas that might need improvement?

### **11:30 Summarize Themes and Next Steps** Kelly Altizer and Mike Foreman

- **11:45 Public Comment Period** Commissioner Guthrie
- 12:00 Adjourn

### APPENDIX D

Presentation: Task Force Overview - Commissioner Guthrie

## Introduction and Overview to the Task Force on Transparency in Publicly Funded Animal Testing Facilities



### Joe Guthrie - Commissioner, VDACS Task Force Meeting Patrick Henry Building, Richmond, VA- July 26, 2024

## **Enabling Legislation**

Chapters 675 and 693 of the 2024 Acts of Assembly Patrons: Senator Boysko (SB 411) and Delegate Simonds (HB 580)

### SENATE BILL NO. 411

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Agriculture, Conservation and Natural Resources

on January 30, 2024)

(Patron Prior to Substitute--Senator Boysko)

A BILL to direct the Department of Agriculture and Consumer Services to convene the Task Force on Transparency in Publicly Funded Animal Testing Facilities; report. Be it enacted by the General Assembly of Virginia:

1. § 1. The Department of Agriculture and Consumer Services, in collaboration with the State Council of Higher Education for Virginia (the Task Force), shall convene the Task Force on Transparency in Publicly Funded Animal Testing Facilities for the purpose of identifying potential deficiencies in publicly funded animal testing facilities, as that term is defined in § <u>3.2-6593.2</u> of the Code of Virginia, in the Commonwealth and recommending methods and context for making certain information about such animal testing facilities publicly available, including information pertaining to instances of noncompliance with federal animal welfare regulations, guidelines, or policies, as well as the care, use, and approximate numbers of animals used for research, education, testing, or other experimental, scientific, or medical purposes by each public institution of higher education in the Commonwealth, including (i) representatives from one institution of higher education in the Commonwealth, including (i) representatives from one institution of higher education of higher education in the Commonwealth with Carnegie research classification R1, one institution of higher education in the Commonwealth with Carnegie research classification R2, and one institution of higher education in the Commonwealth with Carnegie research classification R2, and one institution of higher education in the Commonwealth with Carnegie research classification R2, and one institution of higher education in the Commonwealth with Carnegie research classification R2, and one institution of higher education in the Commonwealth animal care and use committee at one of the Commonwealth's publicly funded animal testing facilities; (iv) a Virginia-licensed American College of Laboratory Animal Medicine-certified veterinarian functioning in the role of attending veterinarian at one of the Commonwealth's publicly funded animal testing facilities; (v) a representative of the Virginia Presentative of the Virginia Presentative of the Virginia Presentative on R

The Task Force shall report its findings and recommendations on how to improve transparency at publicly funded animal testing facilities in the Commonwealth to the House Committees on Agriculture, Chesapeake and Natural Resources, Finance, and Appropriations and the Senate Committees on Agriculture, Conservation and Natural Resources and Finance and Appropriations no later than November 1, 2024. Such report shall be submitted as a report document as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.



# Members of the Task Force



- Chair: Joe Guthrie, VDACS
- Vice Chair, Dr. Paul Smith, SCHEV
- R1 Classification Suzanne Griffin Virginia Tech
- R2 Classification Dr. Annette Hildabrand JMU
- HBCU (replacing the R3 Classification) Dean Robert Corley, VSU
- Animal Welfare Advocate 1 Sharon Adams Virginia Alliance for Animal Shelters
- Animal Welfare Advocate 2 Will Lowrey Animal Partisan
- Animal Welfare Advocate 3 Daphna Nachminovitch -PETA
- Institutional Animal Care & Use Committee Member -Dr. D. Josh Cohen - VCU

- American College of Laboratory Animal Testing Facility
   Veterinarian (VA Licensed) Dr. Raphael Malbrue UVa
- Virginia Press Association Steve Weddle VPA
- Virginia Coalition for Open Government Megan Rhyne - VCOG
- Virginia Freedom of Information Advisory Council Corrine Louden FOIA Council
- Senate of Virginia Hon. Jennifer Boysko
- Senate of Virginia Hon. William Stanley, Jr.
- Virginia House of Delegates Hon. Hillary Pugh Kent
- Virginia House of Delegates Hon. Shelly Simonds
- Members may send a designee in their place

## Intro and Overview of the Work of the Task Force

- Inform the General Assembly on this topic as specified by the enabling legislation
  - Topics discussed, areas of consensus, areas where no consensus was reached
  - Provide guidance to GA members on potential legislation and support or opposition to expect
- Document to summarize facilitated discussion
- Series of probably 3 meetings of discussion monthly
  - July 26, August 30, September 20
  - Possibly meet in October to give feedback and revisions to draft document
- In-person meetings (except possibly the October meeting)
  - Provides an equitable opportunity for discussion by all members
  - Sorry, no travel reimbursement available
- Institute for Engagement and Negotiation (IEN) will facilitate
  - Chosen from 4 facilitators interviewed based on experience with task forces and animal issues
- $\circ\,$  Discussion will stay close to the topics specified in the legislation
  - Will begin first topic today
  - Other specific topics in August and September meetings as needed



## Intro and Overview of the Work of the Task Force

- Commissioner as Chair
  - VDACS is convening the task force
  - Importance to VDACS
  - Experience with chairing meetings at a local level
  - Assistance from SCHEV through Dr. Smith
  - Providing guidance and structure to meetings with the benefit of experienced facilitators

### • Public Meeting

- Will be following public meeting policies
- Public is invited to in-person meetings
- Plan to provide online access to meetings
- Meetings will be recorded
- Will provide for in-person comments at end of meetings
  - Sign up prior to first meeting break
- Will always accept written comments
- $\,\circ\,$  VDACS webpage dedicated to this force:

https://www.vdacs.virginia.gov/food-transparency-task-force.shtml

# Questions? Comments...



### APPENDIX E

Meeting Summary, July 26, 2024







### ION STATE COUNCIL OF HIGHER EDUCATION FOR VIRGINIA

### Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities

Patrick Henry Building, East Reading Room July 26, 2024 | 9 AM – 12 PM

### **Executive Summary**

This Commonwealth Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities ("Task Force") was created during the 2023-24 General Assembly session (VA Code Chapter 675 S 411). The main purpose of the Task Force is to identify potential deficiencies in publicly funded animal testing facilities, as that term is defined in §3.2-6593.2 of the Code of Virginia. Furthermore, the Task Force is to recommend methods and context for making certain information about such animal testing facilities publicly available, including information pertaining to instances of noncompliance with federal animal welfare regulations, guidelines, or policies, as well as the care, use and approximate numbers of animals used for research, education, testing, or other experimental, scientific, or medical purposes by each public institution of higher education in the Commonwealth, including animals not covered by the federal Animal Welfare Act (7 U.S.C. §2131 et seq.). The Virginia Department of Agriculture and Consumer Sciences (VDACS) and the State Council of Higher Education for Virginia (SCHEV) were tasked by the General Assembly to hold these meetings; they hired the Institute for Engagement & Negotiation (IEN) to facilitate these meetings.

This first meeting of the Task Force was focused on introducing members to each other and offering suggestions on the first question in the legislation. The session was attended by fifteen (15) appointed members or their designees as well as IEN facilitators and members of the public.

### Welcome & Task Force Protocol

Commissioner of VDACS, Joe Guthrie introduced himself and Dr. Paul Smith (*Senior Associate for Student Mobility Policy and Research, SCHEV*). Both shared how the purpose of this Task Force relates to their agency's mission.

Commissioner Guthrie then reviewed the enacting legislation and the roster of appointed members. He shared the purpose of the Task Force is to gather information for the General Assembly on where there is consensus and where there is no consensus by capturing the group's discussion over the next 3 meetings. The sponsors of this legislation—Senator Jennifer Boysko and Delegate Shelly Simonds—discussed the background and their aspirations for a thoughtful dialogue from this group.

### **IEN Overview and Agenda Review**

Kelly Altizer (*Associate Director of Operations, IEN*), Mike Foreman (*Special Projects Manager, IEN*), and Meredith Keppel (*Senior Associate, IEN*) introduced themselves as the facilitation team for the Task Force. Ms. Altizer reviewed IEN's history with project like these, including their work with the Virginia Department of Forestry's Tree Preservation Survey, the Virginia Department of Environmental Quality's Small Renewable Energy Stakeholder Engagement Strategy, and the Virginia Department of Wildlife Resource's Hunting with Hounds Stakeholder Advisory Committee. Ms. Altizer also reviewed the ethics guidelines that IEN follows and acknowledged that although IEN is a part of the University of Virginia (a stakeholder in the Task Force), the IEN team will be a neutral third-party facilitator. After each meeting, IEN will send out a meeting summary will be sent out. This differs from meeting minutes in that perspectives will not be attributed to individuals unless requested. Mr. Foreman then went over the meeting agenda and the goals for this meeting—including using this time to get to know everyone and start to build trust.

### **Task Force Member Introductions**

Task Force members were asked to introduce themselves and share their connection to this topic and what success for this taskforce looks like to them. The attending

- Honorable Hilary Pugh Kent (VA Delegate District 67)
- Honorable Shelly Simonds (VA Delegate District 70)
- Honorable Jennifer Boykso (VA Senate- District 38)
- Steve Weddle (Virginia Press Association)
- Sharon Adams (Alliance for Animal Shelters)
- Suzanne Griffin (Virginia Polytechnic Institute- R1 University)
- Megan Rhyne (Virginia Coalition for Open Government)
- Dr. Josh Cohen (Animal Care & Use Committee at Virginia Commonwealth University)
- Will Lowry (Lawyer, Animal Partisan)
- Dr. Annette Hildabrand (Attending Veterinarian at James Madison University R2 University)
- Maria Everett (Freedom of Information Act Council, alternate)

- Dr. Raphael Malbrue (University of Virginia, Director / Attending Vet at Center for Comparative Medicine)
- Daphna Nachminovitch (People for the Ethical Treatment of Animals)

### **Requests for Working Together**

Ms. Altizer asked the group if there were any requests or guidelines they would like to set for working together. The IEN team populated the following list of requests before the meeting:

- All perspectives are welcome
- Listen for understanding. Be curious, be open.
- Use courtesy when speaking.
- Electronic etiquette silence what can be silenced.

One addition was made:

• Lean into the topic – all contribute!

### **Group Discussion**

## *In your view, what, if any, deficiencies are there in transparency around publicly funded animal testing facilities?*

Ms. Altizer posed the first question (above) to the group and asked that each Task Force member contribute their thoughts on the topic. The following points and questions appeared in the ensuing discussion:

### 1. Do universities already collect and/or report numbers on animal testing?

- a. Universities report animals covered under the Animal Welfare Act (AWA) to the United States Department of Agriculture. The link to those reports and inspections are posted on the university sites (pursuant to 2023 legislation).
  - i. However, there are no reporting requirements for mice/rats/birds because they are not covered by AWA. But they are the bulk of the animals researched on
    - There are requirements for self-reporting (by <u>AAALAC</u> and the <u>Office of Laboratory Animal Welfare</u> at the National Institutes of Health) if the research is federally funded.
- b. Depending on the university, the source of funding, and the animals being tested on—there are different kinds and places to report this information to.

- i. Institutions do not have to report on federally funded use of rats and mice if contracted by a private company to run experiments.
- ii. However, the six represented universities in Virginia who do animal testing do have Institutional Animal Care and Use Committees (IACUC) which is an independent body that approves research protocols involving animal testing. Researchers fill out a very detailed protocol that is written in lay terms (not all IACUC members are scientists) and that protocol is then voted on by the IACUC members.
- iii. IACUC conducts annual unannounced inspections (called "post-approval monitoring"); but cannot prevent all adverse events from happening given that these are teaching institutions
- iv. IACUC has one non-affiliated member and the attending veterinarian, and the rest are representatives of the research community (experts needed to give opinions on methodology)
- 2. What level of information should be made readily accessible to the public without overly burdening researchers and slowing research progress?
  - a. Are or should IACUCs be considered public bodies?
    - i. Lots of reporting requirements for researchers, but is there proactive disclosure to prevent burdensome FOIA requests?
      - 1. Animal Welfare advocates feel that FOIA costs have been exorbitant to prevent transparency.
    - ii. FOIA has a framework of "assumed open unless there's an exemption" so can we identify what exemptions exist on this topic?
  - b. Universities do not give out all these numbers or reports because of intellectual property concern
    - i. However, most grant funded research must report to the grantor with information about the success and failures of their protocol and USDA's Animal & Plant Health Inspection Service (APHIS) forms are already posted on the university's website.
      - 1. The general public may not consider this information "accessible" as the acronyms and jargon make it difficult to interpret.
      - 2. Universities would like to know *what* information in particular the public wants—can we survey the public?
        - a. Can we analyze current and recent FOIA requests by topic to get a better understanding
  - c. 21st century cures act (federal legislation) mandates that federal agencies reduce regulatory burdens on research
    - i. Required federal agencies to collaborate on how to reduce reporting requirements for researchers
    - ii. Burdening researchers with reporting may not just slow down their work it may impede the university's ability to attract and retain talented professionals.

- d. Do we need to just improve communication of what reports and information are already out there?
- e. Shelters and other animal-related industries have to do reporting to VDACS (<u>Animal Custody Records</u>). Why can't universities do a similar thing—could VDACS host a website like this?
  - i. Universities worry about what would be reported continuous reporting may be difficult with the breeding and population dynamics of currently excluded species (animals, rats, and birds).
  - ii. Universities fear reporting numbers without the context of the research may not tell the full story—don't want the public taking numbers that may inflate or deflate for outside factors (such as gaining more researchers / expanding labs) to be taken as poor animal management.
    - 1. Can we make a report that is inclusive of how the research advances human and animal welfare; the economy; societal needs?

### \*\* After Meeting Note: SCHEV may be a better host for this than VDACS

- f. All local and state govt agencies struggle with this question of burden of public records, but transparency is not for the government to decide. The public defines transparency by deciding what information they are interested in.
  - i. The data / information is their right to obtain
  - ii. We need to clarify the FOIA exemptions
  - iii. Transparency is not about the ethical researchers—it's about safeguards for the "bad apples"

### 3. What is the purpose of this information being publicly disclosed?

- a. There's no measurables for non-numeric assertions around improvements in animal welfare in research
- b. Want to protect against situations like Envigo RMS LLC (where federal Marshalls seized 450 beagles and the company was fined \$35 million for knowingly violating the AWA).
  - i. Envigo was commercial—Universities have different motivations being state / non-profit and ethics around animal testing are important to university researchers. In fact, researchers *self-report* to IACUC at universities and there are ethical guidelines that publications look at before allowing research to be published.
    - 1. Is self-governance enough? What about researchers who may not follow their own protocol? Transparency protects everyone.
      - a. Part of the caution about disclosure is intellectual property concerns
    - 2. Reminder that Envigo animals were purchased by public testing facilities
- c. Yes, the numbers don't say everything; but they aren't a *barrier* to telling the story. We need the numbers to know how to the address & hold universities

account for the 3 Rs of animal research: Replacement, Reduction and Refinement

- d. The <u>FDA Modernization Act 2.0</u> said we should move away from animal-based testing so we need to establish a baseline for the testing of animals like rats and mice that aren't covered by AWA, so we know which direction we are moving.
- 4. How can we organize logistics to be the most accessible to the public while being the least burdensome on researchers?
  - a. There is a lot of information out there—how do we gather in one place to make it easily accessible?
    - i. Case study: the General Assembly and Virginia Press Association made a repository for public notices several years back.
    - ii. Can we look at how other states are doing this?
  - b. Suggested that VDACS host a database similar to the animal custody record reports database kept for the other animal deaths (shelters, breeders, etc.); then universities could report and it could be hosted / maintained by the Commonwealth

\*\* After Meeting Note: SCHEV may be a better host for this than VDACS

A second question was then posed by Mr. Foreman: *What is working well, or what are areas that might need improvement?* 

The following successes were listed:

- 1. This Task Force has assembled the right people and given us time (*outside of the General Assembly session*) to talk about this issue.
  - Greater communication between stakeholders has elucidated information already—such as what information is collected.
- 2. Virginia has the great higher education institutes
  - The Commonwealth was just named the best state for business and the universities are a large part of why.
- 3. There is a lot of reporting and oversight already happening for universities. Belief that universities take their ethical responsibilities seriously.
  - Federal regulatory oversight provides mechanisms for continuous improvement through inspections and citations.
  - a. Additional oversight happens through IACUC which acts as an independent body.

The following improvements were listed:

- 1. Past animal welfare violations— baboon experiments at Eastern Virginia Medical School and Envigo—how do we prevent this from happening again??
  - a. Is self-governance enough?

- 2. Lots of information is being reported *but* not a lot of access to those reports.
  - a. How to make not just available, but *accessible* (those who don't understand the acronyms, where to go, what is in a report, etc.). Accessibility is key to transparency
  - b. Take the burden of reporting off the researchers— have administrators deliver data to the public in best way possible
- 3. Translating research success to public knowledge.
  - b. This Task Force has an opportunity to get the public the information they truly want.
  - c. Better communication—especially between animal welfare community and universities. Improve relationships. And how to point the public towards information that is already being written up (no need to duplicate efforts).

### **Summarize Themes and Next Steps**

Ms. Altizer checked for understanding with the group by summarizing the discussion in the following list:

- There is a lot of information that exists. How can we make it easily accessible for folks looking for it?
- Context is important when giving information but is not essential; folks would like the numbers even if no context is given.
- Desire to be careful about how transparency impacts the state and may slow down research.
- Conversations on this topic and with the universities moves the needle a lot.
- Need to better understand FOIA exemptions and whether IACUCs are public bodies.
- Greater understanding desired around what the public truly wants to know

A suggestion was offered that future meetings break the information into buckets of (1) what is currently accessible; (2) what can be made more accessible; and (3) what should stay accessible under FOIA request only.

The group agreed on this list as a summary of the discussion.

### **Public Comment Period**

Commissioner Guthrie closed the meeting by reminding Task Force members about the next meetings on:

August 30<sup>th</sup> in the Monroe Building (no room number yet) September 20<sup>th</sup> is back in the Patrick Henry Building (East Reading Room) Finally, the meeting was opened for public comment. The only comment came from Lisa Ballance (Associate Vice President for Strategy and Regulatory Affairs, Virginia Commonwealth University) who noted that the USDA website is searchable for every report from Virginia. A member of the public wouldn't need to go to each institution's website to find the reports.

The meeting adjourned at 11:46 am.

### APPENDIX F

Final Meeting Minutes, July 26, 2024

### **FINAL MINUTES**

Task Force on Transparency in Publicly Funded Animal Testing Facilities Patrick Henry Building East Reading Room 1111 E. Broad St Richmond, Virginia

Friday, July 26, 2024

The meeting of the Task Force on Transparency in Publicly Funded Animal Testing Facilities (Task Force) convened at approximately 9:00 a.m. on Friday, July 26, 2024, at the Patrick Henry Building. Commissioner of Agriculture and Consumer Services Joseph Guthrie called the meeting to order.

### PRESENT

Joseph Guthrie

Dr. Paul Smith Suzanne Griffin Dr. Annette Hildabrand Daphna Nachminovitch

Sharon Adams Will Lowrey Dr. D. Josh Cohen

Dr. Raphael Malbrue

Steve Weddle Megan Rhyne Maria Everett Hon. Jennifer Boysko Hon. Hillary Pugh Kent Hon. Shelly Simonds Dr. Dr. Stephan Wildeus

### REPRESENTING

Chair, Virginia Department of Agriculture and Consumer Services (VDACS) Vice Chair, State Council of Higher Education in Virginia R1 University, Virginia Tech R2 University, James Madison University Animal Welfare, People for the Ethical Treatment of Animals Animal Welfare, Virginia Alliance for Animal Shelters Animal Welfare, Animal Partisan Institutional Animal Care & Use Committee Member, Virginia Commonwealth University American College of Laboratory Animal Testing Facility Veterinarian, University of Virginia Virginia Press Association Virginia Coalition for Open Government Virginia Freedom of Information Advisory Council Senate of Virginia, Senate District 38 Virginia House of Delegates, House District 67 Virginia House of Delegates, House District 70 Historically black colleges and universities replacing R3 University, Virginia State University

### ABSENT

Hon. William Stanley, Jr.

Senate of Virginia, Senate District 7

### STAFF PRESENT

Kelly Altizer, Associate Director of Operations, Institute for Engagement & Negotiation (IEN) Mike Foreman, Special Projects Manager, IEN Meredith Keppel, Senior Associate, IEN Kevin Schmidt, Director of Office of Policy, Planning, and Research, VDACS Isaac Joseph, Policy Analyst, VDACS

### INTRODUCTION

Commissioner Guthrie began the meeting by introducing himself and Dr. Paul Smith and provided an overview of the Task Force and the Task Force's mandate from the General Assembly pursuant to Chapters 675 and 693 of the 2024 Acts of Assembly. Commissioner

Guthrie also asked the bill patrons, Senator Boysko and Delegate Simonds, as well as Delegate Kent to provide introductory comments.

Kelly Altizer (Associate Director of Operations, IEN), Mike Foreman (Special Projects Manager, IEN), and Meredith Keppel (Senior Associate, IEN) introduced themselves as the facilitation team for the Task Force. Ms. Altizer reviewed IEN's history with similar projects. Ms. Altizer also reviewed the ethics guidelines that IEN follows and acknowledged that although IEN is a part of the University of Virginia (a stakeholder in the Task Force), the IEN team will be a neutral third-party facilitator. Mr. Foreman reviewed the meeting agenda and the goals for this meeting. Each member of the Task Force introduced themselves, the organization they were representing, and what success for this Task Force looked like for them.

### BREAK

At approximately 9:55 a.m. the Task Force took a short break and reconvened at approximately 10:10 a.m.

### DISCUSSION

IEN posed each member of the Task Force with the question: *In your view, what, if any, deficiencies are there in transparency around publicly funded animal testing facilities?* Each member of the Task Force had an opportunity to voice their concerns and questions regarding the systems in place for reporting or making publicly available information about animal testing at public universities. Task Force members engaged in discussion and answered each other's questions.

IEN then posed each member of the Task Force with the question: *What is working well, or what are areas that might need improvement?* Each member of the Task Force had an opportunity to answer the question.

Following the discussion, Ms. Altizer summarized the following themes and next steps:

- There is a lot of information that exists. How can we make it easily accessible for folks looking for it?
- Context is important when giving information but is not essential; folks would like the numbers even if no context is given.
- There is a desire to be careful about how transparency impacts the state and may slow down research.
- Acknowledgement that conversations on this topic and with the universities moves the needle a lot.
- There is a need to better understand FOIA exemptions and whether Institutional Animal Care and Use Committees are public bodies.
- Greater understanding desired around what the public truly wants to know.

A suggestion was offered that future meeting topics cover (i) what information is currently accessible, (ii) what information can be made more accessible, and (iii) what information should only be available when requested.

The group agreed on this list as a summary of the discussion.

The discussion concluded at approximately 11:40 a.m.

### **PUBLIC COMMENT**

At approximately 11:45 a.m. the Task Force opened to receive public comment from in-person attendees. Lisa Balance, Associate Vice President for Strategy and Regulatory Affairs, Virginia Commonwealth University, noted that the U.S. Department of Agriculture website is searchable for every report from Virginia, including inspection reports. A member of the public would not need to go to each institution's website to find the reports.

### ADJOURNMENT

At approximately 11:50 a.m. the Task Force adjourned.

### APPENDIX G

Presentation: Current Reporting Requirements - Dr. R. Malbrue

## Presentation to the Task Force on Transparency in Publicly Funded Animal Testing Facilities

Aug. 30, 2024

### Dr. Raphael Malbrue, DVM, MS, CertAqV, DACLAM

University of Virginia

Attending Veterinarian and Director for the Center for Comparative Medicine

## Organization Name, Acronyms, Affiliated Regulations, and Guidelines Presentation to the Task Force on Transparency in Publicly Funded Animal Testing Facilities | 08.30.24

Organization Name	Organization Acronym	Affiliated Regulations/Guidelines	Links
United States Department of Agriculture- Animal & Plant Health Inspection Service	USDA-APHIS	Animal Welfare Act (AWA) Animal Welfare Regulations (AWR)	https://www.nal.usda.gov/animal-health-and- welfare/animal-welfare-act https://www.aphis.usda.gov/media/document/1716 4/file
Office of Laboratory Animal Welfare, National Institutes of Health (NIH)	OLAW (NIH)	<ul> <li>Public Health Service (PHS) Policy on Humane use and Care of Laboratory Animals</li> <li>U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training</li> <li>Guide for the Care and Use of Laboratory Animals ("The Guide")</li> </ul>	https://olaw.nih.gov/policies-laws/phs-policy.htm https://olaw.nih.gov/policies-laws/gov- principles.htm https://grants.nih.gov/grants/olaw/guide-for-the- care-and-use-of-laboratory-animals.pdf
AAALAC International (legal name)	AAALAC	A private, nonprofit organization that promotes the humane treatment of animals in science through a voluntary accreditation program administered by veterinarians specializing in laboratory animal medicine, among other experts. Accreditation is entirely voluntary. Some federal agencies, for example, require AAALAC accreditation of a research institution, in order to even apply for grants.	https://www.aaalac.org/
Institutional Animal Care & Use Committee	IACUC	All federal regulations	https://www.aalas.org/iacuc
U.S. Food and Drug Administration	FDA	Federal Food, Drug, & Cosmetic Act (FD&C) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Toxic Substances Control Act (TSCA)	https://www.fda.gov/regulatory-information/laws- enforced-fda/federal-food-drug-and-cosmetic-act- fdc-act https://www.epa.gov/laws-regulations/summary- federal-insecticide-fungicide-and-rodenticide-act https://www.epa.gov/chemicals-under-tsca
Center for Disease Control & Prevention	CDC	Title 42 CFR-Public Health Biosafety in Microbiological & Biomedical Laboratories (BMBL)	https://www.ecfr.gov/current/title-42 https://www.cdc.gov/labs/pdf/SF19_308133- A_BMBL6_00-BOOK-WEB-final-3.pdf
National Science Foundation	NSF	National Science Foundation Act (NSF Act)	https://www.nsf.gov/od/ogc/leg.jsp
Department of Defense	DOD	All federal regulations	https://www.defense.gov/Resources/DOD-Rules- and-Guidance-Documents/
Veterans Affairs	VA	All federal regulations	https://www.va.gov/orpm/?next=%2Fmy-va%2F
Environmental Protection Agency	EPA	"Good Laboratory Practices" regulatiのかs (GLP)	https://www.epa.gov/compliance/good-laboratory- practices-standards-compliance-monitoring- program

# **Current Reporting Requirements:**

Applicable Federal Regulation and Oversight Agency by Species and Funding

Type of Funding	Type of Animal	Animal Welfare Act (AWA)	Public Health Service (PHS)
Federal	Covered Species	YES	YES
Federal	Other Vertebrate	No	YES
Private	Covered Species	YES	No
Private	Other Vertebrate	No	No
Federal or Private	Invertebrate	No	No

# Related Legislation, Regulations, and Guidelines Presentation to the Task Force on Transparency in Publicly Funded Animal Testing Facilities | 08.30.24

Legislation/Regulations/Guidelines	Description	Link
Animal Welfare Act (AWA)	Passed by Congress in 1966, the Animal Welfare Act (AWA) sets general standards for humane care and treatment that must be provided for certain animals that are bred for commercial sale, sold sight unseen (Internet sales), exhibited to the public, used in biomedical research, or transported commercially. Congress assigned the U.S. Department of Agriculture (USDA) the responsibility for enforcing the AWA. The Animal and Plant Health Inspection Service (APHIS) is the agency within USDA responsible for ensuring this occurs.	<u>https://www.aphis.usda.gov/media/</u> <u>document/17164/file</u>
Public Health Service (PHS) Policy on Humane use and Care of Laboratory Animals	The Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) provides the regulatory framework for the use of live, vertebrate animals in any activity supported or conducted by the PHS agencies and U.S. Department of Health and Human Services components, or with entities which have an MOU with NIH.	<u>https://olaw.nih.gov/policies-</u> laws/phs-policy.htm
U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training	The U.S. Government Principles were published in the U.S. Federal Register on May 20, 1985, and are included in the PHS Policy. They provide the ethical framework for currently accepted approaches in the care and housing of research animals. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, these principles are considered.	<u>https://olaw.nih.gov/policies-</u> laws/gov-principles.htm
21st Century Cures Act	The legislation provides NIH with critical tools and resources to advance biomedical research across the spectrum, from foundational basic research studies to advanced clinical trials of promising new therapies.	<u>https://www.congress.gov/bill/114th</u> -congress/house-bill/34
FDA Modernization Act 2.0	This bill authorizes the use of certain alternatives to animal testing, including cell-based assays and computer models, to obtain an exemption from the Food and Drug Administration to investigate the safety and effectiveness of a drug. Has passed the Senate.	https://www.congress.gov/bill/117th -congress/senate-bill/5002
"Good Laboratory Practices" (GLP)	Prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.	<u>https://www.accessdata.fda.gov/scri</u> pts/cdrh/cfdocs/cfcfr/CFRSearch.cfm <u>?CFRPart=58</u>
The Guide & Ag Guide	The Guide is an internationally accepted primary reference on animal care and use, and its use is required in the United States by the Public Health Service Policy.	<u>The Guide - AAALAC</u>
Biosafety in Microbiological & Biomedical Laboratories (BMBL)	Biosafety in Microbiological and Biomedical Laboratories (BMBL) has served as the cornerstone of biosafety practice in the United States since its initial release in 1984. 52	<u>https://www.cdc.gov/labs/bmbl/inde</u> <u>x.html</u>

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# **Publicly Available:**

# USDA Animal Care Public Search Tool

- Inspection Reports
- Annual Reports

This site will provide information and records that shed light on the USDA Animal and Plant Health Inspection Service's (APHIS) administration of the Animal Welfare Act (AWA). APHIS' Animal Care program is responsible for the dayto-day administration of the AWA, including establishing acceptable standards of humane care and treatment for regulated animals and monitoring and achieving compliance through inspections, enforcement, education, and cooperative efforts.

The AWA and its associated regulations seek to ensure the humane handling, care, treatment, and transportation of certain warm-blooded animals used or intended for use in research, exhibition, or as pets. Animal dealers and exhibitors must obtain a license, and research facilities, carriers, and intermediate handlers must obtain a registration. Animal Care inspectors conduct inspections of licensee and registrant animals, records, and facilities to assess compliance with the AWA and its regulations, and document their observations and professional assessments in inspection reports. Licensees and registrants must notify Animal Care of changes in their operations and file periodic updates with Animal Care, including annual reports of animal use by research facilities.

This Public Search Tool provides a list of persons licensed and registered under the AWA, inspection reports, and research facility animal use annual reports. Individuals or businesses seeking information or records that are not available through this Public Search Tool may be able to find what they are looking for elsewhere on APHIS' website at https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare, or by submitting a request under the Freedom of Information Act (FOIA). Information on how to submit a FOIA request to APHIS can be found at https://www.aphis.usda.gov/aphis/resources/foia.

#### What are my search options?

#### List of persons licensed or registered under the Animal Welfare Act (AWA)

This site contains information on dealers, exhibitors, research facilities, carriers, and intermediate handlers who have obtained a license or registration under the AWA.

#### Inspection reports

This site contains reports of inspection prepared by inspectors of the USDA's Animal Care program. An inspection report documents an inspector's observations and professional assessments of compliance at facilities regulated under the AWA. Animal Care has added standard operating procedures to allow us to conduct inspections virtually so that we can ensure animal welfare even in situations in which we cannot safely be physically present at a facility. If you would like to review these SOPs they can be found at this link: https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa\_publications/ct\_publications\_and\_guidance\_documents

#### **Animal Welfare Enforcement Actions**

This searchable page provides access to the APHIS' final enforcement records for the Animal Welfare Act and Horse Protection Act.

#### **Teachable Moments**

This site contains teachable moments prepared by inspectors of the USDA's Animal Care program.

#### Research facility animal use annual reports

This site contains information on the numbers and types of animals used for research purposes during a given fiscal year. Research facilities must submit an annual report of this information to Animal Care.

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#### **Inspection Reports Search**

To locate inspection reports prepared by Animal Care inspectors, enter the known information in the License/Registration Type and/or State fields and then click the Search button. Additional search options and information may be available for certain business entities, such as the names and addresses of corporations with commercial addresses.

Click on the link to the left of any entry to see the associated inspection report. To ensure that accurate information is received, the certificate number should be in XX-XXXX format.

License/Registration Type	City Customer Number	State	Zip Code
View Licensees View Registrants View Inspection	n Reports		
Use the search button above to view results.			
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APHIS.usda.gov	Non-Discrimi	nation Statement	FOIA
USDA.gov	Information C	Juality	APHIS eFile Privacy Policy
Accessibility Statement	USA.gov		Plain Writing
USDA Privacy Policy	WhiteHouse.	gov	AskUSDA

# USDA Inspection Reports Search:

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Click on the link to the left of any entry to see the associated inspection report. To ensure that accurate information is received, the certificate number should be in XX-X-XXXX format.

#### License/Registration Type City State Zip Code ۸ RESEARCH FACILITY VIRGINIA (VA) Customer/Organization Name Customer Number Certificate Number Certificate number should be in xx-x-xxxx format Search Clear View Licensees **View Registrants** View Inspection Reports Filter Options: CFR Direct Critical Repeat Animal Name Animal Category Filter Clear Export To CSV Rows 1 - 100 of 259 > Site Name View Report Licensee/Registrant Information Inspection Date Non-Compliant Items Legal Name 6/24/2024 **REVIVICOR INC** LUNGLLC View Inspection Report 0 Customer Number: 30615 Direct: Certificate Number: 52-R-0113 Non-Critical: 0 Critical: 0 **Teachable Moments:** 0 View Inspection Report 6/20/2024 VIRGINIA TECH CARILION RESEARCH V A Polytechnic Institute & State University Customer Number: 492 Direct: 0 **INSTITUTE (VTCRI)** Certificate Number: 52-R-0012 Non-Critical: Δ Critical: 0 **Teachable Moments:** 6/17/2024 View Inspection Report Customer Number: 500524 Direct: 0 **TEMPLAR MEDICAL** Templar Medical LLC

# USDA Inspection Reports Search:

- In the License/Registration field, Type: "Research Facility"
- In the State field, Type: "Virginia"
- Select: "Inspection Reports"
- Select: Search
- Result: Inspection reports from
   Virginia Research Facilities

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#### **Annual Reports Search**

To access information regarding the annual use of animals by research facilities, you may enter information in any field and then click the Search button.

Click on the link to the left of any entry to see the associated inspection report. To ensure that accurate information is received, the certificate number should be in XX-XXXX format.

Year	City	State	Zip Code
2023	* )	VIRGINIA (VA)	<b>▲</b> ] [
Customer/Organization Name	Customer Number	Certificate Number	
Search		Certificate number should be in xx-x-xxxx format	
View Registrants View Annual R	eports		
		Rows 1 - 24 of 24	Export To C
Query Reports	Registrant Information		Address
Query Annual Reports	Customer/Organization Name (DBA):	US Department Of The Interior (U.S Geological Survey)	OFFICE OF ECOSYSTEMS, US GEO SURVE
	Customer Number:	431	12201 SUNRISE VALLEY DR, MS 300
	Certificate Number:	10-F-0008	HERNDON, VA 20192
	Registration Type:	Class F - Federal Research Facility	COUNTY:Fairfax
	Certificate Status:	Active	
	Status Date:		
Query Annual Reports	Customer/Organization Name (DBA):	Washington and Lee University	PARMLY HALL
	Customer Number:	482	LEXINGTON, VA 24450
	Certificate Number:	52-R-0013	COUNTY:Lexington City
	Registration Type:	Class R - Research Facility	
	Certificate Status:	Active	
	Status Date:		
Query Annual Reports	Customer/Organization Name (DBA):	NORTHERN VIRGINIA COMMUNITY COLLEGE	21200 Campus Drive, LA Building
	Customer Number:	483	STERLING, VA 20164
	Certificate Number:	21-R-0255	COUNTY:Loudoun

Class R - Research Facility

# USDA Annual Reports Search:

All institutions have their annual reports and inspections posted on the USDA site.

- In Year field, Select Year
- In the State field, Type: "Virginia"
- Select: Search
- Result: Annual reports from Virginia Facilities

**Registration Type:** 

# LIS

#### **VIRGINIA LAW**

Code of Virginia

Q

# Virginia Laws and Policies:

- 3.2-6593.2. Animal testing facilities; public notification.
- 3.2-6593.1. Animal testing facilities; adoption of dogs and cats.
- Freedom of Information Act (FOIA)

•Code of Virginia	Code of Virginia Table of Contents » Title 3.2. Agriculture, Animal Care, and Food » Subtitle V. Domestic Animals » Chapter 65. Comprehensive Animal Care » Article 13. Animal Research » § 3.2-6593.2. Animal testing facilities;
Popular Names	public notification
2024 Updates	← Section → ⊖ Print PDF Semail
SECTION LOOK UP	
ex. 2.2-4007.01 Go	§ 3.2-6593.2. Animal testing facilities; public notification.
Administrative Code	A. For the purposes of this section:
	"Animal" means any live vertebrate nonhuman species except fish.
Constitution of Virginia	"Animal testing facility" means any facility of a state agency or institution of higher education that confines and uses animals for research, education, testing, or other experimental, scientific, or medical purposes. "Animal testing facility" does not include any agricultural operation, as that term is defined in § 3.2-300, or any
Charters	agricultural education event.
Authorities	"Animal test method" means a process or procedure that uses animals for research, education, testing, or experimental, scientific, or biomedical purposes.
Compacts	"Animal Welfare Act" means the federal Animal Welfare Act (7 U.S.C. § 2131 et seq.).
	"APHIS" means the U.S. Department of Agriculture Animal and Plant Health Inspection Service.
Uncodified Acts	"Contract testing facility" means any partnership, corporation, association, or other legal relationship that conducts research, education, testing, or experimental, scientific, or biomedical studies on behalf of another entity.
	"Critical noncompliance" means an instance of noncompliance that resulted in a serious or adverse effect on the health and well-being of one or more animals, as determined by the U.S. Department of Agriculture Animal and Plant Health Inspection Service.
	"Federal facility" means any building or infrastructure used or to be used by the federal government, including any building or infrastructure located on lands owned by the federal government.
	"Inspection report" means any report issued by the U.S. Department of Agriculture Animal and Plant Health Inspection Service to an animal testing facility.
	B. Any animal testing facility, contract testing facility, or manufacturer that uses an animal test method shall display a link to its annual report (APHIS Form 7023), as submitted to the U.S. Department of Agriculture pursuant to the Animal Welfare Act, on the homepage or landing page of the facility's or manufacturer's website on or before December 1 for the preceding federal fiscal year.
	C. Any animal testing facility shall, within 30 days of receiving an inspection report, make such inspection report publicly available along with any other relevant U.S. Department of Agriculture incident reports and relevant documents generated from internal reviews by either (i) displaying a link to access such information on the homepage or landing page of the animal testing facility's website or (ii) if such animal testing facility does not have a website, issuing a press release or other similar publication.
	D. If an animal testing facility operated by an institution of higher education in the Commonwealth receives a citation for critical noncompliance under the Animal Welfare Act or regulations adopted thereunder, such animal testing facility shall notify the leadership of such institution of higher education, including the president, dean, and board of visitors or board of trustees.
	E. The provisions of this section shall not apply to any federal facility or privately owned licensed veterinary practice.
	2023, cc. 532, 533. <u>https://law.lis.virginia.gov/vacode/title3.2/chapter65/section3.2-6593.2/</u>
	57 https://law.lis.virginia.gov/vacode/title3.2/chapter65/section3.2-6593.1

https://www.foia.gov//

# All Virginia Public and Private USDA registrants:

Effective July 1, 2023, in compliance with the <u>General</u> <u>Assembly's Animal Research</u> <u>Legislation</u>, all Virginia higher education institutions will post USDA animal facility inspection and annual reports and the university response when inspection reports are made available by the USDA.

Presentation to the Task Force on Transparency in Publicly Funded Animal Testing Facilities | 08.30.24

Institution	Classification	Link
Eastern Virginia Medical School	Public	<u>https://www.evms.edu/research/research_administration/</u> <u>evms_research/research_compliance_integrity/</u>
George Mason University	Public	https://oria.gmu.edu/topics/animal-subjects/
Old Dominion University	Public	https://ww1.odu.edu/impact/compliance/animals
University of Richmond	Private	https://iacuc.richmond.edu/overview/reports.html
University of Virginia	Public	https://sites.research.virginia.edu/center-comparative- medicine
Virginia Commonwealth University	Public	https://research.vcu.edu/resources/animal-research/
Virginia Tech	Public	<u>https://www.research.vt.edu/iacuc/usda-animal-</u> inspection-annual-reports.html
Washington & Lee	Private	<u>https://my.wlu.edu/provosts-office/administrative-</u> <u>resources/committees/administrative-</u> <u>committees/institutional-animal-care-and-use</u>

# Virginia Public Institution webpage example:

Effective July 1, 2023, in compliance with the <u>General</u> Assembly's Animal Research Legislation, all Virginia higher education institutions will post USDA animal facility inspection and annual reports and the university response when inspection reports are made available by the USDA.

V7 VIRGINIA TECH.	۲	APPLY	VISIT	GIVE	shop v I	Resources for 🗸 🗸
RESEARCH AND INNOVATION				MENU		SEARCH 🔍
Research and Innovation / IACUC / USDA Animal Inspection and Annual Reports						
—						
Explore					+	

## USDA Animal Inspection and Annual Reports

Effective July 1, 2023, in compliance with the General Assembly's Animal Research Legislation, Virginia Tech will post USDA animal facility inspection and annual reports and the university response when inspection reports are made available by the USDA.

VIEW VIRGINIA TECH'S CURRENT ANNUAL REPORT

INSPECTION DATE	SITE	NAME	REPORT AND RESPONSE
06/20/2024	FRALIN BIOMEDICAL RESEARCH INSTITUTE AT VTC	VA POLYTECHNIC INSTITUTE & STATE UNIVERSITY	View Inspection Report
03/21/2024	MARION DUPONT SCOTT EQUINE MEDICAL CENTER	VA POLYTECHNIC INSTITUTE & STATE UNIVERSITY	View Inspection Report
01/29/2024	VIRGINIA TECH	VA POLYTECHNIC INSTITUTE & STATE UNIVERSITY	View Inspection Report
10/04/2023	VIRGINIA TECH	VA POLYTECHNIC INSTITUTE & STATE UNIVERSITY	View Inspection Report
07/05/2023	VIRGINIA TECH	VA POLYTECHNIC INSTITUTE & STATE UNIVERSITY	View Inspection Report and Response

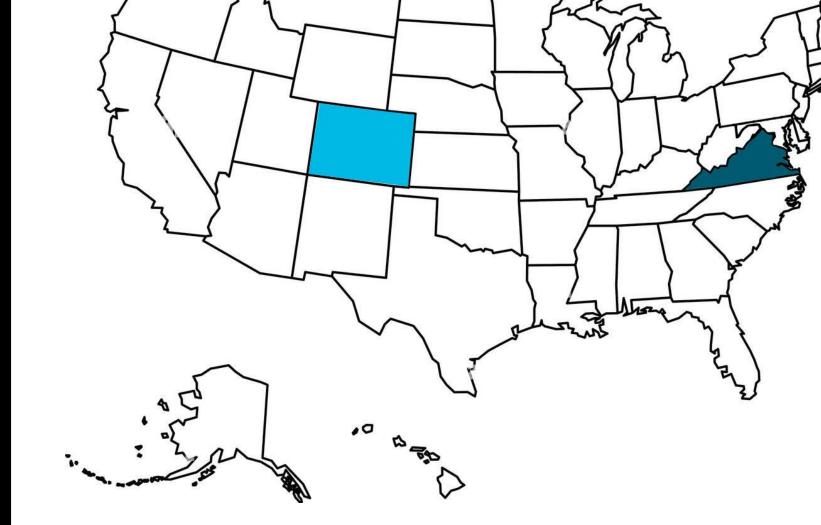
This information is also available on USDA's Animal and Plant Health Inspection Service's website inspection reports or annual reports page. From the USDA inspection reports page:

Enter Virginia Tech's certificate number 52-R-0012

Select "search," and the tab "view inspection reports"

# What are other states doing?

- Colorado is the <u>ONLY</u> state that has attempted something similar to Virginia
- Introduced Legislation, Not Passed



Presentation to the Task Force on Transparency in Publicly Funded Animal Testing Facilities | 08.30.24

https://leg.colorado.gov/sites/default/files/documents/2024A/bills/fn/2024a\_sb067\_f1.pdf

# Membership of the Institutional Animal Care and Use Committee (IACUC):

Under the

Animal Welfare Regulations (AWR), the Guide, and the Public Health Service (PHS) Policy on Humane use and Care of Laboratory Animals

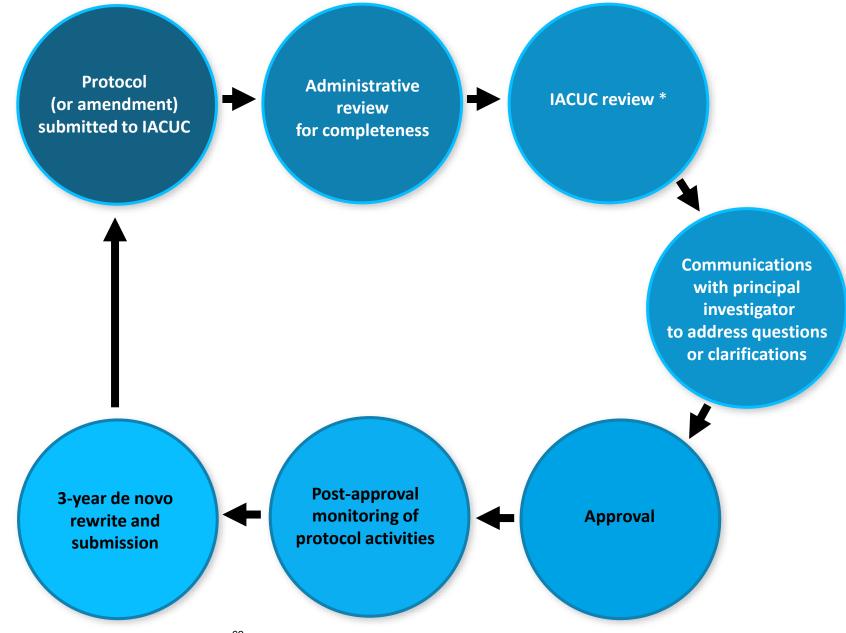
# **IACUC Membership**

Animal Welfare Regulations (AWR)	The Guide	Public Health Service (PHS) Policy
At least 3 members, including:	At least 4 members, including:	At least 5 members, including:
Chairperson	Scientist using animals	Scientist using animals
Veterinarian with training and experience in lab animal medicine	Veterinarian with training and experience in lab animal medicine	Veterinarian with training and experience and has program authority
Public member	Public member	Public member
No more than 3 of the members can be from the same administration	Nonscientist	Nonscientist

# Institutional Animal Care and Use Committee (IACUC) Protocol Submission and Review Process:

\*Includes but is not limited to veterinarian review of potentially painful or distressful procedures; justification/rationale of species and animal numbers; appropriate living conditions for the species; provision of veterinary care, consideration of the **3Rs (Reduction, Refinement, Replacement**); alternatives to painful/distressful procedures; personnel qualifications and training; appropriate euthanasia methods; and scientific and humane endpoints.

Presentation to the Task Force on Transparency in Publicly Funded Animal Testing Facilities | 08.30.24



# Freedom of Information Act (FOIA) related to Animal Research Activity:

Data over 3-Year Period (FY 2022-24)

Presentation to the Task Force on Transpa	rency in
Publicly Funded Animal Testing Facilities	08.30.24

Institution	Total Number Of Requests	Number of Requestors	Resolved
Eastern Virginia Medical School	37	<ul> <li>32: PETA</li> <li>2: Animal Partisan</li> <li>1: Stop Animal Exploitation Now (SAEN)</li> <li>1: Harvard Law Animal Rights Group</li> <li>1: Lady Freethinker</li> </ul>	100%
George Mason University	5	3: PETA 2: Animal Partisan	100%
James Madison University	2	2: PETA	100%
Old Dominion University	5	4: PETA 1: Animal Partisan	100%
University of Virginia	12	8: PETA 1: Animal Partisan 1: UVA Student Group 2 : No affiliation	100%
Virginia Commonwealth University	8	<ul><li>3: PETA</li><li>1: Rise for Animals</li><li>1: Physicians Committee for Responsible Medicine</li><li>3: Local Richmond resident</li></ul>	100%
Virginia Tech	26 63	<ul><li>12: PETA</li><li>4: Animal Partisan</li><li>1: White Coat Waste Project</li><li>6: persons who claim no affiliation (1 requestor made 3 requests)</li></ul>	100%

# **Questions?**

#### APPENDIX H

List of Acronyms and Definitions - Dr. R. Malbrue

# Organization Name, Acronyms, Affiliated Regulations, and Guidelines Presentation to the Task Force on Transparency in Publicly Funded Animal Testing Facilities | 08.30.24

Organization Name	Organization Acronym	Affiliated Regulations/Guidelines	Links
United States Department of Agriculture- Animal & Plant Health Inspection Service	USDA-APHIS	Animal Welfare Act (AWA) Animal Welfare Regulations (AWR)	https://www.nal.usda.gov/animal-health-and- welfare/animal-welfare-act https://www.aphis.usda.gov/media/document/1716 4/file
Office of Laboratory Animal Welfare, National Institutes of Health (NIH)	OLAW (NIH)	<ul> <li>Public Health Service (PHS) Policy on Humane use and Care of Laboratory Animals</li> <li>U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training</li> <li>Guide for the Care and Use of Laboratory Animals ("The Guide")</li> </ul>	https://olaw.nih.gov/policies-laws/phs-policy.htm https://olaw.nih.gov/policies-laws/gov- principles.htm https://grants.nih.gov/grants/olaw/guide-for-the- care-and-use-of-laboratory-animals.pdf
AAALAC International (legal name)	AAALAC	A private, nonprofit organization that promotes the humane treatment of animals in science through a voluntary accreditation program administered by veterinarians specializing in laboratory animal medicine, among other experts. Accreditation is entirely voluntary. Some federal agencies, for example, require AAALAC accreditation of a research institution, in order to even apply for grants.	https://www.aaalac.org/
Institutional Animal Care & Use Committee	IACUC	All federal regulations	https://www.aalas.org/iacuc
U.S. Food and Drug Administration	FDA	Federal Food, Drug, & Cosmetic Act (FD&C) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Toxic Substances Control Act (TSCA)	https://www.fda.gov/regulatory-information/laws- enforced-fda/federal-food-drug-and-cosmetic-act- fdc-act https://www.epa.gov/laws-regulations/summary- federal-insecticide-fungicide-and-rodenticide-act https://www.epa.gov/chemicals-under-tsca
Center for Disease Control & Prevention	CDC	Title 42 CFR-Public Health Biosafety in Microbiological & Biomedical Laboratories (BMBL)	https://www.ecfr.gov/current/title-42 https://www.cdc.gov/labs/pdf/SF19_308133- A_BMBL6_00-BOOK-WEB-final-3.pdf
National Science Foundation	NSF	National Science Foundation Act (NSF Act)	https://www.nsf.gov/od/ogc/leg.jsp
Department of Defense	DOD	All federal regulations	https://www.defense.gov/Resources/DOD-Rules- and-Guidance-Documents/
Veterans Affairs	VA	All federal regulations	https://www.va.gov/orpm/?next=%2Fmy-va%2F
Environmental Protection Agency	EPA	"Good Laboratory Practices" regulatioိဗ်ိs (GLP)	https://www.epa.gov/compliance/good-laboratory- practices-standards-compliance-monitoring- program

# Related Legislation, Regulations, and Guidelines

Presentation to the Task Force on Transparency in Publicly Funded Animal Testing Facilities | 08.30.24

Legislation/Regulations/Guidelines	Description	Link
Animal Welfare Act (AWA)	Passed by Congress in 1966, the Animal Welfare Act (AWA) sets general standards for humane care and treatment that must be provided for certain animals that are bred for commercial sale, sold sight unseen (Internet sales), exhibited to the public, used in biomedical research, or transported commercially. Congress assigned the U.S. Department of Agriculture (USDA) the responsibility for enforcing the AWA. The Animal and Plant Health Inspection Service (APHIS) is the agency within USDA responsible for ensuring this occurs.	<u>https://www.aphis.usda.gov/media/</u> <u>document/17164/file</u>
Public Health Service (PHS) Policy on Humane use and Care of Laboratory Animals	The Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) provides the regulatory framework for the use of live, vertebrate animals in any activity supported or conducted by the PHS agencies and U.S. Department of Health and Human Services components, or with entities which have an MOU with NIH.	<u>https://olaw.nih.gov/policies-</u> <u>laws/phs-policy.htm</u>
U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training	The U.S. Government Principles were published in the U.S. Federal Register on May 20, 1985, and are included in the PHS Policy. They provide the ethical framework for currently accepted approaches in the care and housing of research animals. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, these principles are considered.	<u>https://olaw.nih.gov/policies-</u> laws/gov-principles.htm
21st Century Cures Act	The legislation provides NIH with critical tools and resources to advance biomedical research across the spectrum, from foundational basic research studies to advanced clinical trials of promising new therapies.	https://www.congress.gov/bill/114th -congress/house-bill/34
FDA Modernization Act 2.0	This bill authorizes the use of certain alternatives to animal testing, including cell-based assays and computer models, to obtain an exemption from the Food and Drug Administration to investigate the safety and effectiveness of a drug. Has passed the Senate.	https://www.congress.gov/bill/117th -congress/senate-bill/5002
"Good Laboratory Practices" (GLP)	Prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.	<u>https://www.accessdata.fda.gov/scri</u> pts/cdrh/cfdocs/cfcfr/CFRSearch.cfm <u>?CFRPart=58</u>
The Guide & Ag Guide	The Guide is an internationally accepted primary reference on animal care and use, and its use is required in the United States by the Public Health Service Policy.	<u>The Guide - AAALAC</u>
Biosafety in Microbiological & Biomedical Laboratories (BMBL)	Biosafety in Microbiological and Biomedical Laboratories (BMBL) has served as the cornerstone of biosafety practice in the United States since its initial release in 1984. 67	<u>https://www.cdc.gov/labs/bmbl/inde</u> <u>x.html</u>

#### APPENDIX I

Meeting Agenda, August 30, 2024









## Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities

James Monroe Building 101 N 14th St, Richmond, VA 23219

> Aug 30, 2024 9 AM – 12 PM

## Participants Agenda

## 8:45 Coffee

- **9:00 Welcome, Introductions, and Approve Minutes** Chairman and Commissioner of Agriculture Joe Guthrie
- 9:15 Review of Agenda, Meeting Summary, and Group Requests
   Kelly Altizer, Associate Director of Operations, Institute for Engagement & Negotiation (IEN)
   Mike Foreman, Special Projects Manager, IEN
   Meredith Keppel, Senior Associate, IEN

#### 9:30 Presentation on Key Facts and Q&A

10:00 Initiate Small Group Work Facilitated by IEN

How can we increase/improve transparency within publicly funded animal testing facilities in the following areas? -

- Information Content and Clarity
- Information Accessibility
- Information Tracking
- 10:45 Break
- 10:55 Small Work Group Report Out
- **11:10 Large Group Review of Draft Recommendations** Facilitated by IEN
- 11:45 Chair Remarks, Next Steps, and Public Comment Period
- 12:00 Adjourn

#### APPENDIX J

Meeting Summary, August 30, 2024









## Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities

James Monroe Building, Conference Room 2 August 30, 2024, | 9 AM – 12 PM

## Introduction

The second meeting of the Commonwealth Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities was held on August 30, 2024, at the Monroe Building in Richmond, Virginia. The session was attended by sixteen (16) appointed members or their designees as well as IEN facilitators and members of the public. The following members were present:

Commissioner, Joseph Guthrie (Chair) Virginia Department of Agriculture and Consumer Services (VDACS) Dr. Kirstin Pantazis (Alternate Vice Chair) State Council of Higher Education for Virginia (SCHEV) Delegate Shelly Simonds (D, VA-70) Delegate Hillary Pugh Kent (R, VA-67) Senator Jennifer Boysko (D, VA-38) Corrine Louden, Freedom of Information Advisory Council (FOIA Council) Daphna Nachminovitch, People for the Ethical Treatment of Animals (PETA) Dr. Robert Corely, III, Virginia State University Aimee Perron Seibert, Virginia Press Association (VPA) Sharon Adams, Virginia Alliance for Animal Shelters (VAAS) Dr. Annette Hildabrand, James Madison University (JMU) Dr. Raphael Malbrue, University of Virgina (UVA) Will Lowrey, Animal Partisan Dr. D. Josh Cohen, Virginia Commonwealth University (VCU) Megan Rhyne, Virginia Coalition for Open Government (VCOG) Suzanne Griffin, Virginia Polytechnic Institute and State University (VT)

## Welcome, Introductions, and Approval of Minutes

Commissioner of Agriculture and Consumer Services Guthrie introduced himself and Kirstin Pantazis (*Associate for Academic Affairs*), who served as alternate Chair for Dr. Paul Smith. Both shared how the purpose of this task force relates to their agency's mission. Members introduced themselves, and time was offered for institutions who had missed the first meeting to answer the question of "what success for this task force looks like for you?" The designee from Virginia State University answered that as dean and director of land-grant programs, he represents the agricultural, academic, research, and Cooperative Extension programs. He

defined success as a framework with four acknowledgements: (1) Virginia has great institutions that desire to be transparent and do what's right; (2) A public concern has been raised; (3) We may be able to leverage / identify data that already exist to increase transparency which may eliminate public concerns; and (4) We can reframe from measures that overburden institutions without improving transparency or animal welfare.

Additionally, the group approved the July meeting minutes.

## **Review of Agenda and Meeting Summary**

Kelly Altizer reviewed the agenda for the day and discussed how the focus of the small group questions came from the July meeting summary. She emphasized that small groups would focus on a single topic, but could branch into the others as time permitted, and that the large group discussion would provide an opportunity for all members to contribute to all topics.

## **Small Group Discussions**

## Group #1: Information content and clarity

The group consisted of Senator Jennifer Boysko, Will Lowry (Animal Partisan), Suzanne Griffith (VT), and Aimee Perron Siebert (VPA) and was facilitated by Meredith Keppel from the Institute for Engagement & Negotiation.

Discussion started with asking what information is desired by the public. The list produced included:

- Animal count (by species) *including non-Animal Welfare Act animals (rats, mice, and some birds)*
- State of animals (alive / dead, transferred, released)
- Purchase cost of animals
- Adverse event reports (as defined by the Office of Laboratory Animal Welfare)

This led to a conversation about how information is wanted to measure progress on the 3 Rs of animal testing (refinement, replacement, reduction). It was acknowledged that the 3 Rs are embedded as a philosophy into the Institutional Animal Care and Use Committees (IACUCs). However, there is little available information that are hard and fast metrics of success.

The group then moved to discuss whether and where the information desired may be addressed in reports that already exist. The reports that were highlighted include:

- USDA Animal and Plant Health Inspection Service (APHIS) Annual Reports
  - Cover AWA animal count and pain/distress levels- excludes mice, rats, and some birds
  - Posted on USDA website and (by Virginia law) on each institution's website as well.

### - APHIS Inspection Reports

- Reports on whether violations were found and what corrective action is needed (available on USDA website).
  - If violation was resolved in fines, that settlement would be posted on USDA website. However, many violations are simply resolved through corrective action.
- NIH Office of Laboratory Animal Welfare (OLAW) Annual Report
  - Available only by requests pursuant to either the federal or Virginia Freedom of Information Act (FOIA).
  - Adverse events not included in annual report
- American Association for Accreditation of Laboratory Animal Care (AAALAC) Reports
  - AAALAC is not a public body, so these reports are not public record, and therefore, not governed by FOIA.
  - Voluntary association to improve animal welfare—includes protections for mice and rats
  - o Only six Virginia universities are affiliated with AAALAC

With this information, the group concluded there is no publicly available information on the following: **adverse events** or **non-AWA animal counts.** Discussion on whether generating or sharing this information would truly answer the question (demonstrating progress on 3Rs) ensued; ultimately, the group agreed that a narrative report (modeled after a sustainability report) may allow the university to set their own metrics for "progress on 3 Rs" while also being held accountable by the public if they do not meet their goals. This process may also allow for the universities to provide context on why numbers fluctuate and why the research being done may justify the use of animals.

## Group #2: Information accessibility

The group consisted of Delegate Hillary Pugh Kent, Daphna Nachminovitch (PETA), Dr. Annette Hildabrand (JMU), Dr. Josh Cohen (VCU), and Megan Rhyne (VCOG) and was facilitated by Kelly Altizer from the Institute for Engagement & Negotiation

The group began their discussion around the requirements of FOIA, with a group member noting that while all publicly funded entities are required to post certain specific information, compliance is lacking. Missing links and missing components are commonly observed, and this was noted as a widespread issue not specific to only the subject matter at hand. Currently the courts are the only enforcement mechanism for remedying this issue, which makes it difficult to fix. This generated other related questions and ideas including:

• How to make University websites more user-friendly so that information can be more easily accessed.

• How to get buy-in from those in communications, website, and similar roles within the University (including those who process FOIA requests) to remove the burden of providing information away from scientists.

Cost of information accessibility was another significant issue for the group. Those requesting information often encounter staggering costs (one participant shared an example of a request that was quoted at a cost of \$8,000). Those providing information indicated that some types of requests require evaluation by several people before they can be released, which could include staff members who have high hourly rates, and this increases the internal cost of processing the request. There is the need to protect intellectual property and specific types of employee information from being shared, which can contribute to the amount of time the request takes to review. For the Universities, there is an interest in ensuring that Virginia's requirements are not more restrictive than neighboring states (and other states in general) because this would put them at a competitive disadvantage in terms of research, staffing, etc.

Other points raised in this portion of the discussion include:

- The public has a right to know if violations occurred, why they occurred, if changes were made, etc. A group member shared that this had led to the initial exploration of the idea of a "carve out", or a request that FOIA costs be waived if the request pertained to violations and information that the public should have a right to know. However, this approach was not pursued in recognition that there are equivalent issues in every arena (e.g. violations in health care facilities, nursing homes, etc.)
- Some requests generate the need for additional requests once the initial information is procured, depending on what they contain.
- FOIA estimates are not supposed to charge for multiple levels of review.
- The law only protects personnel records and student information from being shared but does not protect other types of information from being shared.
  - Federal and state guidelines on this are different (e.g. federal reports allow for the names of IACUC volunteers to be removed).
  - o Universities often feel an obligation to protect their staff.

Group members also discussed the information available via the USDA's website, the constraints of the information shared there, and additional information not currently captured. Participants noted that the USDA reports summarize but are not comprehensive, meaning they do not indicate why things happened, what can be done to prevent a violation, if it was a repeat violation, etc. FOIA is currently the only method for procuring this additional information if it exists. USDA inspectors are typically "generalists" who do not specialize in lab animals, which can result in notes that aren't as detailed as some would like. Vet records are often handwritten, which can be a barrier to information accessibility.

A group member noted that the FOIA Council is currently developing a document to advise on effective FOIA requests, to help those who are submitting requests understand how to narrow them in a way that gets the information and reduces unnecessary time and expense.

## Group #3: Information tracking (timing)

Group 3 consisted of Delegate Shelly Simonds, Dr. Corley (VSU), Sharon Adams (VAAS), Dr. Malbrue (UVA), and Corrine Louden (FOIA Council) and was facilitated by Dr. Kristina Weaver, a consultant with the Institute for Engagement & Negotiation.

The discussion began by affirming that it is difficult to talk about timing and tracking without knowing *what* you are tracking. The question arose of whether there would need to be a "system" level review by the General Assembly and what that may entail. It was suggested that this review would be driven by external factors (such as public interest) and that the current information that is available is not "user friendly." There was an acknowledgement that FOIA is the primary means through which to access most information on this topic and that may provide barriers. However, it would be important to universities that context is added to any reporting system to explain the "why" of data.

The conversation then turned to how to address this challenge. A proposal was made that a database like the Animal Custody one held by VDACS could provide information on (1) funding, (2) cumulative animal counts, and (3) currently available reports (APHIS annual and inspection). There is a desire to have a Virginia specific report given that federal reporting and inspections missed, for example, what happened at Envigo incident. A Virginia-specific database may be a way to allow universities to protect intellectual property and provide more anonymity by aggregating data at a state level. Since this information flow [source of animal and what happens to animal] is already being reported to IACUCs, institutions would just need to report that to VDACS, potentially reducing administrative burdens.

This proposal was challenged with the worry that straight aggregate data without context could be dangerous. A suggestion for improvement was to add an asterisk to data where universities could provide more information in a popout box if desired. The question was raised of whether this data was what the public desired— could we create a mechanism to gauge information needs?

The proposal was adapted to suggest that any submissions to VDACS could include a statement (accompanying the requested data) to explain / contextualize any changes. There was also the acknowledgement that while shelters currently provide this data on an annual basis as a point in time count, some universities may not have the resources (census management software and staff) to undertake this kind of endeavor without major costs. There was agreement, however, that the timing of yearly (which is what both shelters and institutions currently do) is sufficient.

#### **Response to First Meeting Questions**

Before shifting to a larger discussion, the Chair allowed time for VSU to answer the questions from the first meeting. Their responses are captured below:

# In your view, what, if any, deficiencies are there in transparency around publicly funded animal testing facilities?

• VSU has a great IACUC and wonderful working relationships with USDA. The main problem that is being demonstrated in this task force lies in information transfer. Institutions may need more transparency around reports to show what is already being done.

## What is working well, or what are areas that might need improvement?

• As stated before, great working relationships with government partners. But information about this work needs to be shared in digestible ways.

## Large Group Discussion

Ms. Keppel, Ms. Altizer, and Dr. Weaver from IEN shared a report out from each of the small groups. Task force members were invited to ask clarifying questions and add ideas to any topics they felt might be missing. The topics that emerged from this discussion were:

## "Unlevel Playing Field"

By creating a different reporting schema for just Virginia, there is a fear this will create an "unlevel playing field."

- This may signal to other states and researchers that Virginia is not where you want to go. Or researchers may go private.
- This "unlevel playing field" already exists as animal welfare institutes (like shelters) are already doing this reporting but with less money.
  - Comparing university research to animal shelter data is not 1-to-1 as IACUCs approve the *largest* number of animals that can be tested on. This may not be what's actually used.
    - The public may not want the details of the lab's methodology and how that may justify their use. They may just want aggregate data.
- Concern about going above and beyond federal regulations
  - Federal schemas are not robust for mice, rats, and birds. A group member shared that approximately 90% of animals tested in Virginia are non-AWA and there is no reporting available on them.
    - Even OLAW adverse event violations are self-reported.
  - Worry about whether this is signaling to researchers that the numbers could be used in future to restrict their research.

 Shelters report adverse events and euthanasia as well in their annual reports. This information has been used to harm in past but there is an obligation to share information about use of taxpayer dollars

### **Balancing Needs**

This is not a binary choice of sacrificing research quality for animal welfare information

- How do we balance the two needs? We don't need to pit our needs against each other.
- We do need to establish a baseline around the 3 Rs so that we can measure success as we move towards non-animal research.
- Public transparency can be an asset to our universities.

#### Universal Transparency Problem

There are elements of this problem and a level playing field that are universal for agencies and institutions that fall under FOIA. There is a universal fear around what will happen if information is released. In fact, there is some direct comparison to law enforcement and fear about what do you do with the people who don't understand the information provided. There may be a potential that they could misinterpret or even manipulate data to do harm.

## **Moving Towards Proposals**

There is a fear that there is too much context to capture without creating a massive administrative burden on institutions. However, some ideas emerged in Small Groups about how to address this:

- Placing an asterisk next to number with context in pop-out window [database held by SCHEV or VDACS]
- Narrative report
  - Central Question: How do we measure progress on the 3Rs? If not numbers, then what? How can we look back in 10, 15, 20 years and compare it to our current state?
  - o It's the institution's goal. How can they make these goals more than aspirational?

Discussion emerged on how proposals from the group would be evaluated, and whether members would be voting for them. Ms. Altizer and Dr. Weaver explained that IEN's preference is to use consensus testing rather than voting. In this approach members use 1 to 3 fingers to indicate their level of support for a proposal. Those indicating that they cannot support a proposal are asked what changes are needed in order to address their concerns. This process generally results in stronger proposals and surfaces the interests and concerns of members to be reflected in the final report.

Some members of the task force shared concerns that without an official vote, there would be power lost in the recommendations. IEN will provide task force members with an example of a report where this method has been used to better illustrate what the final product could look like.

The Chair requested that members share proposals with VDACS staff (either himself or Stacy Metz) and they will be compiled to share with the whole task force ahead of the next meeting.

#### **Next Step and Public Comment**

Justin Bell (Office of the Attorney General, General Counsel for VDACS) was asked whether IACUCs are considered public bodies. He deferred and requested time to seek an opinion from the Office of the Attorney General and do more research. He suggested that the FOIA council do a brief presentation or submit slides to the task force on FOIA's purpose and exemptions.

Public comments were given and will be reflected in the final report.

Commissioner Guthrie reminded members that the next meeting of the task force will be held on September 20<sup>th</sup> at the Patrick Henry Building, and he adjourned the meeting.

#### APPENDIX K

Final Meeting Minutes, August 30, 2024

#### FINAL MINUTES

Task Force on Transparency in Publicly Funded Animal Testing Facilities James Monroe Building 101 N 14th St. Richmond, Virginia

Friday, August 30, 2024

The second meeting of the Task Force on Transparency in Publicly Funded Animal Testing Facilities (Task Force) convened at approximately 9:00 a.m. on Friday, August 30, 2024, at the James Monroe Building. Commissioner of Agriculture and Consumer Services Joseph Guthrie called the meeting to order.

#### PRESENT

#### REPRESENTING

PREJENI	REPRESENTING
Joseph Guthrie	Chair, Virginia Department of Agriculture and Consumer Services (VDACS)
Dr. Kristin Pantanzis	Alternate Vice Chair, State Council of Higher Education in Virginia
Suzanne Griffin	R1 University, Virginia Tech
Dr. Annette Hildabrand	R2 University, James Madison University
Daphna Nachminovitch	Animal Welfare, People for the Ethical Treatment of Animals
Sharon Adams	Animal Welfare, Virginia Alliance for Animal Shelters
Will Lowrey	Animal Welfare, Animal Partisan
Dr. D. Josh Cohen	Institutional Animal Care & Use Committee Member,
	Virginia Commonwealth University
Dr. Raphael Malbrue	American College of Laboratory Animal Testing Facility Veterinarian, University of Virginia
Aimee Seibert	Virginia Press Association
Megan Rhyne Corrine	Virginia Coalition for Open Government
Louden	Virginia Freedom of Information Advisory Council
Hon. Jennifer Boysko	Senate of Virginia, Senate District 38
Hon. Hillary Pugh Kent	Virginia House of Delegates, House District 67
Hon. Shelly Simonds	Virginia House of Delegates, House District 70
Dr. Robert Corley, III	Historically black colleges and universities replacing R3
-	University, Virginia State University

#### ABSENT

Hon. William Stanley, Jr.

Senate of Virginia, Senate District 7

#### STAFF PRESENT

Kelly Altizer, Associate Director of Operations, Institute for Engagement & Negotiation (IEN) Dr. Kristina Weaver, IEN Meredith Keppel, Senior Associate, IEN Kevin Schmidt, Director, Office of Policy, Planning, and Research, VDACS Isaac Joseph, Policy Analyst, VDACS

#### INTRODUCTION

Commissioner Guthrie called the meeting to order and asked that the members of the Task Force reintroduce themselves to each other. Commissioner Guthrie mentioned that written comments submitted to the Task Force would be included in the Task Force's report and that comments made during the Task Force meetings would be summarized and included in the meeting minutes.

Before the Task Force adopted the meeting minutes from the previous meeting, Dr. Corley, as a representative from Virginia State University that was not present at the previous meeting, was given an opportunity to provide his perspective and answers to the same questions that were posed to members of the Task Force at the previous meeting. The Task Force's next order of business was to review and approve the minutes for the July 26, 2024, meeting. Senator Boysko made a motion to adopt the meeting minutes, and Dr. Annette Hildabrand seconded. The meeting minutes were adopted unanimously by the Task Force.

Kelly Altizer then asked the Task Force to review a meeting summary prepared by IEN that summarized the discussion and points made during the Task Force's July 26, 2024, meeting. The members of the Task Force had no comments, edits, or additions to the meeting summary. Kelly Altizer then reviewed the agenda for the day's meeting.

Before the Task Force broke into small group discussions, Commissioner Guthrie called the Task Force's attention to a report and presentation that Dr. Malbrue had prepared concerning the current reporting requirements of public animal testing facilities. Dr. Malbrue did not give the presentation, but briefly summarized it and copies of the presentation were provided to members of the Task Force.

#### SMALL GROUP DISCUSSIONS

The Task Force began the discussion at approximately 9:30 a.m. by breaking out into three separate groups to discuss three separate topics related transparency.

The first group consisted of Senator Boysko, Suzanne Griffin, Will Lowrey, and Aimee Seibert and was facilitated by Meredith Keppel. This group was tasked with discussing what kinds of information are desired by the public. The group discussed the number of animals, the species, the status or disposition of the animals, any adverse events or violations of law, added context for the data reported, and other metrics that might demonstrate progress towards the "3 Rs" (replacement, reduction, refinement). The group then discussed whether existing reports might already contain the information desired.

The second group consisted of Delegate Kent, Dr. Annette Hildabrand, Daphna Nachminovitch, Dr. Josh Cohen, and Megan Rhyne and was facilitated by Kelly Altizer. This group was tasked with discussing the methods for accessing the information desired by the public. The group discussed the requirements of the Virginia Freedom of Information Act, websites or repositories where existing reports can be accessed, the cost of accessing the information, and whether the burden of reporting could be shifted from researchers.

The third group consisted of Delegate Simonds, Dr. Robert Corley, Corrine Louden, Dr. Raphael Malbrue, and Sharon Adams and was facilitated by Dr. Kristina Weaver. This group was tasked with discussing the timing or frequency of information tracking. The group discussed the possibility of providing for a Virginia-specific report or a Virginia-specific database or repository for collecting reported information. The group also discussed the sufficiency of yearly reporting frequency.

#### BREAK

At approximately 10:20 a.m. the Task Force took a short break and reconvened at approximately 10:40 a.m.

#### LARGE GROUP DISCUSSION

When the Task Force reconvened, each smaller group reported to the larger group the topics and proposals the smaller group had discussed. The discussion was opened to the full Task Force for anyone to add any ideas or comments to the report from each smaller group.

The discussion continued until it concluded at approximately 11:45 a.m.

#### **PUBLIC COMMENT**

At approximately 11:50 a.m., the Task Force opened to receive public comment from in-person attendees. Three persons provided public comments to the Task Force.

Naomi Charalambakis spoke on behalf of Americans for Medical Progress. Ms. Charalambakis expressed concern that requiring research institutions to report only numbers without context may result in misinterpretation and misuse of that data.

R. Wayne Barbee, a retired biomedical researcher and animal welfare consultant, expressed his opinion that current reporting requirements are sufficient to meet the public's demand for information about animal testing and that he is concerned about the cost-benefit ratio for any new requirements.

Dave Schabdach, from the Office of Research and Innovation at Virginia Tech, expressed concern over the quantity of FOIA requests that public research institutions already receive from the public.

#### ADJOURNMENT

At approximately 12:00 p.m. the Task Force adjourned.

#### APPENDIX L

Meeting Agenda, September 20, 2024









# Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities

Patrick Henry Building East Reading Room 1111 E. Broad St. Richmond

Sep 20, 2024 (9 AM - 12 PM)

## <u>Agenda</u>

#### 8:45 Coffee

- **9:00 Welcome, Introductions, and Approve Minutes** Chairman and Commissioner of Agriculture Joe Guthrie
- 9:15 Review Reports for Task Force Members
- **9:30** Group Requests, Review of Agenda, and Review of Meeting Summary Kelly Altizer, Associate Director of Operations, Institute for Engagement &

#### Negotiation (IEN)

Mike Foreman, Special Projects Manager, IEN Meredith Keppel, Senior Associate, IEN

- 9:45 Review Consensus Testing Process Kelly Altizer, Mike Foreman
- **10:00 Evaluation of Proposals** Kelly Altizer, Mike Foreman
- 10:30 Break
- **10:40 Continued Evaluation of Proposals** Mike Foreman, Kelly Altizer
- 11:35 Review of Next Steps Commissioner Guthrie
- **11:45 Chair Remarks and Public Comment Period** Commissioner Guthrie
- 12:00 Adjourn

#### APPENDIX M

VDACS Office of Veterinary Services Brief – Dr. C. Broaddus

The Office of Veterinary Services (OVS), within the Virginia Department of Agriculture and Consumer Services, meets the agency's primary mission of promoting the economic growth and development of Virginia agriculture by preparing for, responding to and mitigating the effects of agricultural animal diseases on livestock and poultry. The main mission of OVS is to investigate agricultural animal disease outbreaks and contain the spread of disease. OVS staff accomplish this by preparing for emergency disease response, specifically for foreign animal diseases, or those not found currently in the United States but that would be economically devastating should they enter the US. Examples of these diseases include African Swine Fever, Foot and Mouth Disease and Avian Influenza. Virginia Code grants the state veterinarian and his representatives the authority to quarantine and destroy animals as necessary to contain disease.

OVS staff work to manage economically significant animal diseases of interest through the animal disease traceability program, where cooperative work with the United States Department of Agriculture (USDA) requires certain livestock species to be individually uniquely identified with identification tags in order to trace animal movement in the event of a disease incursion. Additionally, movement of livestock and poultry is tracked using certificates of veterinary inspection, of which OVS staff review approximately 29,000 annually.

There are currently 34 livestock markets throughout the state and OVS staff are present in markets to ensure animal health and safety on sale day. OVS staff review and approve the sale and distribution of certain veterinary vaccines and biologics in Virginia. Staff work with producers and veterinarians on biosecurity training. Additionally, OVS staff work with USDA to administer the Contagious Equine Metritis quarantine program, to protect Virginia horses from the economic impact of CEM, which is not currently endemic in the United States.

OVS provides subject matter expertise on Virginia's Comprehensive Animal Care Laws. These laws outline the minimum standards of care for companion and agricultural animals, define criminal acts of animal cruelty, provide guidelines for animal seizure and mandate the existence and training of animal control officers.

Primary responsibility for enforcing Virginia's animal care laws rests with local animal control and law enforcement agencies. Animal control officers are one of only four animal care professionals in Virginia that are required to complete initial training and continuing education (veterinarians, licensed veterinary technicians and certified wildlife rehabbers being the other three). OVS staff work closely with animal control officers across the Commonwealth, and with the Virginia Animal Control Association, by providing veterinary expertise to such agencies as they enforce these laws to ensure the humane treatment of Virginia's animal population.

OVS is responsible for enforcing sections of Virginia's Comprehensive Animal Care Laws and regulations related to animal shelters in Virginia. There are two types of animal shelters in Virginia: public and private. Every locality is mandated to operate or contract to operate a public animal shelter. All animal shelters and pet shops that sell dogs and cats in Virginia are subject to unannounced inspections by OVS staff. In addition, OVS staff provide training to animal control officers and animal shelter workers throughout the state.

OVS does not currently have the capacity or funding to conduct compliance reviews or other activities related to institutions performing animal research, entities with which the program does not have expertise or experience. Estimates to perform additional service in that area are approximately \$251,000 for the first year, and ongoing annual costs of \$111,000. This includes development and operating costs of an IT system as well as an additional employee.

FTE	Salary	Fringe benefits	Combined annua	al E	Equipment and Supplies	Total FTE cost	
Compliance Officer *	45,00	0	21,339	66,339	10,000	\$	576,369
Technology costs							
One time Implementation costs	\$175,000	h					
-							
Annual IT costs **	\$35,000	)					
Year one costs	\$76,369+ \$175,000= \$251,369						
Ongoing annual costs	\$76,369+ \$35,000= \$111,369						
	φ, 0,000 φ11,000						

\*Additional staff necessary to deal with the database and compliance issues.

\*\*This is a rudimentary cost estimate that was developed in order to consider the potential costs of having VDACS implement some kind of research animal testing reporting tool/database, and is subject to change.

### APPENDIX N

Presentation: Current Animal Research Reporting – D. Nachminovitch & W. Lowrey

## TRANSPARENCY IN PUBLICLY FUNDED ANIMAL TESTING FACILITIES:

# **INFORMATION AND RESOURCES**

Daphna Nachminovitch, PETA Will Lowrey, Animal Partisan

September 16, 2024

## TRANSPARENCY IS "A LACK OF ANY HIDDEN AGENDAS WITH ALL INFORMATION BEING AVAILABLE."

(Source: <u>Black's Law Dictionary</u>)

More than two dozen facilities—most of which receive some public funding—use animals in <u>experiments in Virginia</u>. However, due to a lack of consistent, comprehensive reporting requirements, critical information pertaining to the numbers, use, and care of these animals remains hidden from the public, even when those animals suffer and/or die as a result of animal welfare violations.

## TRANSPARENCY DEFICIENCIES AT OVERSIGHT ORGANIZATIONS

Two federal agencies—U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (<u>APHIS</u>) and the National Institutes of Health's (NIH) Office of Laboratory Animal Welfare (<u>OLAW</u>)—regulate compliance with federal animal welfare standards at animal testing facilities.

- USDA APHIS enforces the Animal Welfare Act (<u>AWA</u>), the only federal law intended to protect animals used in experiments, but it only applies to a small fraction of the animals used.
- NIH OLAW requires facilities to adhere to guidelines set forth in the <u>PHS Policy on Humane Care and Use of Laboratory Animals</u>, but these guidelines are mostly recommendations, not requirements, and **do not have the force of law**.

OLAW records and certain APHIS records, including some pertaining to federal violations, can only be obtained via FOIA requests. This process is often costly as well as time-consuming. Fulfillment of requests to federal agencies can take months even *years*—hindering timeliness, relevance and effectiveness of efforts to improve and advance animal welfare.

## **ENFORCEMENT CONCERNS AND REPORTING DEFICIENCIES AT OVERSIGHT ORGANIZATIONS**

## USDA APHIS

APHIS enforces the AWA which **does not include rats, mice, birds bred for research, or cold-blooded animals—e.g., fish, reptiles, and crustaceans.** Approximately <u>95%</u> of species used in experiments are not covered.

In 2005, the USDA's Office of Inspector General (OIG) found that APHIS was "not aggressively pursuing enforcement actions against violators of AWA" and that "the fines are usually minimal and not always effective in preventing subsequent violations."

In December 2019, the USDA started posting fines. One of the largest fines posted since is for Virginia Tech in the amount of **\$18,950** for seven violations of the AWA.

As of 2019, APHIS had only **66** Veterinary Medical Officers to annually inspect over **850** research facilities.

## NIH OLAW

OLAW oversees all public and private facilities that receive NIH funding for activities involving **vertebrate animals only** per the <u>Health Research Extension Act of 1985</u>.

To receive NIH funding, a facility must obtain an Animal Welfare Assurance, an agreement between the facility and OLAW. Virginia public universities have chosen to have their Assurances **apply only to animals used in federally funded experiments**.

Animal testing facilities only need to report the "<u>total number of</u> <u>animals proposed</u>," and serious violations are <u>self-reported</u> by the institutions. **OLAW does not inspect or fine entities**.

## **OLAW has only suspended one domestic PHS Assurance since 1986**, when they halted all experimentation on vertebrates at Columbia University over "deficiencies in four general areas," including the sterility of post-surgical recovery areas. The suspension only applied to "warm-blooded vertebrates, with the exception of rodents," and it was lifted less than five months later.

# AAALAC

The Association for Assessment and Accreditation of Laboratory Animal Care (<u>AAALAC</u>) is a private organization that offers an expensive "accreditation" program for facilities. **AAALAC records are not publicly accessible**. AAALAC's <u>Council on Accreditation</u> is made up of people who work at the very facilities the organization accredits – including a representative from Virginia Tech.

- Accredited facilities must submit an annual report of all animals used in experiments, but these numbers **do not include animals held and/or bred** during the reporting period. **This information is not publicly posted.**
- AAALAC conducts <u>site visits</u> which are scheduled in advance, and only every **3** years.
- Envigo was AAALAC-accredited.
- Virginia Tech is AAALAC-accredited, and they were in good standing with AAALAC when they were fined \$18,950 by the USDA.
- One study showed that "AAALAC-accredited sites had more AWA NCIs [noncompliant items] on average compared with nonaccredited sites. AAALACaccredited sites also had more NCIs related to improper veterinary care, personnel qualifications, and animal husbandry." <sup>93</sup>

	AAALAC Annual
University	Fees Paid in 2023
EVMS	\$5,607.00
UVA	\$9,602.00
VCU	\$7,723.00
VT	\$9,602.00

# CASE IN POINT: ENVIGO

Federally licensed, AAALAC-accredited entities can egregiously and repeatedly violate the AWA—even receive USDA citations by the dozens—and continue to operate without consequences.



"The university purchased animals from Envigo in 2020 as this vendor currently maintains USDA license standards and is AAALAC accredited." (Virginia Tech statement) **2020**: <u>SB669</u> (Boysko/Stanley) sought to prohibit breeding dogs and cats to be used in experiments, as well as the sale of dogs or cats for experiments overseas. Opposition to SB669 included Envigo and Virginia Tech. The bill died in committee.

2021: PETA's <u>undercover investigation</u> exposes Envigo.

**2021/2022**: Between July 2021 and March 2022, the USDA cites Envigo for 73 federal animal welfare violations, including **27 repeat** and **six critical** violations. **No fines or penalties are ever issued by the USDA-APHIS.** 

**2022**: Envigo is raided by federal and state law enforcement agents (not including USDA-APHIS). Boysko and Stanley lead efforts on beagle protection bills to protect dogs and cats bred for experiments in Virginia. Five bills are <u>signed into law</u>.

**2024**: Envigo pleads guilty to charges of conspiracy to violate the AWA and the federal Clean Water Act, resulting in more than <u>\$35 million in penalties</u>, the largest ever in AWA history.

## SOME VIRGINIA UNIVERSITIES PROMOTE ADHERENCE TO THE 3RS, BUT NONE MEASURES PROGRESS

The 3Rs are a set of principles that advocate for alternatives to the use of animals in scientific studies (replacement), lowering the number of animals used (reduction), and changes that make the procedures performed on animals less distressing and/or painful (refinement).

	The principle of the 3Rs was introduced in <b>1959</b> by W.M.S. Russell and R.L. Burch in <u><i>The Principles of Humane</i></u> <u><i>Experimental Technique</i></u> .	University	3Rs Pledge Posted on Website	3Rs Metrics Posted on Website
		EVMS	<u>No</u>	No
16	Their <u>mission</u> aimed "to diminish, by methods appropriate to its special character as a university organization, the sum	GMU	No	No
	total of pain and fear inflicted by man on animals."	JMU	<u>No</u>	No
-	After 65 years no matrice aviet to show that taxpayor dollars	ODU	No	No
	After <b>65 years</b> , <b>no metrics exist</b> to show that taxpayer dollars are being used to achieve these agreed-upon universal goals.	VSU	No	No
	When well it non-animal massarah mathada ana availahla na	UVA	Yes	No
16	When valid non-animal research methods are available, no federal law requires experimenters to use such methods instead	VCU	Yes	No
	of animals.	VT	Yes	No

# EXAMPLES OF OLAW REPORTS

OLAW uses an **honor system** whereby institutions self-report violations, and only when the animals involved are vertebrates and part of a federally funded protocol. The following selfreported violations were obtained via FOIA requests, and many detail prolonged and painful deaths due to lab staff negligence. None were publicly posted.

- From May 2019 to May 2023, VCU self-reported 14 separate violations where a lack of food and/or water resulted in the <u>deaths of at least 61 mice from starvation</u> <u>and/or dehydration</u>.
- In October 2023, UVA self-reported that a "misplaced cage [confining mice] was discovered and the <u>occupants were</u> <u>found dead</u>." One month later, the school self-reported that <u>four mice died from "water deprivation</u>."
- In **February 2023**, VT self-reported that a wild-caught bird "was inadvertently <u>left in a holding crate and died</u>."
- In **February 2020**, EVMS self-reported that <u>eight weanling</u> <u>mice were found dead</u> because they were not "able to reach the food." Six months later, <u>two mice died</u> because they

could not access their water.

In a UVA <u>experiment</u>, mice's "dorsal skin was tented and pinned to a corkboard." (Jarrod A. Call et al, Free Radical Biology and Medicine)

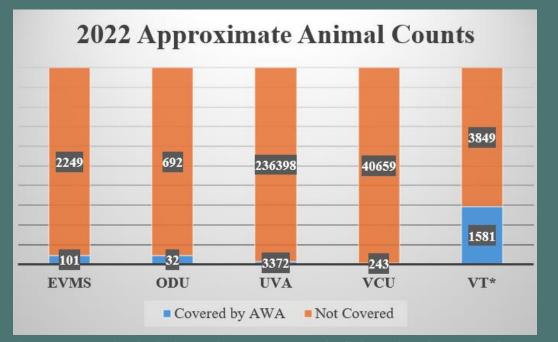
96



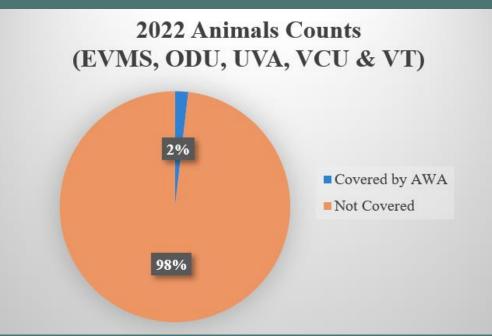
## ANIMALS USED IN EXPERIMENTS AT PUBLICLY FUNDED VIRGINIA UNIVERSITIES BY THE NUMBERS

In 2023, PETA submitted FOIA requests to AAALAC-accredited public universities in Virginia to obtain the approximate number of animals they used in experiments, including those not reported to USDA APHIS. These records show that **the overwhelming number of animals who are experimented on are not federally covered, and information about their numbers, care, and use is not made publicly available**.

97



\*VT's count included " rodent cages" and "fish tanks" instead of animals, so the number of animals not covered by the AWA is far higher. These numbers do not include animals held but not used in protocols.



Mice, rats, fish, captive-bred birds, reptiles, amphibians, and cephalopods accounted for the species used in experiments who are not federally protected.

## **IACUC MEMBERSHIP**

Several OIG audits have shown that IACUC oversight is inadequate. For example, in 2014, OIG highlighted that from 2009 to 2011, USDA inspectors cited 531 experimentation facilities for 1,379 violations stemming from the IACUCs' failure to adequately review and monitor the use of animals.

"As a result, animals are not always receiving basic humane care and treatment and, in some cases, pain and distress are not minimized during and after experimental procedures."

(Source: 2014 OIG Audit)

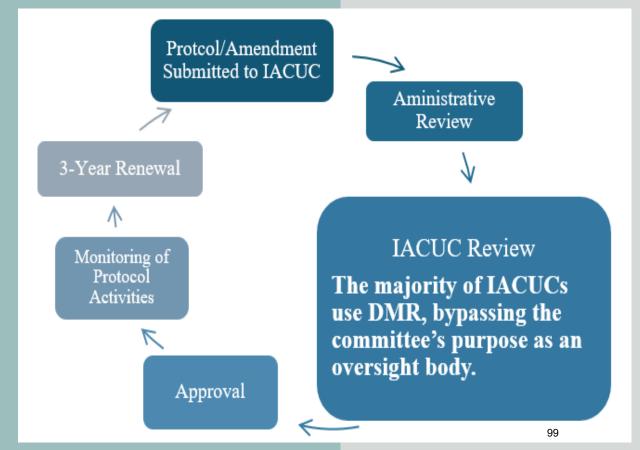
Institutional Animal Care and Use Committees (IACUCs) are oversight bodies within individual institutions that are responsible for ensuring that animal-use protocols adhere to the AWA and/or the PHS Policy. IACUC transparency is inconsistent, and the <u>required makeup</u> of the IACUC body **allows for bias**.

- Universities with animal testing facilities often have IACUCs consisting of ~8 members.
- Only one person who is not affiliated with the institution is required.
- Two of the members must be a veterinarian and a scientist with expertise in experiments that use animals.
- The remaining members are paid employees of the institution, and up to three members can work in the same department.

## THE FLAWED IACUC REVIEW PROCESS

## **DMR vs. FCR**

Designated member review (DMR) is the process where a protocol using animals may be approved after it is approved by only **one** IACUC member. A full committee review (FCR) is the process where the entire IACUC must review and approve a protocol.



- One study "revealed that DMR is overwhelmingly used as the default system for reviewing protocols and modifications to protocols, with several institutions using it more than 80% of the time."
- In September 2021, APHIS cited EVMS for a critical violation and issued an official warning after an experimenter performed multiple major survival surgeries on baboons without a scientific justification or prior USDA approval. EVMS' IACUC Chair had approved the protocol, which allowed each baboon to be subjected to up to six C-sections.

## INCREASED TRANSPARENCY = A DECREASE IN FOIA REQUESTS

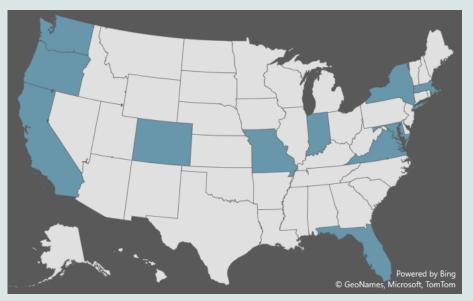
PETA and Animal Partisan FOIA Fees (2022-		
	2024)	
	Paid	Estimates Not Pursued
EVMS	\$3,967.48	\$607.75
GMU	\$700.00	\$0.00
ODU	\$238.18	\$5,539.58
UVA	\$0.00	\$10,917.89
VCU	\$271.95	\$29,454.21
VT*	\$0.00	\$891.33
Total	\$5,177.61	\$47,410.76

\*Two VT FOIA requests were estimated to take **1,400** hours to search and review records (not included).

## SIMILAR LEGISLATIVE EFFORTS

**California:** The <u>Transparency in Research Act</u> was introduced in 2019 and would have required that state-funded institutions disclose information about their animal research activities, including the species and number of animals used.

**Colorado:** <u>SB24-067</u> was introduced this year and would have required that animal testing facilities submit an annual report to the Colorado Department of Public Health & Environment containing the total number of animals used in experiments, including those held and bred but not used in protocols.



**Florida:** <u>SB368</u> was introduced this year and would have required that animal testing facilities <u>submit an annual report</u> to the Florida Department of Agriculture and Consumer Services containing the total number of animals used for experimentation and their use per species.

**Indiana:** <u>HB1292</u> was introduced this year and would have required that the Indiana State Board of Animal Health establish a registry of animal testing facilities and "track the number of live animals" used in experiments at each facility.

**Maryland:** In 2023, <u>SB0495</u> was introduced and would have required that animal testing facilities submit an annual report to the Maryland Department of Agriculture containing the "number of each species of vertebrate animals owned and used" by the facility.

**Missouri:** <u>SB1319</u> was introduced this year and is up for a House hearing. If passed, the <u>bill</u> would require that universities that receive state funding post annually on their websites critical information pertaining to animal testing, including total funding used, funding sources, active protocols, documents related to AWA violations, efforts to adhere to the 3Rs, species of animals used, and animal counts. The animal counts would be required to include the total number of animals adopted out from laboratories as well as the number of animals euthanized.

**Washington:** <u>HB2304</u> was introduced this year and would have required that the University of Washington's (UW) Washington National Primate Research Center publish information annually pertaining to experiments involving nonhuman primates, including the number of primates used in experiments and for breeding purposes as well as any who were injured or died in relation to USDA citations and any who were killed or died while on protocol.

# SIMILAR LEGISLATION THAT PASSED



Milo, a "breeding monkey" confined at Oregon Health & Science University.

**California:** California requires that institutions that do **not** receive funding from the NIH submit an application to the California Department of Public Health if they intend to use animals **not** covered under the AWA. Along with the application, they must also <u>report</u> the number and source of mice, rats, and other noncovered animals they intend to use.

**Massachusetts:** The city of Cambridge, where Harvard University and MIT are located, passed a <u>law</u> in 1989 requiring that any institution planning to conduct experiments on vertebrate animals must apply for a permit. All laboratories are inspected annually by the commissioner of laboratory animals, who also reviews research programs, protocols, and procedures. The <u>law</u> requires that during the annual visit, institutions provide information on the number and species of animals used.

**New York:** The <u>Public Health Act</u> requires that all research facilities that test on animals be annually approved by the New York Department of Health Commissioner, and they are also subject to inspection by the health department. Additionally, "[o]nly laboratories that hold a New York State <u>clinical laboratory</u> <u>permit</u> are authorized to perform testing on specimens originating from New York," adding another layer of oversight.

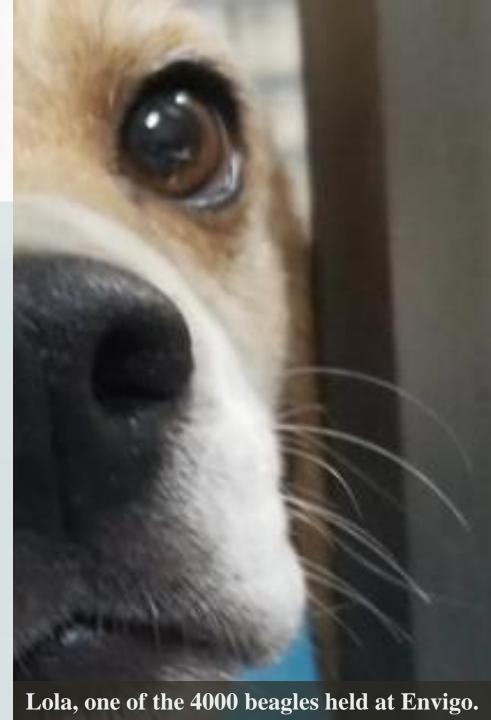
**Oregon:** An Oregon <u>law</u> requires that Oregon Health & Science University, where the <u>Oregon National Primate Research Center</u> is located, publish information annually pertaining to experiments involving nonhuman primates (NHPs), including the number of primates used in experiments and for breeding purposes as well as any who were injured or died in relation to USDA citations. This new legislation came about after many years of the <u>USDA citing the university</u> for federal animal welfare violations.

## THE PUBLIC CARES ABOUT ANIMALS USED IN EXPERIMENTS

Over the last 10 years, eight European countries have signed <u>national</u> <u>Transparency Agreements</u>, pledging to provide the public with crucial information relating to experiments using animals.

"The rationale is that more transparency will increase public confidence in the appropriate conduct and regulation of animal research and therefore help to maintain public acceptance." –<u>Varga et al</u>

- A 2018 Pew Research <u>survey</u> showed that 52% of Americans oppose the use of animals in experiments.
- Animal protection NGOs are funded by private donations from millions of people who rely on these groups to fight for transparency and justice.
- In December 2022, the FDA Modernization Act 2.0 was signed into law, eliminating the requirement that new drugs be tested on animals, and the NIH convened a group to assist the institution in "prioritizing the development and use of NAMs," also known as New Approach Methodologies or Non-Animal Methods.



### **APPENDIX O**

Information Regarding Transparency in Animal Testing in Other States – M. Rhyne & D. Nachminovitch

From: To:	rr-VDACS.Commissioner Suzanne Griffin; Hildabrand, Annette - hildabak; Robert N. Corley; Daphna Nachminovitch; Sharon Adams; Will Lowrey; D. Joshua Cohen; raphael.malbrue@virginia.edu; Steve Weddle; Megan Rhyne; Louden, Corrine (OSIG); senatorstanley@senate.virginia.gov; senatorboysko@senate.virginia.gov; Aimee Perron Seibert; Bell, Justin I.; delhkent@house.virginia.gov; Smith, Paul (SCHEV); Schmidt, Kevin (VDACS); Joseph, Isaac (VDACS); Pantazis, Kirstin (SCHEV); Kirstin (SCHEV) <kirstinpantazis@schev.edu></kirstinpantazis@schev.edu>
Cc:	Office Contact
Subject:	Fw: Additional states and localities that have attempted to legislate on transparency in animal testing RE: Colorado bill
Date:	Monday, September 16, 2024 5:06:56 PM
Attachments:	image001.png image002.png Outlook-enbrn3c5.png

### Good afternoon,

Please see below the email from Task Force Member, Ms.Nachminovitch, in response to Ms. Rhyne's email that was previously sent to all members.

Best Regards,

Joe



Joseph W. Guthrie Commissioner Virginia Department of Agriculture and Consumer Services

 Phone: 804.786.3501

 Website: www.vdacs.virginia.gov

 E-mail: vdacs.commissioner@vdacs.virginia.gov

 Address: 102 Governor Street, Richmond, Virginia 23219

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From: Daphna Nachminovitch <DAPHNAN@peta.org>

Sent: Monday, September 16, 2024 1:26 PM

To: rr-VDACS.Commissioner <vdacs.commissioner@vdacs.virginia.gov>

Cc: Metz, Stacy (VDACS) <Stacy.Metz@vdacs.virginia.gov>

**Subject:** Additional states and localities that have attempted to legislate on transparency in animal testing RE: Colorado bill

Good afternoon, and thank you for this information from Megan. I thought it would be useful for task force members to be made aware of additional states and localities that have attempted to tackle this issue. Information previously shared with the task force stated that Colorado was the "ONLY state to have attempted something similar to Virginia." This is incorrect. Additional states and localities, with hyperlinks to proposed legislation, are listed below. Please let me know if you have any questions. Thank you in advance for sharing this

information with the task force.

## Legislative Attempts Pertaining to Transparency in Animal Testing

- 1. **California:** The <u>Transparency in Research Act</u> was introduced in 2019 and would have required that state-funded institutions disclose information about their animal research activities, including the species and number of animals used. The bill was not signed into law. California already requires that institutions that do **not** receive funding from the National Institutes of Health submit an application to the California Department of Public Health if they intend to use animals **not** covered under the federal Animal Welfare Act (AWA). Along with the application, they must also <u>report</u> the number and source of mice, rats, and other non-covered animals they intend to use.
- 2. **Colorado:** <u>SB24-067</u> was introduced this year and would have required that animal testing facilities submit an annual report to the Colorado Department of Public Health & Environment containing the total number of animals used in experiments, including those held and bred but not used in protocols. In March, the Senate Health and Human Services Committee voted to postpone the bill indefinitely.
- 3. Florida: <u>SB368</u> was introduced this year and would have required that animal testing facilities <u>submit an annual report</u> to the Florida Department of Agriculture and Consumer Services containing the total number of animals used for experimentation and their use per species.
- 4. **Indiana:** <u>HB1292</u> was introduced this year and would have required that the Indiana State Board of Animal Health establish a registry of animal testing facilities and "track the number of live animals" used in experiments at each facility.
- 5. **Maryland:** In 2023, <u>SB0495</u> was introduced and would have required that animal testing facilities submit an annual report to the Maryland Department of Agriculture containing the "number of each species of vertebrate animals owned and used" by the facility.
- 6. **Massachusetts:** The city of Cambridge, where Harvard University and MIT are located, passed a <u>law</u> in 1989 requiring that any institution planning to conduct experiments on vertebrate animals must apply for a permit. All laboratories are inspected annually by the commissioner of laboratory animals, who also reviews research programs, protocols, and procedures. The <u>law</u> requires that during the annual visit, institutions provide information on the number and species of animals used during the previous year.
- 7. **Missouri:** <u>SB1319</u> was introduced this year and is up for a House hearing. If passed, the <u>bill</u> would require that universities that receive state funding post annually on their websites critical information pertaining to animal testing, including total funding used, funding sources, active protocols, documents related to AWA violations, efforts to adhere to the 3Rs, species of animals used, and animal counts. The animal counts would be required to include the total number of animals adopted out from laboratories as well as the number of animals euthanized.
- 8. New York: The Public Health Act requires that all research facilities that test on animals

be annually approved by the New York Department of Health Commissioner, and they are also subject to inspection by the health department. Additionally, "[o]nly laboratories that hold a New York State <u>clinical laboratory permit</u> are authorized to perform testing on specimens originating from New York," adding another layer of oversight.

- 9. **Oregon:** An Oregon <u>law</u> requires that Oregon Health & Science University, where the <u>Oregon National Primate Research Center</u> is located, publish information annually pertaining to experiments involving nonhuman primates (NHPs), including the number of primates used in experiments and for breeding purposes as well as any who were injured or died in relation to U.S. Department of Agriculture (USDA) citations. This new legislation came about after many years of the <u>USDA citing the university</u> for federal animal welfare violations.
- 10. Washington: <u>HB2304</u> was introduced this year and would have required that the University of Washington's (UW) Washington National Primate Research Center publish information annually pertaining to experiments involving NHPs, including the number of primates used in experiments and for breeding purposes as well as any who were injured or died in relation to USDA citations and any who were killed or died while on protocol.

**From:** rr-VDACS.Commissioner <vdacs.commissioner@vdacs.virginia.gov> **Sent:** Thursday, September 12, 2024 1:11 PM

**To:** Suzanne Griffin <srgriffin@vt.edu>; Hildabrand, Annette - hildabak <hildabak@jmu.edu>; Robert N. Corley <RCORLEY@VSU.EDU>; Daphna Nachminovitch <DAPHNAN@peta.org>; Sharon Adams <sharonadams980@gmail.com>; Will Lowrey <wlowrey@animalpartisan.org>; D. Joshua Cohen <djcohen@vcu.edu>; raphael.malbrue@virginia.edu; Steve Weddle <stevew@vpa.net>; Megan Rhyne <mrhyne@opengovva.org>; Louden, Corrine (OSIG) <Corrine.Louden@osig.virginia.gov>; senatorstanley@senate.virginia.gov; senatorboysko@senate.virginia.gov; Aimee Perron Seibert <aimee@commonwealthstrategy.net>; Bell, Justin I. <jbell@oag.state.va.us>;

delhkent@house.virginia.gov; Smith, Paul (SCHEV) <PaulSmith@schev.edu>; Schmidt, Kevin (VDACS) <Kevin.Schmidt@vdacs.virginia.gov>; Joseph, Isaac (VDACS) <Isaac.Joseph@vdacs.virginia.gov>; Pantazis, Kirstin (SCHEV) <KirstinPantazis@schev.edu>; Pantazis, Kirstin (SCHEV) <KirstinPantazis@schev.edu>; Pantazis, Kirstin (SCHEV)

<KirstinPantazis@schev.edu>

**Cc:** Office Contact <contact@simondsfordelegate.com>

Subject: Fw: Colorado bill

## Good afternoon,

Task Force Member, Ms. Rhyne, shared the following information below and requested that it also be shared with the Task Force members. Please be aware, that the link will take you to the Colorado General Assembly and you have the option to review the PDFs. If you are unable to download the PDFs, please advise.

Our office will continue to share information as it is received.

## Best Regards,

Joe



Joseph W. Guthrie Commissioner Virginia Department of Agriculture and Consumer Services

Phone: 804.786.3501 Website: www.vdacs.virginia.gov E-mail: vdacs.commissioner@vdacs.virginia.gov Address: 102 Governor Street, Richmond, Virginia 23219

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From: Megan Rhyne <<u>mrhyne@opengovva.org</u>>
Sent: Tuesday, September 10, 2024 6:02 PM
To: rr-VDACS.Commissioner <<u>vdacs.commissioner@vdacs.virginia.gov</u>>
Cc: Metz, Stacy (VDACS) <<u>stacy.metz@vdacs.virginia.gov</u>>
Subject: Colorado bill

Dear Commissioner Guthrie —

I've been reading the public comments submitted to the animal-testing task force, and I've seen a few references to Colorado. The States United for Biomedical Research comments, for instance, say that Colorado rejected "similar reporting and transparency requirements to those that are under consideration in Virginia." I wanted the group to see what that effort looked like so they can judge for themselves how that proposal compares to what may be sought here in Virginia.

Health-Related Research Test Subjects | Colorado General Assembly leg.colorado.gov

Thank you for your time and attention to this. I've been learning so much!

Megan

-----

Megan Rhyne Virginia Coalition for Open Government P.O. Box 2576 Williamsburg VA 23187 540-353-8264 www.opengovva.org

blue-book) is now online

## <u>Colorado General Assembly (/)</u>

## < <u>Share</u>

## sb24-067 Health-Related Research Test Subjects

Concerning standards for facilities that use test subjects in health-related research.

SESSION: 2024 Regular Session

SUBJECT: Public Health

**BILL SUMMARY** 

The bill requires a facility that uses animals for health-related research to:

- Submit annual reports to the department of public health and environment regarding the use of animals in the facility; and
- Transfer dogs and cats owned by the facility to animal shelters and pet animal rescues before euthanizing the animal.

(Note: This summary applies to this bill as introduced.)

View Recent Bill Text

View Recent Fiscal Note

## **PRIME SPONSORS**



Senator Sonya Jaquez Lewis (/legislators/sonya-jaquez-lewis)



Representative Lorena García (/legislators/lorena-garcia)



Representative Manny Rutinel (/legislators/manny-rutinel)

## COMMITTEES

### Senate Health & Human Services (/committees/health-human-services/2024-regular-session).

## Status

Introduced	
Lost	

## Menu

Bill Text

## **Bill Text**

All Versions (1	<u>L)</u> .	$\odot$
DATE	BILL TYPE	DOCUMENTS
01/22/2024	Introduced	<u>PDF (https://leg.colorado.gov/sites/default/files/documents/2024A/bills/2024a_067_01.pdf)</u>

## **RELATED BILLS**

HB23-1218 Health Facility Patient Information Denied Service (/bills/hb23-1218)

SB18-271 Improve Funding For Marijuana Research (/bills/sb18-271)

### SB18-045

## **RELATED PUBLICATIONS**

**Staff Publications** 

Legislative Efforts to Control Prescription Drug Prices (/publications/legislative-efforts-control-prescription-drug-prices)

Other

<u>Arapahoe House Presentation to the Opioid Interim Committee (/publications/arapahoe-house-presentation-opioid-interim-committee)</u>

(/bills)

Issue Briefs

<u>Understanding Nuclear Energy's Role in an Energy Portfolio (21-04) (/publications/understanding-nuclear-energys-role-energy-portfolio-21-04)</u>





<u>Find a Bill</u>

Find My Legislator

<u>(/house-district-map)</u>



<u>How a Bill Becomes a Law</u> (/sites/default/files/bill\_becomes\_law\_chart.pdf)



Colorado General Assembly 200 E Colfax Avenue Denver, CO 80203 <u>comments.ga@coleg.gov (mailto:comments.ga@coleg.gov)</u>

**RESOURCES & INFORMATION** 

Colorado Open Records Act Maximum Hourly Research and Retrieval Fee (https://leg.colorado.gov/node/1669596/)

Legislative Resources & Requirements (/legislative-resources-requirements)

Legislative Workplace Study (/publications/legislative-workplace-study)

<u>RFP Conduct the 2025 Colorado Property Assessment Study (https://leg.colorado.gov/sites/default/files/rfp\_24-25\_property\_tax\_audit.pdf)</u>

Rules & Regulations of Executive Agencies (/executive-agency-rules-regulations)

Salaries for Legislators, Statewide Elected Officials, and County Officers (https://leg.colorado.gov/agencies/legislative-councilstaff/salaries-legislators-and-county-officers)

State Home (http://www.colorado.gov/)

<u>Transparency Online Project (https://data.colorado.gov/stories/s/fjyf-bdat)</u>

POLICIES

Accessibility (https://leg.colorado.gov/accessibility)

Language Interpretation Services Policy (https://leg.colorado.gov/sites/default/files/images/updated\_colorado\_legislative\_branch\_interpretation\_services\_policy.pdf)

Remote Testimony and Remote Participation Policies (/node/2328306/)

Open Records Requests & Policy (/open-records-requests)

Privacy Policy (http://leg.colorado.gov/sites/default/files/privacypolicy.pdf)

Public Wi-Fi (http://leg.colorado.gov/sites/default/files/publicwifi.pdf)

Workplace Expectations (https://leg.colorado.gov/workplace-expectations)

Workplace Harassment Policy (https://leg.colorado.gov/workplace-harassment-policy)

FOR LEGISLATORS & STAFF

Ethics Tutorial (https://sites.google.com/view/coga-ethics-tutorial/)

IT Login (https://leg.colorado.gov/user/login)

Social Calendar (/social-calendar)

House and Senate Rules (/house-senate-rules)

<u>Policy on Member Requests for CSP Protection</u> (<u>https://leg.colorado.gov/sites/default/files/images/executive\_committee\_policy\_for\_seeking\_csp\_protection.pdf)</u>

### **APPENDIX P-1**

Submitted Proposal 1 – Delegate Shelly Simonds

From: To:	rr-VDACS.Commissioner Suzanne Griffin; Hildabrand, Annette - hildabak; Robert N. Corley; Daphna Nachminovitch; Sharon Adams; Will Lowrey; D. Joshua Cohen; raphael.malbrue@virginia.edu; Steve Weddle; Megan Rhyne; Louden, Corrine (OSIG); senatorstanley@senate.virginia.gov; senatorboysko@senate.virginia.gov; Aimee Perron Seibert; Bell, Justin I.; delhkent@house.virginia.gov; Smith, Paul (SCHEV); Schmidt, Kevin (VDACS); Joseph, Isaac (VDACS); Pantazis, Kirstin (SCHEV); Kirstin (SCHEV) <kirstinpantazis@schev.edu></kirstinpantazis@schev.edu>
Cc:	Office Contact
Subject:	Fw: Recommendation idea
Date: Attachments:	Tuesday, September 17, 2024 10:46:51 AM <u>Outlook-fidsg1sd.png</u>

Good morning, Task Force Members,

Please see the proposal as submitted to us.

### Best Regards,

Joe



Joseph W. Guthrie Commissioner Virginia Department of Agriculture and Consumer Services

Phone: 804.786.3501 Website: <u>www.vdacs.virginia.gov</u> E-mail: <u>vdacs.commissioner@vdacs.virginia.gov</u> Address: <u>102</u> Governor Street, Richmond, Virginia 23219

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From: Office of Delegate Simonds <contact@simondsfordelegate.com>
Sent: Monday, September 16, 2024 4:30 PM
To: Guthrie, Joe (VDACS) <Joseph.Guthrie@vdacs.virginia.gov>
Cc: Metz, Stacy (VDACS) <Stacy.Metz@vdacs.virginia.gov>
Subject: Recommendation idea

Recommendation suggestion from Del. Simonds

During our Task Force meetings, our university partners have expressed a sincere commitment to the ethical treatment of animals used in academic research and we have learned that universities do have rigorous in-house procedures to track the animals used in research as part of IACUC protocols.

At issue is that these research protocols and documentation are not available to the

public, despite well established public interest in animal testing. Therefore we have a disconnect between the rigorous tracking happening inside the university and public access to this information.

I propose that our task force recommend a new requirement that all public universities doing research using animals publish an IACUC annual report summarizing data from current IACUC protocols and giving context for this research. Every report would be required to include the following data:

The total number of animals used for research including birds, mice and rats with such animals identified according to species.

How they were acquired or purchased or adopted.

•

The number of animals born at the facility during the preceding calendar year.

•

The disposition of the animals by group at the end of the calendar year; meaning the number of animals euthanized, lost, adopted, transferred, traded or sold to other facilities during the preceding calendar year.

•

The number of animals who experienced adverse events during the preceding year identified by species, where adverse events means those unexpected incidents that lead to harm, or endanger the well-being of animals or humans at a research facility.

•

The dollar amount expended by each facility in the preceding calendar year for the use of animals in research to procure and maintain the animal.

The report would include data on animals used across the university so as to protect intellectual property in specific experiments. The report would also allow universities to provide context and organize the information the way they prefer, to include the narrative context of their research programs and how they are addressing the international principals of the "Three Rs" replacement reduction and refinement.

I hope we can discuss this idea at our upcoming meeting. Sincerely, Del. Shelly Simonds The Office of Delegate Shelly Simonds House District 70 <u>contact@simondsfordelegate.com</u> Richmond: (804) 698-1070; Room 1106 District: (757) 276-3022

### **APPENDIX P-2**

Submitted Proposal 2 – D. Nachminovitch & W. Lowrey

### Animal Testing Transparency Task Force Proposal for Discussion

Original legislation: SB411 and HB580

An animal testing facility (as defined <u>here</u>) that uses an animal test method shall annually submit to the <mark>Virginia Department of Agriculture and Consumer Services (VDACS) or to the State Council of Higher Education for Virginia (SCHEV) in a format prescribed by [the agency] the following information.</mark>

- 1. The total number of animals (on hand both at the beginning of the reporting period and at the end of the reporting period) used or held, for research, education, testing, or experimental, scientific, or biomedical purposes with such animals identified and grouped according to use and species;
- 2. The number of animals purchased and/or acquired from, including via transfer or trade with, other animal testing facilities or suppliers, during the preceding calendar year, with such animals identified and grouped according to species, and including the names and locations of the facilities supplying the animals, and identifying the numbers of each species supplied by each such facility;
- 3. The number of animals born at the facility during the preceding calendar year, with such animals identified and grouped according to species;
- 4. The number of animals euthanized, lost, adopted, transferred, traded or sold to other facilities during the preceding calendar year, with such animals identified and grouped according to disposition outcome and species;
- 5. The number of animals who died unassisted during the preceding calendar year, identified and grouped according to species;
- 6. The number of animals who experienced adverse events during the preceding calendar year, identified and grouped according to species; where the term "adverse events" means "those unexpected incidents that lead to harm, or endanger the well-being of animals or humans at a research facility."
- 7. The dollar amount expended by such facility during the preceding calendar year on activities that involved the use of animals in research, education, testing, experimental, scientific, or biomedical purposes where such dollar amount shall include amounts spent to procure and maintain the animals (including food, housing, veterinary care, administrative costs, animal care technicians, and other related costs) as well as amounts spent during the course of use of the animal.

**Commented [A1]:** Highlighted to be discussed/determined

### **APPENDIX P-3**

Submitted Proposal 3 – University of Virginia



### Subject: Recommendations for Enhancing Transparency in Animal Research

### Commissioner Guthrie,

I hope this message finds you well. I am writing on behalf of most, if not all, institutions represented on the task force on transparency in publicly funded animal testing facilities. Below is a list of recommendations that we believe will further enhance transparency in animal research conducted at public institutions within the Commonwealth.

At the heart of our institutions' mission is a deep commitment to responsible, ethical research and a genuine desire to address public concerns. We value the trust and investment the public has placed in our work, and it is our goal to ensure that our practices not only uphold the highest standards of care but also reflect the interests and concerns of the communities we serve.

With that in mind, we have carefully considered the following recommendations, which we feel will promote a clearer, more transparent relationship between public institutions and the public when it comes to animal research:

### **Goals:**

- 1. To provide greater transparency
- 2. To facilitate public access to information compiled and required under existing regulatory schemes governing laboratory animal research
- 3. To support the Commonwealth's ability to advance research that is vital for the advancement of both human and animal condition, and minimize burdens placed on researchers and institutions

### **Recommendations:** *On or before July 1 of each year*

- Each institution that holds USDA registration shall provide its most recent annual report to the USDA APHIS on its required form that provides the number of animals by species
- Each institution that holds USDA registration shall provide a copy of each USDA APHIS inspection report (which includes the VMO findings from inspection potentially including citation) as well as the institution's response, if applicable
- Each institution shall generate a summary of all FOIA requests received over the preceding fiscal year related to animal research including requesting party
- Each institution shall provide a narrative report of the federal and state requirements applicable to the institution's animal research program as well as such institution's additional internal processes designed to strengthen its commitment for the ongoing improvement of animal care and welfare

# UNIVERSITY of VIRGINIA

- Include institution's philosophy and approach to advancing the 3Rs in animal research (Replacement, Reduction, and Refinement)
- Include general information about the professional qualifications of the institution's IACUC
- The State Council of Higher Education for Virginia (SCHEV) shall provide a landing page on its website directing to <u>the above reports</u> for ease of public access so interested parties can readily access the information in one location
- Institutions shall establish of an annual Higher Education Biomedical Research Day (at the Virginia General Assembly) that is organized by the institutions to provide awareness, outreach and education about biomedical research activities in the Commonwealth and the opportunity for meaningful dialogue about the programs with the public

We believe that by implementing these steps, we can strengthen public trust and ensure that the research being conducted within the Commonwealth is both ethical and transparent.

Thank you for considering these recommendations. We would be happy to engage in further dialogue and provide additional details if needed at the upcoming task force meeting. Please don't hesitate to reach out with any questions or thoughts.

Respectfully,

lon

Raphael A. Malbrue, DVM, MS, CertAqV, DACLAM Director & Attending Veterinarian Center for Comparative Medicine Phone:434-924-5058 I Fax:434-924-0354 I Email: yyb6wq@virginia.edu

#### **APPENDIX P-4**

VAAS



#### Fw: Recommendations for Annual Reporting by publicly funded Virginia institutions

From rr-VDACS.Commissioner <vdacs.commissioner@vdacs.virginia.gov>

Date Tue 9/17/2024 10:45 AM

- To Suzanne Griffin <srgriffin@vt.edu>; Hildabrand, Annette hildabak <hildabak@jmu.edu>; Robert N. Corley <RCORLEY@VSU.EDU>; Daphna Nachminovitch <daphnan@peta.org>; Sharon Adams <sharonadams980@gmail.com>; Will Lowrey <wlowrey@animalpartisan.org>; D. Joshua Cohen <djcohen@vcu.edu>; raphael.malbrue@virginia.edu <raphael.malbrue@virginia.edu>; Steve Weddle <stevew@vpa.net>; Megan Rhyne <mrhyne@opengovva.org>; Louden, Corrine (OSIG) <Corrine.Louden@osig.virginia.gov>; senatorstanley@senate.virginia.gov <senatorstanley@senate.virginia.gov>; senatorboysko@senate.virginia.gov <senatorboysko@senate.virginia.gov>; Aimee Perron Seibert <aimee@commonwealthstrategy.net>; Bell, Justin I. <jbell@oag.state.va.us>; delhkent@house.virginia.gov <delhkent@house.virginia.gov>; Smith, Paul (SCHEV) <PaulSmith@schev.edu>; Schmidt, Kevin (VDACS) <Kevin.Schmidt@vdacs.virginia.gov>; Joseph, Isaac (VDACS) <Isaac.Joseph@vdacs.virginia.gov>; Pantazis, Kirstin (SCHEV) <KirstinPantazis@schev.edu>
- Cc Office Contact <contact@simondsfordelegate.com>

1 attachments (523 KB) APHIS\_7023.pdf;

Good morning, Task Force Members,

Please see the proposal as submitted to us.

Best Regards,

Joe



Joseph W. Guthrie Commissioner Virginia Department of Agriculture and Consumer Services

Phone: 804.786.3501 Website: www.vdacs.virginia.gov E-mail: vdacs.commissioner@vdacs.virginia.gov Address: <u>102 Governor Street, Richmond, Virginia 23219</u>

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From: Sharon Adams <sharonadams980@gmail.com> Sent: Friday, September 13, 2024 11:54 AM To: Guthrie, Joe (VDACS) <Joseph.Guthrie@vdacs.virginia.gov>
Cc: Metz, Stacy (VDACS) <Stacy.Metz@vdacs.virginia.gov>
Subject: Recommendations for Annual Reporting by publicly funded Virginia institutions

Dear Commissioner Guthrie, co-Chair Smith and Members of the Task Force,

Please accept this proposal as the VAAS recommendation for approval by the Transparency Task Force to be forwarded for action by the Virginia Legislature.

Virginia law requires that publicly-funded entities provide an array of annual reports and public information to inform its citizenry, to encourage participation in the democracy, and to ensure accountability. The purpose of requiring publicly available and comprehensive reports including the number of animals being held and used for experimental purposes in taxpayer-funded institutions is consistent with Virginia's requirements for other animal handling organizations and the responsibility associated with using tax dollars to support an organization's work.

The concerns presented to the Transparency Task Force regarding the publication of information regarding animals being held for and used for experimental purposed in Virginia seem to be the following:

### 1. It would be costly to produce animal counts or additional reports.

Inasmuch as Dr. Malbrue has presented documents reflecting where some information is already being collected, it doesn't appear that aggregating the information for a Virginia report would support the astronomical increased costs presented as an obstacle. All of the information that we believe should be reported is already being collected as part of any research protocol and the IACUC application process.

### 2. The information is either irrelevant or confusing without context.

The institutions can provide context by directing the interested parties to the websites of each institution where further explanations and information can be offered. Every institution believes that the research it is performing is valuable. Its researchers must make the case for conducting that research during the IACUC application process. Accordingly, the institutions would be the very best advocate for these activities and could provide context to their liking. The institution need not present information on ongoing research that would compromise it but can readily present information and make broader statements about the ongoing intent and perceived benefits of its research.

# 3. Production of this information will negatively impact future research efforts in Virginia.

The institutions have provided no evidence supporting this assertion. In fact, many sources suggest that researchers may actually benefit from more transparency which

could improve accountability, obtain valuable input for institutional decision making, and bolster public confidence.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7912879/ https://speakingofresearch.com/2018/02/20/basel-declaration-society-conferencecalls-for-greater-transparency-in-animal-research/

https://news.uoguelph.ca/2022/08/how-institutional-transparency-could-improveanimal-research/

### 4. The information may not be of interest to the public.

The argument that its unknown whether the public is interested in this topic is refuted by numerous studies and surveys. For example, a Pew Research article reflecting the opinions of the public relative to animal research-

https://www.pewresearch.org/short-reads/2018/08/16/americans-are-dividedover-the-use-of-animals-in-scientific-research/. According to this survey, the public already has opinions regarding animal research and 52% oppose it. Those opinions would be enhanced by access to accurate and complete information. Notwithstanding that research, hundreds of organizations large and small are required to report annually on public websites including those not directly receiving taxpayer funds, indicating the General Assembly's recognition that the citizens of the Commonwealth value data on the workings of the government and other entities. For example, all nonprofit organizations must file an annual report with the State Corporation Commission.

It is a foundational expectation that organizations receiving taxpayer funds, as well as many others, are publicly accountable for the activities supported by those funds. In fact, higher education institutions have an obligation to publish an array of information, for

example <u>https://law.lis.virginia.gov/vacode/title23.1/chapter4/section23.1-409/</u>. Surely responsibly posting about the sentient animals being held and used for research at a publicly funded institution is at least as relevant to the public as "the average wage of undergraduate alumni within 20 years of graduation" which is currently required to be reported annually. (See above statute)

### Therefore the proposal outline below is recommended for adoption:

A. The APHIS Annual Report of Research Facility for each institution should be posted on the SCHEV website annually and be accompanied by the following additional information by species, to include all species used in research, including those currently excluded by the Animal Welfare Act: (See Attachment A below)

1. Number of animals purchased by the research facility, transferred in or out of the research facility, or bred in the research facility.

2. Number of animals euthanized or died unassisted.

3. Number and description of Adverse Events as defined by the National Institutes of Health.

B. The addition of the aforementioned data for other species of currently excluded animals should accompany the annual report, including the count of such animals.

Finally, the inclusion of the amount of Virginia and federal taxpayer funding for animal research for each institution should be posted along with the above-mentioned report.

We believe that all of this information is already being collected as a consequence of the research itself or the management of the animals in the institutions' care. Counting the number of animals in the care of the institution once per year does not seem to be an onerous burden. The posting of each public institution's annual report will enable any interested party to follow the progress of that institution in achieving the 65-year-old goal of the 3Rs: <u>Reducing, Refining and Replacing the</u> number of animals used for experimentation. The report will also enable the institutions to provide further context to their research activities by linking each report to its website.

Respectfully submitted, Sharon Quillen Adams, MPA Chair, Virginia Alliance for Animal Shelters

(Attachment Annual Report of Research Facility)

This report is required by law	reviewing the collection of inf (7 U.S.C. 2143 and 9 C.F.R.		ording to the re	gulations can result	t in an order to	Interagency Report Control	Fiscal	0579-0036
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Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	which e teachin surgery conduc accomp distress and for appropr analges	iate anesthetic,	experime conducted distress tu appropria tranquilizi affected ti interpreta experime of the pro these anii	f animals upon which teaching, nts, research, surgery, or tests we i involving accompanying pain or o the animals and for which the us te anesthetic, analgesic, or ng drugs would have adversely te procedures, results, or ion of the teaching, research, nts, surgery, or tests. (An explana cedures producing pain or distress mals and the reasons such drugs used must be attached to this repo	e of tion s on	TOTAL NUMBE OF ANIMALS (Cois. C + D + F
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#### APHIS Form 7023 Site Addendum for FY:

Registration Number:

Customer ID Number:

Facility Business Address Information:

Telephone:

Facilities Site(s) Address Information:

Site Codes:

#### INSTRUCTIONS FOR COMPLETION OF APHIS FORM 7023 (Refer to U.S.C. 7 Section 7A and 9 C.F.R. Section 2.36)

ITEM 1 -	Enter registration number as assigned to the Research Facility by United States Department of Agriculture (USDA).
ITEM 2 -	Enter the complete name and address of the Headquarters Research Facility as registered with USDA. If the name or business address has changed, notify the Fort Collins, CO office in writing as soon as possible. Correcting the information on your annual report packet is not sufficient.
ITEM 3 -	List the location of each site where the animals were housed and used in actual research, teaching, testing experimentation, or held for such purposes. (Attach additional sheets if necessary). Provide the information but do not provide the building or room numbers.
ITEMS 4 - 13 -	DO NOT enter the numbers in Column A. DO NOT add numbers entered into Column B into the totals in Column F. Column F is to only show the combined totals in Column C, D, and E from APHIS Forms 7023 and APHIS Form 7023A or some other type of attached continuation.
ITEM 12 -	List by common name all other farm animal species
ITEM 13, Other -	List by common name all other species covered by the Regulations. (This will include wild and exotic species.) Use additional sheets if necessary or APHIS Form 7023A. Report wild rodents. DO NOT report the use of laboratory rats and mice (genera <i>rattus</i> and <i>mus</i> ) bred for research. DO NOT report birds. DO NOT report reptiles, fish, and other animals exempt for the regulations under the AWA. DO NOT include animals used in clinical trials in the context of a Veterinary- Client relationship, and DO NOT include animals in a field study as defined under the Animal Welfare Act. If there are questions about a particular activity, contact the Fort Collins, CO office for guidance.

**CERTIFICATION** - Must be signed by the Chief Executive Officer (C.E.O.) of the Registered Research Facility or other Institutional Official (*I.O.*) having authority to legally commit on behalf of the Registered Research Facility. Sign, print or type Name and Title, and Date.

RETURN COMPLETED FORM WITH AN ORIGINAL SIGNATURE OF C.E.O. OR I.O. TO THE FORT COLLINS, CO OFFICE.

#### **Privacy Act Notice**

Authority: The Animal Welfare Act (AWA), 7 U.S.C. 2131 *et seq.*, and the regulations issued thereunder, 9 CFR parts 1 through 4; and the Horse Protection Act (HPA), 15 U.S.C. 1821 *et seq.*, and the regulations issued thereunder, 9 CFR parts 11 and 12.

Purpose: This system supports APHIS' administrative activities and enforcement of the AWA and HPA.

#### **Routine Uses:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a (b) of the Privacy Act, records maintained in the system may be disclosed outside USDA as follows:

(1) APHIS may disclose the name, city, State, license or registration type and/or status, or change of a license or registrant to any person pursuant to 9 CFR 2.38(c) and 2.127;

(2) APHIS may disclose annual reports submitted to APHIS by licensees and research facilities to any person pursuant to 9 CFR 2.7 and 2.36;

(3) APHIS may disclose inspection reports and other regulatory correspondence issued to licensees and registrants [from the agency] to any attending veterinarian in order to carry out duties under the AWA pursuant to 9 CFR 2.33 and 2.40;

(4) APHIS may disclose the name, telephone number and other contact information, location, inspection reports, and regulatory and other correspondence of licensees, registrants, permitees, and applicants for the same, to appropriate Federal, foreign, State, local, Tribal, or other public authority agencies or officials, in order to carry out duties under the AWA or State, local, Tribal or other public authority on the same subject pursuant to 7 U.S.C. 2145(b);

(5) APHIS may disclose inspection reports of licensees and registrants, and permit status, to any pet store or other entity that is required under State, local, Tribal, or other public authority to verify a licensee, registrant, or permitee's compliance with the AWA;

(6) APHIS may disclose information to the National Academies of Sciences, Engineering, and Medicine, and any other research institution engaged or approved by the Department, to the extent APHIS deems the disclosure necessary to complete research and/or compile a report in furtherance of the Department's mission;

(7) APHIS may disclose final adjudicatory AWA and HPA decisions or orders by an appropriate authority to any person;

(8) APHIS may disclose to any person the name, city, and State or other information to the extent necessary for proper identification of persons (referred to as "Designated Qualified Persons" or "DQPs") that are or have been qualified to detect and diagnose a horse that is sore or otherwise inspect horses for purposes of enforcing the HPA and of horse industry organizations or associations (referred to as "HIOs") that have currently or have had in the past DQP programs certified by the USDA;

(9) APHIS may disclose to any regulated horse owner, HIO, and other entities responsible for licensure or required to verify compliance with the HPA, HPA inspection findings and regulatory and other correspondence issued to persons or entities regulated under the HPA;

(10) APHIS may disclose to any person the name, city, and State or other information to the extent necessary for proper identification of any person or entity who has been disqualified, suspended, and/or otherwise prohibited from showing or exhibiting any horse, or judging or managing any horse show, horse exhibition, horse sale, or horse auction under the HPA and the terms of such action;

(11) APHIS may disclose to any person the name, city, and State or other information to the extent necessary for proper identification of any regulated individual or entity whose license or permit has been suspended, revoked, expired, terminated, or denied under the AWA and the terms of such action;

(12) APHIS may disclose to appropriate law enforcement agencies, entities, and persons, whether Federal, foreign, State, local, or Tribal, or other public authority responsible for enforcing, investigating, or prosecuting an alleged violation or a violation of law or charged with enforcing, implementing, or complying with a statute, rule, regulation, or order issued pursuant thereto, when a record in this system on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or court order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative, or prosecutive responsibility of the receiving entity;

(13) APHIS may disclose to the Department of Justice when the agency, or any component thereof, or any employee of the agency in his or her official capacity, or any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or the United States, in litigation, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected;

(14) APHIS may disclose information in this system of records to a court or adjudicative body in administrative, civil, or criminal proceedings when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are to be for a purpose that is compatible with the purpose for which the agency collected the records;

(15) APHIS may disclose information from this system of records to appropriate agencies, entities, and persons when: (a) USDA suspects or has confirmed that there has been a breach of the system of records; (b) USDA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, USDA (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with USDA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;

(16) APHIS may disclose information from this system of records to another Federal agency or Federal entity, when the USDA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach;

(17) APHIS may disclose information in this system of records to USDA contractors and other parties engaged to assist in administering the program, analyzing data, developing information management systems, processing Freedom of Information Act requests, and conducting audits. Such contractors and other parties will be bound by the nondisclosure provisions of the Privacy Act;

(18) APHIS may disclose information in this system of records to USDA contractors, partner agency employees or contractors, or private industry employed to identify patterns, trends, or anomalies indicative of fraud, waste, or abuse;

(19) APHIS may disclose information in this system of records to a Congressional office from the record of an individual in response to any inquiry from that Congressional office made at the written request of the individual to whom the record pertains;

(20) APHIS may disclose information in this system of records to the National Archives and Records Administration or to the General Services Administration for records management activities conducted under 44 U.S.C. 2904 and 2906; and

(21) APHIS may disclose information in this system of records to the Treasury Department as necessary to carry out any and all functions within their jurisdiction, including but not limited to, processing payments, fees, collections, penalties, and offsets.

**Disclosure:** Furnishing this information is voluntary; however, failure to furnish this information may impede your ability to comply with the requirements of the Animal Welfare Act, regulations, and standards.

#### APPENDIX Q

Information Regarding Stress, Crowding, and Competition for Resources On Mortality Rates in Rodent Population – D. Nachminovitch

#### Stress, Crowding, Competition for Resources Contribute to Mortality in Rodent Populations: A Welfare Issue

According to <u>Dr. Susan Brown</u>, who has decades of expertise and experience working with many small animal mammal species and who has served as an on-site expert on a number of cruelty to animals cases involving thousands of rodents: "Cannibalism is not the norm between adult rats [and] mice [who] are kept in an environment that has adequate resources for the number of animals in the cage and that provides adequate personal space."

Cannibalism is typically a manifestation of stress. In the study <u>Effects of enrichment devices on</u> <u>stress-related problems in mouse breeding</u>, the authors write that cannibalism of newborn pups "is probably stress-related," and the study found that "the provision of enrichment devices may lead to increased survival in mouse litters."

Cyagen, a company that breeds "genetically modified rodent models" for use in animal testing, states that among the <u>main reasons</u> mother mice eat their babies are malnutrition and environmental stressors, including "high stocking densities, tight spaces, and high temperatures," as well as bright lights, loud noises, and unusual smells. Similarly, according to a Merck Veterinary Manual <u>article</u>, female mice "may abort, abandon, or eat their babies due to inadequate food, lack of water, overcrowded group housing, inadequate nesting materials, sick or deformed pups, or excessive noise."

The authors of the paper <u>All the Pups We Cannot See: Cannibalism Masks Perinatal Death in</u> <u>Laboratory Mouse Breeding but Infanticide is Rare</u> found that infanticide was "rare" and was "not a principal cause of death and that most of the cannibalized pups were already dead at the start of the events." These deaths almost always occurred in crowded cages housing more than one mother and/or litter. Most importantly, this paper notes that these "[h]igh mortality rates are an animal health and welfare concern and the loss of large numbers of pups violates the 3Rs principle."

#### APPENDIX R

Meeting Summary, September 20, 2024



VIRGINIA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES





#### STATE COUNCIL OF HIGHER EDUCATION FOR VIRGINIA

### Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities

Patrick Henry Building September 20, 2024

#### Introduction

The third meeting of the Commonwealth Legislative Task Force on Transparency in Publicly Funded Animal Testing Facilities was held on September 20, 2024, at the Patrick Henry Building in Richmond, Virginia. The session was attended by all seventeen (17) appointed members or their designees as well as facilitators from the Institute for Engagement & Negotiation (IEN) and members of the public. The following members were present:

Commissioner, Joseph Guthrie (Chair) Virginia Department of Agriculture and Consumer Services (VDACS) Dr. Paul Smith (Vice Chair) State Council of Higher Education for Virginia (SCHEV) Delegate Shelly Simonds (D, VA-70) Delegate Hillary Pugh Kent (R, VA-67) Senator Jennifer Boysko (D, VA-38) Senator William Stanley (D, VA-20) - remote Corrine Louden, Freedom of Information Advisory Council (FOIA Council) Daphna Nachminovitch, People for the Ethical Treatment of Animals (PETA) Dr. Robert Corely, III, Virginia State University Steve Weddle, Virginia Press Association (VPA) Sharon Adams, Virginia Alliance for Animal Shelters (VAAS) Dr. Annette Hildabrand, James Madison University (JMU) Dr. Raphael Malbrue, University of Virginia (UVA) Will Lowrey, Animal Partisan Dr. D. Josh Cohen, Virginia Commonwealth University (VCU) Megan Rhyne, Virginia Coalition for Open Government (VCOG) Suzanne Griffin, Virginia Polytechnic Institute and State University (VT)

#### Welcome, Introductions, and Approval of Minutes

Commissioner of Agriculture and Consumer Services Guthrie introduced himself and Dr. Paul Smith (SCHEV), Vice Chair. Members introduced themselves, and minutes from the August meeting were passed. A remote meeting policy offered by the Chair and was passed by the Task Force. This will allow for remote participation for members with a planned October virtual meeting to review the draft report prior to submission to the General Assembly.

Chair Guthrie asked Senator Stanley to introduce himself and share his response to the initial prompt asking what success in the Task Force would look like, in his view. He explained that Envigo was within his district, and he feels very passionately about this issue. He believes that more steps are needed to protect all animals—not just companion animals which have become better protected following the Envigo incident.

#### **Review Reports for Task Force Members**

Mr. Justin Bell, Office of the Attorney General, was asked to share information about Institutional Animal Care and Use Committees (IACUCs). Specifically, the Task Force wanted to know if IACUCs have a responsibility to public disclosure and whether they are public bodies under the Freedom of Information Act (FOIA). Mr. Bell reviewed a circuit court decision from the 1980s that points to IACUCs not being public bodies. Additionally, an attorney general's opinion from 2001 explains that Institutional Review Boards (IRBs) are not public bodies under Virginia law, and Mr. Bell feels that IRBs are analogous to IACUCs. There was discussion about whether an amendment to that section of the law was reviewed as part of the 2001 opinion.

The group agreed there is significant confusion on this topic and suggested that perhaps legislators may consider clarification in the future. A point was made that if legislators wanted to clarify IACUCs under FOIA, it would be important to note that IACUC records fall under public record, not that they are a public body under FOIA, as that would trigger public meeting notice requirements.

After Mr. Bell, Dr. Charles Broaddus, State Veterinarian, spoke about the Office of Veterinary Services (OVS) which is part of VDACS. He noted that OVS does not interact with universities currently; rather, they primarily prepare for, respond to, and mitigate the outbreak of agricultural animal disease in livestock and poultry. Their main mission is to investigate and contain the spread of agricultural disease. Dr. Broaddus also shared that OVS is happy to take on more duties as the General Assembly sees fit, but they estimated they would need at least one more full-time employee (FTE) as well as over \$250,000 in the first year to establish a database. It is estimated that an additional \$110,000 would be needed to keep the software running on an annual basis. There was a request for more information on how the cost was derived. The Commissioner agreed that Dr. Broaddus would provide the quote from VDACS IT.

Megan Rhyne (VCOG) provided information about a bill she had seen referenced several times in public comment and by the Task Force. This information was provided in the packet given to each Task Force member

Daphna Nachminovitch (PETA) provided an overview of the presentation she created with Will Lowery (Animal Partisan). She highlighted that the impetus for the legislation that precipitated the Task Force was the high number of APHIS violations by Virginia institutions. Ms. Nachminovitch also pointed out that the Animal Welfare Act is the only federal regulation which protects some of the animals tested on (again, reminding members that rats, mice, and some birds are excluded). She also wanted to bring to the Task Force's attention that there is a difference between designated member review (DMR) vs. full committee review (FCR) which changes the IACUC process. There was a question about self-reporting of adverse events to NIH's Office of Laboratory Animal Welfare (OLAW) and whether this information is publicly available. Ms. Nachminovitch confirmed that the information in their presentation was obtained through FOIA. There was a follow-up question about whether the majority of research at the universities is federally funded and, therefore, required to self-report to OLAW. The universities said that it varies by institution but that a significant amount of their research is federally funded.

#### **Review of Agenda and Meeting Summary**

Mike Foreman (IEN) reviewed the agenda for the day and reintroduced the group requests/ground rules that guide engagement for the Task Force.

#### **Review Consensus Testing Process**

Kelly Altizer (IEN) reviewed the process for consensus testing and how members would indicate their level of support for a proposal using a 3, 2, or 1. which corresponds to the following:

- (3) Full support for the proposal
- (2) Has some questions or concerns, but can accept the proposal
- (1) Cannot support the proposal as written

Ms. Altizer explained to the group that index cards would be used to allow for anonymous testing for consensus, but that discussion would follow to allow concerns to surface and adjustments to be made to the proposal where needed. Questions were answered about other logistics related to testing for consensus.

Commissioner Guthrie had invited Task Force members to submit their ideas for draft proposals prior to the meeting. Draft proposals were submitted by Dr. Raphael Malbrue, Delegate Shelly Simonds, Daphna Nachminovitch & Will Lowrey, and Sharon Adams, and all are included in Appendix A.

#### **Proposal Review and Evaluation**

Mr. Foreman and Ms. Altizer shared that the IEN team had identified some areas of common ground between the draft proposals submitted, and were offering a combination of those ideas as a start point for testing for consensus. The Commissioner shared that he and Dr. Smith (SCHEV) would abstain from participating in the tests for consensus.

Midway through the consensus testing process, the Commissioner identified that more time was needed, and participants agreed to extend the meeting time until 1:00 p.m. in order to ensure more material could be covered by the group.

#### **Proposal Evaluation: Part One**

Proposals considered in the first round of testing for consensus included:

- A) The SCHEV website will be used for additional information on animal testing [note: this is in response to concerns raised by members that information can be difficult to find and located in many different places, so it would be helpful if there one location where information could be found]
- B) The universities will provide APHIS annual and inspection reports to be posted on the SCHEV web site.
- C) The universities will annually produce a report to document their progress on the 3 Rs to be posted on the SCHEV website.

	Proposal A	Proposal B	Proposal C
No Support	0	1	3
Support with Concerns	3	2	2
Full Support	12	11	10
ABSTAIN		1	
TOTAL	15	15	15
% of NO SUPPORT	0%	7%	20%
% of SUPPORT with concerns	20%	13%	13%
% of FULL SUPPORT	80%	73%	67%

#### Table 1. Consensus Tabulation for Proposals A, B, and C

## Discussion of Proposal A: The SCHEV website will be used for additional information on animal testing

Ms. Altizer noted that this point was raised in the Task Force's first meeting, and at the time members thought that the VDACS website might be an appropriate venue for this information. However, after that meeting, SCHEV was identified as a better fit. Dr. Smith reminded the group that this was because they already have mechanisms in place to receive and post other information from the Universities, while VDACS does not.

Some members expressed concerns about whether the public would know to look at SCHEV's site for this information but were not opposed to it being posted there.

This proposal achieved consensus (3-12, 2-3, 1-0).

## **Discussion of Proposal B -** The Universities will provide APHIS annual and inspection reports to be posted on the SCHEV web site.

Some members expressed concerns that this does not advance transparency since the universities already have to post the reports on their website. In general, group members were supportive of measures that make it easier for people to access information.

This proposal received strong support but did not achieve consensus (3-11, 2-2, 1-1, 1 abstention).

## Discussion from Proposal C - The universities will annually produce a report to document their progress on the 3 Rs to be posted on the SCHEV website.

Group members were generally supportive of more information being shared by the universities, but some members did not want to support this proposal without the inclusion of specific components which were evaluated by the group in the next section below.

One member noted a concern about creating additional reporting burden for researchers.

This proposal received strong support but did not achieve consensus (3-10, 2-2, 1-3).

#### Proposal Evaluation: Part Two

In the second portion of proposal evaluation, group members considered six proposed indicators to be included in an annual report by the universities. They are as follows:

- D) The total number of laboratory animals held in the care of research institutions (excludes agriculture)
- E) How animals were acquired by research institutions (purchased or adopted)
- F) Census Number<sup>1</sup> of animals born at research institutions in last year
- G) The disposition of all animals at research institutions over the last year (euthanized, lost, adopted, transferred, traded, or sold to other facilities).
- H) Adverse events at research institutions during the preceding year (identified by species, as defined by NIH)
- I) The money spent by each research facility in the preceding calendar year for the use of animals in research to procure and maintain the animal.

<sup>1</sup> The word "census" was changed to "number" by the Task Force during the discussion to increase clarity of the statement

The following general discussion points came out during the initial Task Force dialogue:

- Animal as defined by this proposal is "all animals except for fish."
- This would be reported by animal research facilities—which specifically excludes agriculture per Virginia Code
- Reporting these numbers does not preclude the universities from reporting additional context or information with it.
- Adverse event definition from OLAW: "unexpected incidents that lead to harm or endanger the well-being of animals and humans at a research facility."
- Suggestion to change animals "born" to "animals who make it past weaning" as with many rodents there are often issues with interacting with just born animals (puts undue stress on dames) and the fact that many rodent dames eat their young
  - Rebuttal: would not want to change to only animals weaned for primates or dogs / cats / etc. when there are several issues with babies of these species

	Proposal D	Proposal E	Proposal F	Proposal G	Proposal H	Proposal I	
No Support	2	3	3	3	3	4	
Support with Concerns	4	1	3	1	5	2	
Full Support	9	11	9	11	7	9	
TOTAL	15	15	15	15	15	15	
% of NO SUPPORT	13%	20%	20%	20%	20%	27%	
% of SUPPORT with concerns	27%	7%	20%	7%	33%	13%	
% of FULL SUPPORT	60%	73%	60%	73%	47%	60%	

Table 2. Consensus tabulation for Proposals D through I

Each proposal is reflected below along with the comments, ideas, and questions that were raised in the discussion:

## **Discussion of Proposal D:** Total number of laboratory animals held in the care of research institutions

Concerns about the economic cost, burden on researchers, and animal by animal count

- Change could be to make it an approximation or capacity at the research or a range of animals at an institution
- Difficulty around language and precision of counting. In order to make these counts, financial software needs to be acquired, and FTEs need to be hired.

- Question posed—if you know a general amount of food acquired, can you not aggregate to estimate the number of animals?
  - The food is not tracked centrally, it is still difficult to aggregate and takes time and resources
- Discussion about whether these numbers are already being tracked and whether they can just be shared with SCHEV?
  - Universities noted that the numbers submitted to their IACUCs reflect the *maximum* number of animals proposed.
- Universities are not opposed to providing a point in time count of animals; but it would still require financial support
  - 0

This proposal received strong support but did not achieve consensus (3-9, 2-4, 1-2).

## **Discussion From Proposal E:** How animals were acquired by research institutions (purchased or adopted)

- Question about whether animals are inspected when they are acquired
  - Attending vets inspect commercial facilities from which the institution acquires animals from
- With more explanation that animals would just be number of animals purchased vs adopted, etc., some opposition may become more likely to find common ground
- Clarified that information wanted is number of animals acquired through purchase or through adoption

#### Discussion From Proposal F- Number of animals born at research institutions in last year

- Reminded the group about the rodent example put forward before—trying to count rodents born during a year is incredibly difficult (do we count rodents who die via miscarriage or in birth or directly after birth?)
  - Many rodents are culled in biomedical research because they do not have the right genotype
- Suggestion that this would be particularly difficult for rodents (could be a category in G)

## <u>Discussion From Proposal G</u>- The disposition of all animals at research institutions over the last year

- Estimated animals within the categories of euthanized, lost, adopted, transferred, traded, or sold
- Discussion about how some of these datasets are not able to be done through point in time; they are ongoing which requires more resources
  - Universities made the point that this information is not something they are against; they just want to be responsible with taxpayer money given that there is an associated cost
- Clarification that the inclusion of this information would require yearlong tracking
  - $\circ$  Accounting for  ${\it every}$  animal and where they came from / where they end up

- Much of the difficult capturing disposition and breeding numbers revolves around rodents' population colony

## Discussion From Proposal H- Adverse events at research institutions during the preceding year

No new comments raised

This proposal received some support but did not achieve consensus (3-7. 2-5, 1-3).

### **Discussion From Proposal I**- The money spent by each research facility in the preceding calendar year for the use of animals in research to procure and maintain the animal

- Financial data is very difficult to aggregate and is well protected. This may be incredibly burdensome to report.
- There is an assumption that money given by the federal government is reported and tracked, so the information is already available, however those reports do not give a granular budget breakdown.
  - This proposal received strong support but did not achieve consensus (3-9, 2-2, 1-4).

#### Summary of Consensus Results

Many of the proposals received strong overall support from the group. In general, animal and transparency advocates sought changes that would make specific data available and more readily accessible than it currently is. Most representatives from animal testing facilities were receptive to the different types of information being requested, and sought to help Task Force members understand some of the challenges inherent in procuring that information, as well as the burden it would represent from a financial and personnel perspective.

#### **Next Steps**

The Commissioner shared that VDACS would be working on the draft report, and that a virtual meeting would be held on October 11<sup>th</sup> so that Task Force members could share their comments on the document prior to its submission to the General Assembly.

#### **Chair Remarks and Public Comment Period**

Public comments were provided in-person by two people and those will be reflected in the final report.

The Task Force adjourned at 1 pm.

### **Appendix A: Submitted Proposals**

## Proposal #1 - University Proposal (submitted by UVA on behalf of the partner institutions)

#### Commissioner Guthrie,

I hope this message finds you well. I am writing on behalf of most, if not all, institutions represented on the task force on transparency in publicly funded animal testing facilities. Below is a list of recommendations that we believe will further enhance transparency in animal research conducted at public institutions within the Commonwealth.

At the heart of our institutions' mission is a deep commitment to responsible, ethical research and a genuine desire to address public concerns. We value the trust and investment the public has placed in our work, and it is our goal to ensure that our practices not only uphold the highest standards of care but also reflect the interests and concerns of the communities we serve.

With that in mind, we have carefully considered the following recommendations, which we feel will promote a clearer, more transparent relationship between public institutions and the public when it comes to animal research:

#### Goals:

- To provide greater transparency
- To facilitate public access to information compiled and required under existing regulatory schemes governing laboratory animal research
- To support the Commonwealth's ability to advance research that is vital for the advancement of both human and animal condition, and minimize burdens placed on researchers and institutions

#### Recommendations: On or before July 1 of each year

- Each institution that holds USDA registration shall provide its most recent annual report to the USDA APHIS on its required form that provides the number of animals by species
- Each institution that holds USDA registration shall provide a copy of each USDA APHIS inspection report (which includes the VMO findings from inspection potentially including citation) as well as the institution's response, if applicable
- Each institution shall generate a summary of all FOIA requests received over the preceding fiscal year related to animal research including requesting party

- Each institution shall provide a narrative report of the federal and state requirements applicable to the institution's animal research program as well as such institution's additional internal processes designed to strengthen its commitment for the ongoing improvement of animal care and welfare
- Include institution's philosophy and approach to advancing the 3Rs in animal research (Replacement, Reduction, and Refinement)
- Include general information about the professional qualifications of the institution's IACUC
- The State Council of Higher Education for Virginia (SCHEV) shall provide a landing page on its website directing to the above reports for ease of public access so interested parties can readily access the information in one location
- Institutions shall establish of an annual Higher Education Biomedical Research Day (at the Virginia General Assembly) that is organized by the institutions to provide awareness, outreach, and education about biomedical research activities in the Commonwealth and the opportunity for meaningful dialogue about the programs with the public

We believe that by implementing these steps, we can strengthen public trust and ensure that the research being conducted within the Commonwealth is both ethical and transparent.

Thank you for considering these recommendations. We would be happy to engage in further dialogue and provide additional details if needed at the upcoming task force meeting. Please don't hesitate to reach out with any questions or thoughts.

Respectfully,

**Raphael A. Malbrue, DVM, MS, CertAqV, DACLAM** Director & Attending Veterinarian Center for Comparative Medicine

#### Proposal #2 - Delegate Simonds

During our Task Force meetings, our university partners have expressed a sincere commitment to the ethical treatment of animals used in academic research and we have learned that universities do have rigorous in-house procedures to track the animals used in research as part of IACUC protocols.

At issue is that these research protocols and documentation are not available to the public, despite well-established public interest in animal testing. Therefore, we have a disconnect between the rigorous tracking happening inside the university and public access to this information.

I propose that our task force recommend a new requirement that all public universities doing research using animals publish an IACUC annual report summarizing data from current IACUC protocols and giving context for this research. Every report would be required to include the following data:

- The total number of animals used for research including birds, mice and rats with such animals identified according to species.
- How they were acquired or purchased or adopted.
- The number of animals born at the facility during the preceding calendar year.
- The disposition of the animals by group at the end of the calendar year; meaning the number of animals euthanized, lost, adopted, transferred, traded or sold to other facilities during the preceding calendar year.
- The number of animals who experienced adverse events during the preceding year identified by species, where adverse events means those unexpected incidents that lead to harm or endanger the well-being of animals or humans at a research facility.
- The dollar amount expended by each facility in the preceding calendar year for the use of animals in research to procure and maintain the animal.

The report would include data on animals used across the university so as to protect intellectual property in specific experiments. The report would also allow universities to provide context and organize the information the way they prefer, to include the narrative context of their research programs and how they are addressing the international principals of the "Three Rs" replacement reduction and refinement.

I hope we can discuss this idea at our upcoming meeting.

Sincerely,

Del. Shelly Simonds

#### Proposal #3 - Animal Partisan / PETA Proposal

Original legislation: <u>SB411</u> and <u>HB580</u>

An animal testing facility (as defined here) that uses an animal test method shall annually submit to the Virginia Department of Agriculture and Consumer Services (VDACS) or to the State Council of Higher Education for Virginia (SCHEV) in a format prescribed by the following information.

- 1. The total number of animals (on hand both at the beginning of the reporting period and at the end of the reporting period) used or held, for research, education, testing, or experimental, scientific, or biomedical purposes with such animals identified and grouped according to use and species.
- 2. The number of animals purchased and/or acquired from, including via transfer or trade with, other animal testing facilities or suppliers, during the preceding calendar year, with such animals identified and grouped according to species, and including the names and locations of the facilities supplying the animals, and identifying the numbers of each species supplied by each such facility.
- 3. The number of animals born at the facility during the preceding calendar year, with such animals identified and grouped according to species.
- 4. The number of animals euthanized, lost, adopted, transferred, traded or sold to other facilities during the preceding calendar year, with such animals identified and grouped according to disposition outcome and species.
- 5. The number of animals who died unassisted during the preceding calendar year, identified and grouped according to species.
- 6. The number of animals who experienced adverse events during the preceding calendar year, identified and grouped according to species; where the term "adverse events" means "those unexpected incidents that lead to harm, or endanger the well-being of animals or humans at a research facility."
- 7. The dollar amount expended by such facility during the preceding calendar year on activities that involved the use of animals in research, education, testing, experimental, scientific, or biomedical purposes where such dollar amount shall include amounts spent to procure and maintain the animals (including food, housing, veterinary care, administrative costs, animal care technicians, and other related costs) as well as amounts spent during the course of use of the animal.

#### Proposal #4- VA Alliance for Animal Shelters

Dear Commissioner Guthrie, co-Chair Smith and Members of the Task Force,

Please accept this proposal as the VAAS recommendation for approval by the Transparency Task Force to be forwarded for action by the Virginia Legislature. Virginia law requires that publicly funded entities provide an array of annual reports and public information to inform its citizenry, to encourage participation in democracy, and to ensure accountability. The purpose of requiring publicly available and comprehensive reports including the number of animals being held and used for experimental purposes in taxpayer-funded institutions is consistent with Virginia's requirements for other animal handling organizations and the responsibility associated with using tax dollars to support an organization's work.

The concerns presented to the Transparency Task Force regarding the publication of information regarding animals being held for and used for experimental purposed in Virginia seem to be the following:

#### It would be costly to produce animal counts or additional reports.

Inasmuch as Dr. Malbrue has presented documents reflecting where some information is already being collected, it doesn't appear that aggregating the information for a Virginia report would support the astronomical increased costs presented as an obstacle. All of the information that we believe should be reported is already being collected as part of any research protocol and the IACUC application process.

#### The information is either irrelevant or confusing without context.

The institutions can provide context by directing the interested parties to the websites of each institution where further explanations and information can be offered. Every institution believes that the research it is performing is valuable. Its researchers must make the case for conducting that research during the IACUC application process. Accordingly, the institutions would be the very best advocate for these activities and could provide context to their liking. The institution need not present information on ongoing research that would compromise it but can readily present information and make broader statements about the ongoing intent and perceived benefits of its research.

## Production of this information will negatively impact future research efforts in Virginia.

The institutions have provided no evidence supporting this assertion. In fact, many sources suggest that researchers may actually benefit from more transparency which could improve accountability, obtain valuable input for institutional decision making, and bolster public confidence.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7912879/

https://speakingofresearch.com/2018/02/20/basel-declaration-society-conference-callsfor-greater-transparency-in-animal-research/ https://news.uoguelph.ca/2022/08/howinstitutional-transparency-could-improve-animal-research/

#### 4. The information may not be of interest to the public.

The argument that it is unknown whether the public is interested in this topic is refuted by numerous studies and surveys. For example, a Pew Research article reflecting the opinions of the public relative to animal <u>research-https://www.pewresearch.org/short-reads/2018/08/16/americans-are-divided-over-the-use-of-animals-in-scientific-research/.</u> According to this survey, the public already has opinions regarding animal research and 52% oppose it. Those opinions would be enhanced by access to accurate and complete information. Notwithstanding that research, hundreds of organizations large and small are required to report annually on public websites including those not directly receiving taxpayer funds, indicating the General Assembly's recognition that the citizens of the Commonwealth value data on the workings of the government and other entities. For example, all nonprofit organizations must file an annual report with the State Corporation Commission.

It is a foundational expectation that organizations receiving taxpayer funds, as well as many others, are publicly accountable for the activities supported by those funds. In fact, higher education institutions have an obligation to publish an array of information, for example <a href="https://law.lis.virginia.gov/vacode/title23.1/chapter4/section23.1-409/">https://law.lis.virginia.gov/vacode/title23.1/chapter4/section23.1-409/</a>. Surely responsibly posting about the sentient animals being held and used for research at a publicly funded institution is at least as relevant to the public as "the average wage of undergraduate alumni within 20 years of graduation" which is currently required to be reported annually. (See above statute)

Therefore, the proposal outline below is recommended for adoption:

The APHIS Annual Report of Research Facility for each institution should be posted on the SCHEV website annually and be accompanied by the following additional information by species, to include all species used in research, including those currently excluded by the Animal Welfare Act: (See Attachment A below)

- Number of animals purchased by the research facility, transferred in or out of the research facility, or bred in the research facility.
- Number of animals euthanized or died unassisted.
- Number and description of Adverse Events as defined by the National Institutes of Health.

B. The addition of the aforementioned data for other species of currently excluded animals should accompany the annual report, including the count of such animals.

Finally, the inclusion of the amount of Virginia and federal taxpayer funding for animal research for each institution should be posted along with the above-mentioned report.

We believe that all of this information is already being collected as a consequence of the research itself or the management of the animals in the institutions' care. Counting the number of animals in the care of the institution once per year does not seem to be an onerous burden. The posting of each public institution's annual report will enable any interested party to follow the progress of that institution in achieving the 65-year-old goal of the 3Rs: <u>Reducing, Refining and Replacing the number of animals used for experimentation</u>. The report will also enable the institutions to provide further context for their research activities by linking each report to its website. Respectfully submitted,

Sharon Quillen Adams, MPA Chair, Virginia Alliance for Animal Shelters

(Attachment Annual Report of Research Facility)

#### **APPENDIX S**

Meeting Minutes, September 20, 2024

#### **DRAFT MINUTES**

Task Force on Transparency in Publicly Funded Animal Testing Facilities Patrick Henry Building 1111 E Broad St. Richmond, Virginia

September 20, 2024

The third meeting of the Task Force on Transparency in Publicly Funded Animal Testing Facilities (Task Force) convened at approximately 9:00 a.m. on September 20, 2024, at the James Monroe Building. Commissioner of Agriculture and Consumer Services Joseph Guthrie called the meeting to order.

PRESENT	REPRESENTING
Joseph Guthrie	Chair, Virginia Department of Agriculture and Consumer Services (VDACS)
Dr. Paul Smith	Vice Chair, State Council of Higher Education in Virginia (SCHEV)
Suzanne Griffin	R1 University, Virginia Tech
Dr. Annette Hildabrand	R2 University, James Madison University
Dr. Robert Corley, III	Historically black colleges and universities replacing R3 University, Virginia State University
Daphna Nachminovitch	Animal Welfare, People for the Ethical Treatment of Animals
Sharon Adams	Animal Welfare, Virginia Alliance for Animal Shelters
Will Lowrey	Animal Welfare, Animal Partisan
Dr. D. Josh Cohen	Institutional Animal Care & Use Committee Member, Virginia Commonwealth University
Dr. Raphael Malbrue	American College of Laboratory Animal Testing Facility Veterinarian, University of Virginia
Steve Weddle	Virginia Press Association
Megan Rhyne	Virginia Coalition for Open Government
Corrine Louden	Virginia Freedom of Information Advisory Council
Hon. Jennifer Boysko	Senate of Virginia, Senate District 38
Hon. Hillary Pugh Kent	Virginia House of Delegates, House District 67
Hon. Shelly Simonds	Virginia House of Delegates, House District 70
Hon. William Stanley, Jr.	Senate of Virginia, Senate District 7 (by remote participation)

#### STAFF PRESENT

Kelly Altizer, Associate Director of Operations, Institute for Engagement & Negotiation (IEN) Mike Foreman, Special Projects Manager, IEN Meredith Keppel, Senior Associate, IEN Isaac Joseph, Policy Analyst, VDACS

#### INTRODUCTION

The meeting began by reviewing the minutes from the previous meeting. Dr. Cohen made a motion to adopt the minutes, and Dr. Corley seconded the motion. The Task Force voted unanimously to adopt the minutes.

The Task Force's next order of business was to review and approve an electronic meeting policy, which covered both remote participation and all-virtual meetings. Commissioner Guthrie explained that the purpose of adopting the policy was so that the Task Force could meet remotely in October if the Task Force felt the need to hold a fourth meeting and so that Senator Stanley could attend today's meeting electronically. Megan Rhyne made a motion to adopt the electronic meeting policy, and Dr. Hildabrand seconded the motion. The Task Force voted unanimously to approve the policy. Once the Task Force adopted the policy, Senator Stanley requested to attend the meeting electronically from a Senate retreat being held in Virginia Beach. As provided in Va. Code § 2.2-3708.3(B)(3), Senator Stanley participated through electronic communications means due to the distance between his principal residence and the meeting location. The Task Force approved Senator Stanley's request.

Commissioner Guthrie asked Justin Bell, Assistant Attorney General, to give a brief presentation on whether an Institutional Animal Care and Use Committee (IACUC) is a public body pursuant to the Virginia Freedom of Information Act (FOIA). This question had been raised during previous Task Force meetings. Mr. Bell provided a summary of relevant case law and answered questions from the task force members.

Commissioner Guthrie asked Dr. Charles Broadus, State Veterinarian and Director, Division of Animal and Food Industry Services, to provide a brief presentation on the potential costs and logistics of implementing a website or database repository for animal testing reports with VDACS. Dr Broaddus provided a summary of the duties of the Office of Veterinary Services, which currently does not include regulatory oversight of animal testing facilities. He also provided a cost estimate of that office providing and maintaining a web-based repository for animal testing reports and answered questions from members of the Task Force.

Ms. Nachminovitch and Mr. Lowrey provided the Task Force an overview of the presentation they had prepared regarding the current reporting requirements to which publicly funded animal testing facilities are subject. Copies of the presentation were distributed to the members of the Task Force.

#### **CONSENSUS TESTING**

At approximately 10:00 a.m., Kelly Altizer and Mike Foreman from IEN explained the process of consensus testing that the Task Force would be using to discuss potential proposals. IEN indicated it would present a list of proposals to the Task Force. These proposals were generated from ideas submitted by members of the Task Force prior to the meeting.

On each proposal, the members of the Task Force would anonymously indicate their level of support by writing a number 1, 2, or 3 on an index card. Level 3 support would indicate that the member fully supports the proposal. Level 2 would indicate that the member can accept with the proposal but has questions or concerns about it. Level 1 would indicate that the member does not support the proposal.

Consensus on a proposal would be achieved if all members voted either 3 or 2 and no member voted 1. After each proposal was introduced, the Task Force would take an initial vote of their level of support. After each vote, the Task Force would discuss their questions and concerns with the proposal.

The proposals and the vote tallies were as follows:

#### Proposal Step #1 - How to increase transparency

Proposal A: SCHEV's website will be used for additional information on animal testing.

- Level 3: 12
- Level 2: 3
- Level 1: 0

Proposal B: Universities will provide the U.S. Department of Agriculture - Animal and Plant Health Inspection Service (APHIS) inspection and annual reports to post on SCHEV's website.

- Level 3: 11
- Level 2: 2
- Level 1: 1

Proposal C: Universities will annually produce a report to document progress on the 3 Rs (refinement, reduction, replacement) for SCHEV's website.

- Level 3: 10
- Level 2: 2
- Level 1: 3

#### Proposal Step #2 – Information that could be included in a report by universities

Proposal D: Total number of laboratory animals (i.e., all vertebrates except fish) in the care of the institution, excluding agricultural animals.

- Level 3: 9
- Level 2: 4
- Level 1: 2

Proposal E: How the animals were acquired.

- Level 3: 11
- Level 2: 1
- Level 1: 3

Proposal F: Census of animals born at the facility in the last year, which also excludes agricultural animals.

- Level 3: 9
- Level 2: 3
- Level 1: 3

Proposal G: Disposition of all animals over the last year (i.e., euthanized, lost, adopted, transferred, traded, or sold).

- Proposal G was grouped with Proposal E and the combined proposal was voted on together.

Proposal H: Adverse events (i.e., unexpected incidents that lead to harm or endanger the wellbeing of animals and humans at a research university) during the last year.

- Level 3: 7
- Level 2: 5
- Level 1: 3

Proposal I: Money spent by the facility procure and maintain animals in the last year.

- Level 3: 9
- Level 2: 2
- Level 1: 4

After votes were tallied for each proposal, the Task Force discussed their questions and concerns for each proposal. The Task Force attempted to reach consensus and understanding by discussing specifics and logistics of implementing the proposals, tweaking the proposals to make them more amenable, and offering alternatives. Consensus was reached on proposal A.

#### **PUBLIC COMMENT**

At approximately 11:30 a.m., the Task Force received public comment from in-person attendees.

Charles Todd Woodson, from the Richmond Animal Advocacy Alliance, expressed concern over the difficulty of obtaining animal testing reports through FOIA. He also suggested that animal testing facilities should identify the specific species of animals they are using for testing in case that species is endangered.

Dr. James Bogenpohl, a member of his university's IACUC, expressed his concern that reporting on progress towards the 3 Rs could be problematic because an increase in federal funding could result in an overall increase in research programs and numbers of animals being tested but that this would not reflect the effort that universities take to implement the 3 Rs at the individual research protocol level.

#### CONTINUED CONSENSUS TESTING AND ADJOURNMENT

The Task Force resumed its discussion of proposals at approximately 11:40 a.m.

The Task Force's discussion continued past the scheduled end-time of 12:00 p.m. until the Task Force adjourned at approximately 1:00 p.m.

The Task Force will hold an all-virtual meeting on October 11 at 10:00 a.m. to review the draft Task Force report.

#### POLICY ON PARTICIPATION IN TASK FORCE ON TRANSPARENCY IN PUBLICLY FUNDED ANIMAL TESTING FACILITIES MEETINGS BY ELECTRONIC COMMUNICATIONS PURSUANT TO VA. CODE § 2.2-3708.3

It is the policy of the Task Force on Transparency in Publicly Funded Animal Testing Facilities (Task Force) that individual members of the Task Force may participate in meetings of the Task Force by electronic communications as permitted by § 2.2-3708.3 of the Code of Virginia. This policy shall apply to the entire membership and without regard to the identity of the member requesting remote participation or the matters that will be considered or voted on at the meeting.

Whenever an individual member wishes to participate from a remote location, the law requires a quorum of the Task Force to be physically assembled at the primary or central meeting location.

When such individual participation is due to a personal matter, such participation is limited by law to two meetings per calendar year or 25 percent of the meetings held per calendar year rounded up to the next whole number, whichever is greater.

Further, it is the policy of the Task Force that the Task Force may hold all-virtual public meetings pursuant to subsection C of § 2.2-3708.3. Such all-virtual public meetings are limited by law to two meetings per calendar year or 50 percent of the meetings held per calendar year rounded up to the next whole number, whichever is greater. Additionally, an all-virtual public meeting may not be held consecutively with another all-virtual public meeting.

Requests for remote participation or that the Task Force conduct an all-virtual public meeting shall be conveyed to the Commissioner of Agriculture and Consumer Services.

Individual participation from a remote location shall be approved unless such participation would violate this policy or the provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia). If a member's participation from a remote location is challenged, then the Task Force shall vote whether to allow such participation.

The request for remote participation or that the Task Force conduct an all-virtual public meeting shall be recorded in the minutes of the meeting. If the Task Force votes to disapprove of the member's participation because such participation would violate this policy, such disapproval shall be recorded in the minutes with specificity. The minutes shall include other information as required by §§ 2.2-3707 and 2.2-3708.3 depending on the type of remote participation or all-virtual public meeting.

This policy applies to all committees and subcommittees of the Task Force.

Version History				
Version	Date	Change Summary		
1	9/20/2024	Original		

#### APPENDIX T

Public Comment (Written)

# Rise<sup>for</sup> Animals.

6 Liberty Square PMB 91098, Boston, MA 02109

riseforanimals.org

September 12, 2024

Joseph Guthrie Co-Chair, Task Force on Transparency in Publicly Funded Animal Testing Facilities Virginia Department of Agriculture and Consumer Services 102 Governor Street Richmond, Virginia 23219 **Delivered via email:** vdacs.commissioner@vdacs.virginia.gov

Paul Smith Co-Chair, Task Force on Transparency in Publicly Funded Animal Testing Facilities State Council of Higher Education for Virginia (SCHEV) 101 North 14th Street, 10th Floor James Monroe Building Richmond, Virginia 23219 **Delivered via email**: PaulSmith@schev.edu

Dear Chair Guthrie, Chair Smith, and Members of the Task Force:

As a national, nonprofit organization that advocates on behalf of other-than-human animals subjected to human experimentation, Rise for Animals is grateful for the opportunity to provide comments to the Task Force on Transparency in Publicly Funded Animal Testing Facilities ("Task Force"), as established by Virginia Senate Bill 411.

In respect of the Task Force's stated purview, Rise for Animals dispenses with any discussion of the ethics or merits (or lack thereof) of animal research and, instead, confines its comments to the question of whether state-funded animal research institutions in Virginia should be compelled to provide to the public additional information on their animal use. And – though the parameters of any such "additional information" remain under discussion – Rise for Animals' comments focus on the information sought by Virginia Senate Bill 411 Section E (as originally introduced),<sup>1</sup> as well as other, relevant information identified to be of interest by members of the Task Force<sup>2</sup> (together "Contemplated Information").

#### Despite the animal research industry's assertions that existent reporting requirements render the Contemplated Information unnecessary and duplicative, the Contemplated Information is <u>not</u> publicly available (if even collected at all).

Representatives of the animal research industry, including the Virginia universities represented on the Task Force and associated industry groups, claim (1) that animal research facilities are subject to onerous reporting requirements that already provide for the Contemplated Information (rendering it unnecessary and duplicative) *and* (2) that it would be impracticable and costly for animal research facilities to provide the Contemplated Information.<sup>3</sup> Neither of these claims prove convincing:

(1) Though state-funded animal research facilities may report some animal use data to (a) the United States Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS"), (b) the National Institutes of Health's Office of Laboratory Animal Welfare ("OLAW"), and (c) the Association for Assessment and Accreditation of Laboratory Animal Care ("AAALAC") International, the Contemplated Information is <u>not</u> currently available to the public.<sup>4</sup>

(a) APHIS reporting is controlled by the Animal Welfare Act ("AWA"), which includes within its scope only certain mammals who together comprise *less than 2% of animals in laboratories.*<sup>5</sup> And – even for those limited animals within the AWA's scope – the reported information has been *found by the federal government to be routinely inaccurate*<sup>6</sup> (*including, on multiple occasions, the information provided by Virginia's state-funded institutions*<sup>7</sup>) and excludes much of the Contemplated Information (e.g., use totals, dispositions).

Annually, animal research institutions must report to APHIS their use of the following animals: dogs, cats, guinea pigs, hamsters, rabbits, non-human primates, sheep (other than those used for agricultural research), pigs (other than those used for agricultural research), and other warm-blooded animals **except** *mice, rats, and birds bred for research* (who, together, comprise *at least* 95-98% of the animals used).<sup>8</sup> Along with mice, rats, and birds bred for research, the AWA excludes from its scope – and, therefore, its reporting requirements – amphibians, reptiles, insects, aquatic species, and farmed animals used in agricultural research.<sup>9</sup> As a result – even *if* accurate – the annual reports submitted by animal research institutions to APHIS very often do not accurately – *or even remotely* – reflect institutional animal use.

By way of Virginia-specific examples only:

In its 2019 Annual Report to APHIS, the University of Virginia reported 758 animals,<sup>10</sup> while, in its February 2019 "Animal Welfare Assurance Statement" filed with OLAW (the most recent to which Rise for Animals presently has access), it reported a January 2019 "Approximate Average Daily Inventory"<sup>11</sup> of *more than 55,568 animals* (a *drastically low estimate* because the University of Virginia reported mice only by "cages", as opposed to individuals, and cages routinely house multiple mice). It follows that **the University of Virginia's 2019 APHIS report reflects** *far less than 1%* of the animals used by the University in 2019.<sup>12</sup>

In its 2021 Annual Report to APHIS, Virginia Polytechnic Institute & State University reported 1,390 animals,<sup>13</sup> while, in its October 2021 "Animal Welfare Assurance Statement" filed with OLAW (the most recent to which Rise for Animals presently has access), it reported an "Approximate Average Daily Inventory" of *around 4,500 animals*<sup>14</sup> (again, a *drastically low estimate* because Virginia Polytechnic Institute & State University reported mice and rats only by "cages" and fish only by "tanks").<sup>15</sup> It follows that **Virginia Polytechnic Institute & State University s 2019 APHIS report reflects** *far less than 30%* of the animals used by the University in 2021.<sup>16</sup>

(b) Animal research institutions that receive funding from the National Institutes of Health must report certain animal use figures to OLAW as rarely as once every five years.<sup>17</sup> Yet – even when reported, and even though available to the public vis-a-vis the Freedom of Information Act<sup>18</sup> – such data both excludes much of the Contemplated Information (e.g., use totals, species, births, deaths) and is far too limited and variable to provide meaningful oversight.

In addition to excluding invertebrate animals from its reporting requirements,<sup>19</sup> OLAW (i) requests only "Approximate Average Daily Inventory" numbers (not, for example, actually animal counts); (ii) allows for "varied methods of accounting for the animals reported" (in fact, "absent explicit reporting instructions from NIH . . . institutions may change their own standards of what they count and report year by year: average cage count, average daily population, total animals acquired or removed . . . without making that explicit");<sup>20</sup> and (iii) does not "compile" this data "for public access".<sup>21</sup> It follows that, as commentators have noted, the animal use figures reported to OLAW are "too variably reported to the NIH to currently be useful for estimating total annual usage."<sup>22</sup>

(c) Animal research institutions may, in exchange for the payment of fees, pursue voluntary accreditation through AAALAC International,<sup>23</sup> and it is *possible* that, in so doing, institutions *may* compile and report the Contemplated Information to AAALAC International. However, **any such reporting to AAALAC** International is of no value to the Task Force because it is neither provided to nor accessible by the public: because AAALAC International is a private, non-governmental organization, AAALAC International records are not accessible by the public (e.g., via a Freedom of Information Act request) or, in fact, even by regulatory government actors (including APHIS).<sup>24</sup>

Also importantly, and despite the loud and frequent suggestions to the contrary by accredited animal research institutions, AAALAC International "accreditation" is associated with *worse*, not better, animal welfare (as well as compliance with federal law);<sup>25</sup> and available evidence strongly suggests that this holds true for Virginia's state-funded institutions.

At present, APHIS has posted on its website 139 "enforcement actions" that are specific to licensed animal research institutions and span April 2020 to July 2024.<sup>26</sup> Of these 139, four – or **almost 3%**<sup>27</sup> – belong to Virginia's state-funded, *AAALAC-accredited institutions*, even though Virginia's public animal research institutions accounted for **less than 0.9%** of APHIS-regulated research institutions in 2023:<sup>28</sup>

Virginia Polytechnic Institute & State University, which boasts of AAALAC International accreditation,<sup>29</sup> received an official warning for improper handling of animals from APHIS in August 2021 and, then, was party to a United States Department of Agriculture Settlement Agreement in March 2024<sup>30</sup> for, in addition to failing to properly regulate animal research protocols, animal care violations spanning 2021, 2022, and 2023:<sup>31</sup>

- Unlawful animal handling, which resulted in "potentially preventable deaths and pain" to piglets
  assigned to a traumatic brain injury experiment; the overheating of a dairy cow who lacked
  access to shade and shelter; and physical harm and death to a gerbil who, in being used for
  blood draw training, was inappropriately subjected to both a restraint device and manual restraint
  (resulting in the animal being restrained "too tightly");
- Unlawful failure to feed, which resulted in the emaciation and death from "prolonged starvation" of a six-day-old piglet who was removed from his/her mother for a research protocol; and
- Unlawful failure to train and instruct personnel, which resulted in the deaths of at least three gerbils whose health was not adequately monitored.

Additionally, Virginia Polytechnic Institute and State University has had institutional animal care failings (i) documented by APHIS, to include *repeated failures* to provide animals with appropriate care,<sup>32</sup> to report concerns about animal health and well-being to the attending veterinarian "in a timely manner",<sup>33</sup> to ensure compliance with federal animal research requirements,<sup>34</sup> and to maintain the structural soundness and cleanliness of animal enclosures;<sup>35</sup> and (ii) reported to and documented by OLAW, including multiple failures to provide animals with appropriate care.<sup>36</sup>

Eastern Virginia Medical School, which boasts of being "continually accredited and approved" by AAALAC International "for more than 20 years",<sup>37</sup> received an official warning from APHIS in 2021 for animal research oversight failures and inadequate facilities that failed to protect research animals from injury.<sup>38</sup> Additionally, APHIS' 2023 records document *multiple and repeated failings* of the Medical School's Institutional Animal Care and Use Committee ("IACUC") "regarding the care and use of animals"<sup>39</sup> and the provision of inadequate veterinary care;<sup>40</sup> APHIS' 2021 records document the unapproved use of primates for "multiple major operative procedures on more than one IACUC approved protocol without prior approval from the APHIS Administrator" and failures to provide safe living environments for animals;<sup>41</sup> and APHIS' 2014 records document unsafe living environments for animals.<sup>42</sup>

Old Dominion University, which prominently features AAALAC International accreditation on its webpage,<sup>43</sup> received an official warning from APHIS in March 2022 for both failing to adequately oversee animal research and failing to provide "adequate veterinary care".<sup>44</sup> Additionally, in 2021, APHIS documented concerns regarding *ongoing* failures to ensure adequate animal care, lawful research oversight, and adequate staff qualifications and training.<sup>45</sup>

The relevance of these findings to the Task Force's purview is compounded by the federal government's own conclusions that "enforcement remains one of the AWA's biggest challenges" and that animal research facilities routinely receive "a smaller number of violations than they actually commit[]", as well as "improperly reduced penalties for violations".<sup>46</sup> (The Task Force should also take note that, as of 2023, multiple of Virginia's state-funded animal research institutions – including Christopher Newport University, College of William & Mary, Virginia State University, and the Virginia-Maryland College of Veterinary Medicine<sup>47</sup> – were *not even* subject to APHIS oversight.<sup>48</sup>)

(2) There is no reason to believe that the provision of the Contemplated Information should be either impracticable or costly for Virginia's state-funded animal research institutions.

The Contemplated Information is of the *most basic* nature, asking state-funded animal research institutions to account for the numbers and species of animals used, as well as their financial investment in animal research. The assertions by these institutions and their affiliates that such information is not only uncollected and unrecorded but also requiring of significant *additional* public monies (for collection, recording, and sharing)<sup>49</sup> should give the Task Force significant pause. Indeed, the claim that this information is not currently available smacks of shocking and *inescapable* dishonesty: **either animal research institutions are** *not* **reporting to APHIS and OLAW diligently-collected and reflective animal use numbers, or they are collecting but remain unwilling to share (if even admit the existence of) this information. (To be sure, how would animal research institutions provide OLAW with accurate "average daily" animal population numbers if they do not track their animal populations? How could animal research institutions justify their professed, large investments in animal care if they did not know, record, and use for the purposes of staffing, budgeting, etc., how many animals are in their care? And, how could animal research institutions purport to undertake "meticulous"<sup>50</sup> research efforts in the absence of any detailed attention to the most fundamental of their "resources" – the animals whose very bodies and lives give rise to their researchers' livelihoods?) As a steward of public dollars,<sup>51</sup> this should be of great concern to the state of Virginia and should trigger** *additional* **inquiries with regard to state-funded animal research operations.** 

Further, the assertion that requiring *this most basic reporting on state-funded activities* would deter the growth of Virginia's research sector<sup>52</sup> seeks to position Virginia as a participant in a race to the bottom,<sup>53</sup> as it invests millions upon millions of dollars in state-funded activities for which there is no meaningful transparency or accountability; it also seeks to encourage Virginia to elevate the interests and preferences of state-funded (though wholly self-interested) professionals over those of their funders (the very members of the public these professionals profess to serve through their endeavors). This is certainly *undesirable for all but the animal research industry*, which frames requests from its funders for basic information as "punitive"<sup>54</sup> and unreasonable – rather, than, as most others would agree, and as articulated by a member of the Task Force, both consistent with data sharing requests made across other sectors *and* representative of "an asset" to the state of Virginia as a whole.<sup>55</sup>

#### Despite the animal research industry's claimed support of transparency, it has laid bare its staunch opposition to *unbiased* information sharing with the public about its practices.

The animal research industry's refusal to provide the Contemplated Information in itself guts any supposed claim of support for industry transparency – indeed, the Contemplated Information is, again, of the most basic nature, seeking nothing more than *raw data* about state-funded animal use and institutional spending. The resulting disconnect between the industry's penchant for touting "transparency" and its actions in vehemently denying the same can be bridged only by recognizing the industry's intentional and strategic cooptation of the concept – indeed, the industry (both as represented on the Task Force and as represented by allied third-parties) wants to avoid sharing any *raw data* in favor of self-selected, spun, and biased narratives (exactly, and ironically, what it accuses animal protection groups of pursuing).

Instead of providing the Contemplated Information, the animal research industry suggests allowing animal researchers to *define "transparency" for the public* and, thereby, facilitates researchers' sharing of *only* self-serving, propagandized information, to include:

- "[T]he value of what has come out of this animal research";<sup>56</sup>
- New scientific findings and the reasons for using animals in research;<sup>57</sup>
- Information that could not "negatively impact" animal research;<sup>58</sup>
- Information that would ensure that animal research "can continue and be fruitful";<sup>59</sup>
- Information intended to "cultivat[e] public trust in science",60 and/or
- Information that would educate the public on "medical innovation made possible through laboratory animal research".<sup>61</sup>

By reframing the conversation in this way – angling to distract the Task Force with and refocus the Task Force on the (supposed) merits of animal research – the animal research industry is patently attempting to skirt the Task Force's clearly-stated purpose. Indeed, the context in which the Contemplated Information is being requested is clear: how many animals are state-funded, animal research institutions operating within the state of Virginia using for research each year? As such, the animal research industry's fixation on "context" is nothing more than a thinly veiled attempt to turn the public's attention away from the (unpopular) issue at hand: animal experimentation. Moreover, should the animal research industry fear any "dangers" associated with the publication of, in its opinion, uncontextualized data, it should be made to account for why these fears do not extend to APHIS' and OLAW's current reporting requirements; why these fears do not extend to responses to Freedom of Information Act requests and state public records requests; and why the response to any honest concerns about potentially misleading, isolated information should be to share *less* or *different* information (not *more* and *relevant* information, which the universities are always free to provide)?

Further, allowing the animal research industry to obfuscate the Task Force's professed focus on actual transparency (as defined by the public) in animal research taking place *within and on behalf of the state of Virginia* would allow the animal research industry to override current public policy; and it would set a truly dangerous precedent, one premised on government-funded actors being allowed to avoid legitimate requests for public information on account of the identities of the persons or entities making these lawful requests and/or the lawful intentions of such persons or entities in making such requests. Lest there by any doubt, one need only consider the recommendation of States United for Biomedical Research<sup>62</sup> and the National Association for Biomedical Research<sup>63</sup> that transparency be impeded because it is supported by "special interest groups" and "animal rights organizations".<sup>64</sup>

Importantly, the groups and organizations thereby (and cumulatively) maligned by the animal research industry *represent members of the general public* – not, as do their maligners, financially vested members of a for-profit industry. Indeed, these groups and organizations exist *because of and to act in furtherance of the general public's interest in animal research*, such that their very existence plainly and convincingly invalidates the animal research industry's claim that members of the general public are not interested in this information. Moreover, not only would a lack of general public interest in this information undercut much of the industry's espoused concerns over misinterpretation of published information (thereby effectively negating one of the animal research industry's primary arguments against increased transparency), but recent surveys confirm both (i) "that support for animal research in general seems to be dwindling, and uncertainty is rising even when no alternatives exist" and (ii) that, even with regard to biomedical research (which "lead[s] in acceptability"), public support is "barely above 50%".<sup>65</sup> It follows that the animal research industry's allegation that the Contemplated Information would *not* be of interest to the general public is not only unfounded but, in fact, plainly contradicted by the available evidence.

For these reasons, as well as many others excluded from these comments in consideration of the Task Force's specifically-delineated focus, Rise for Animals asks the Task Force to recommend to the Virginia State legislature the public reporting of the Contemplated Information, which requires nothing more than the most basic of operational information: the accounting of (i) *lives* used by state-funded animal research entities, and (ii) expenditures made possible by, and supposedly in direct benefit of, taxpayers.

Sincerely,

Is Lindsey Soffes

Lindsey Soffes Program Officer, Rise for Animals lindsey@riseforanimals.org

cc: Stacy Metz, stacy.metz@vdacs.virginia.gov

**RECEIVED** By Stacy E. Metz at 12:39 pm, Sep 12, 2024

#### Endnotes

1. Before stakeholders reached a compromise that resulted in an overhaul of the Bill and the creation of the Task Force, Virginia Senate Bill 411 sought to require the following: "Any animal testing facility, contract testing facility, or manufacturer that uses an animal test method shall make publicly available on or before December 1 for the preceding federal fiscal year the following information: (i) the total number of animals used for research, education, testing, or experimental, scientific, or biomedical purposes with such animals identified and grouped according to species; (ii) a detailed methodology for obtaining such a count of animals; and (iii) the percentage of funds expended by such facility or manufacturer on the activities listed in clause (i) that involved the use of animals compared with the percentage of funds spent on such activities that did not involve the use of animals." **S.B. 411, 2024 Reg. Sess. (1st Draft, Section E, Va. 2024).** https://lis.virginia.gov/cgi-bin/legp604.exe?241+ful+SB411.

2. In the Task Force's first meeting, Senator Boysko expressed interest in data relating to animal births and animal deaths. Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, July 26). [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency-task-force.shtml. In the Task Force's second meeting, Will Lowery expressed interest in data relating to animals' dispositions. Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, August 30). [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency-task-force.shtml.

3. Repeatedly, these claims have been made simultaneously *even though* they cannot exist simultaneously. *See, e.g.,* **Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, July 26).** [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency-task-force.shtml.

4. Rise for Animal acknowledges that, *in theory*, certain of the Contemplated Information *could potentially* be obtainable by the public vis-a-vis the Virginia Public Records Act, though the experience of both Rise for Animals and its colleagues suggests otherwise.

5. Goodman J, Chandna A, Roe K. (2015). *Trends in animal use at US research facilities*. J Med Ethics;41(7):567-9. doi: 10.1136/medethics-2014-102404. Epub 2015 Feb 25. PMID: 25717142 (finding that 98.8% of animals were not covered by the AWA).

6. Lee, C. G. (2016). *The Animal Welfare Act at Fifty: Problems and Possibilities in Animal Testing Regulation*, 95 Neb. L. Rev. 194. http://digitalcommons.unl.edu/nlr/vol95/iss1/6 (reporting that the United States Department of Agriculture's Office of Inspector General "discovered that many facilities, in fact, did not report accurate numbers of animals used in research....").

7. See, e.g., Virginia Polytechnic Institute & State University. (2023). United States Department of Agriculture Animal Health Inspection Service. Inspection Report. Animal Research Laboratory Overview. and Plant https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/ 32649 ("The facility's annual report for FY 2022 did not accurately report all animals used in or held for research. The FY 2022 annual report reported no gerbils. Review of facility records showed that the facility used 24 gerbils beginning on September 27th, 2022 on protocol 22-160. Correct reporting of all required information on the annual report is required so that the public, USDA APHIS Animal Care, and Congress can have knowledge of the number, type, and pain category of animals used- or held for use in research."); Eastern Virginia Medical School. (2015). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/ entity/eastern-virginia-medical-school-1729/records/31771 ("The Annual Report for FY 2014 documents 11 rabbits in column B and 9 rabbits in column C. The USDA inspector's inventory for the 3-11-14 inspection documents 28 rabbits inspected. Acquisition records state that 23 rabbits were acquired in FY 2014 in addition to those rabbits held over from the previous fiscal year. IACUC records document that rabbits were used in at least one category D protocol in FY 2014 (surgery performed). Accurate annual reports are necessary to give a complete summary of the animal use at the facility. The facility shall revise the fiscal year 2014 annual report and resubmit...."); Virginia Polytechnic Institute & State University. (2015). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-stateuniversity-1733/records/32632 ("The fiscal year 2014 Annual Report submitted to Animal Care by the facility listed 34 dogs used in category C. Review of acquisition records of dogs acquired between Oct. 1 2013 and Sept. 30 2014 shows that an additional 34 dogs were obtained for a total of 68 dogs used in category C. Properly identifying animals used in research on the annual report is necessary to inform the Institutional Official and the Animal Care Regional Office of the scope and extent of the animal use at the facility. The 2014 annual report needs to be amended and resubmitted to the Regional Office with all animal use data included."); University of Virginia. (2015). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/university-of-virginia-1732/records/32672. ("At the time of inspection the annual report for 2014 was reviewed. The facility reported 92 rice rats in category C, however it only listed 22 rice rats in Category F. 7 of 13

which is the sum of the numbers for category C, D, and E. This facility has to review its numbers for the use of rice rats and submit a corrected annual report to the USDA."); **Old Dominion University. (2014).** United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/old-dominion-university-1731/records/32657. ("The Annual Report for FY2013 does not state the location of all facilities where animals were housed or used in research. One location where animals were housed during the year in question is not included in block 3 of the report; Facility Locations. In order to remain accurate and comply with regulations, this report needs to be amended and resubmitted to the agency.").

8. **U.S. Department of Agriculture. (1999).** *Code of Federal Regulations, Title 9, Chapter I, Subchapter A, Part 1, section 1.1.* U.S. Government Publishing Office. https://www.ecfr.gov/current/title-9/chapter-I/subchapter-A/part-1/section-1.1.

9. See **U.S. Department of Agriculture. (1999).** Code of Federal Regulations, Title 9, Chapter I, Subchapter A, Part 1, section 1.1. U.S. Government Publishing Office. https://www.ecfr.gov/current/title-9/chapter-l/subchapter-A/part-1/section-1.1; see also Goodman J, Chandna A, Roe K. (2015). Trends in animal use at US research facilities. J Med Ethics;41(7):567-9. doi: 10.1136/medethics-2014-102404. Epub 2015 Feb 25. PMID: 25717142.

10. **University of Virginia. (2019).** United States Department of Agriculture Animal and Plant Health Inspection Service, Annual Report of Research Facility. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/university -of-virginia-1732/records/3979.

11. **University of Virginia. (2019).** National Institutes of Health Office of Laboratory Animal Welfare, PHS Assurance. Annual Report of Research Facility. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/ university-of-virginia-1732/records/18918.

12. Inconsistencies in reporting draw even this approximation into question. For example, the University of Virginia (i) reported zero sheep to APHIS but, in the same year, identified an average daily inventory of three sheep to OLAW; (ii) reported zero Ferrets to APHIS, but, in the same year, identified an average daily inventory of four ferrets to OLAW; and (iii) reported four "Groundhog[s] / Woodchuck[s]" to APHIS but, in the same year, reported no groundhogs or woodchucks to OLAW. See **University of Virginia. (2019).** United States Department of Agriculture Animal and Plant Health Inspection Service, Annual Report of Research Facility. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/university-of-virginia-1732/records/3979; **University of Virginia. (2019).** National Institutes of Health Office of Laboratory Animal Welfare, PHS Assurance. Annual Report of Research Facility. Animal Research Facility. Animal Research Laboratory States Stat

13. **Virginia Polytechnic Institute & State University (2021).** United States Department of Agriculture Animal and Plant Health Inspection Service, Annual Report of Research Facility. Animal Research Laboratory Overview. https://arlo. riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/24780.

14. **Virginia Polytechnic Institute & State University (2019).** National Institutes of Health Office of Laboratory Animal Welfare, PHS Assurance. Annual Report of Research Facility. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/26083 (providing only ranges for rabbits, ferrets, and small ruminants: "Rabbits 0-6", "Ferret <5", "Small ruminants (sheep) <1").

15. In certain entries of its filing, the University also referred to mice and rats interchangeably ("Mice/Rat"), further obfuscating relevant animal use information. **Virginia Polytechnic Institute & State University (2019).** National Institutes of Health Office of Laboratory Animal Welfare, PHS Assurance. Annual Report of Research Facility. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/ records/26083.

16. Inconsistencies in reporting draw even this approximation into question. For example, Virginia Polytechnic Institute & State University reported 89 sheep to APHIS but, in the same year, identified an average daily inventory of "<1" for "Small ruminants (sheep)" to OLAW. See **Virginia Polytechnic Institute & State University (2021).** United States Department of Agriculture Animal and Plant Health Inspection Service, Annual Report of Research Facility. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institutes of Health Office of Laboratory Animal Welfare, PHS Assurance. Annual Report of Research Facility. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institutes of Health Office of Virginia Polytechnic Institute & State University (2019). National Institutes of Health Office of Laboratory Animal Welfare, PHS Assurance. Annual Report of Research Facility. Animal Research Laboratory Overview.

17. **Office of Laboratory Animal Welfare. (2015).** *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (section III). U.S. Department of Health and Human Services. https://olaw.nih.gov/policies-laws/phs-policy.htm

("Approval of the Assurance will be for a specified period of time (no longer than five years) after which time the institution must submit a new Assurance to OLAW.").

18. Freedom of Information Act of 1966, 5 U.S.C. § 552 (2018).

19. **Office of Laboratory Animal Welfare. (2015).** *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (section III). U.S. Department of Health and Human Services. https://olaw.nih.gov/policies-laws/phs-policy.htm.

20. **Carbone, L. (2021).** *Estimating mouse and rat use in American laboratories by extrapolation from Animal Welfare Act-regulated species.* Sci Rep 11, 493, https://doi.org/10.1038/s41598-020-79961-0.

21. **Carbone, L. (2021).** *Estimating mouse and rat use in American laboratories by extrapolation from Animal Welfare Act-regulated species.* Sci Rep 11, 493. https://doi.org/10.1038/s41598-020-79961-0.

22. **Carbone, L. (2021).** *Estimating mouse and rat use in American laboratories by extrapolation from Animal Welfare Act-regulated species.* Sci Rep 11, 493. https://doi.org/10.1038/s41598-020-79961-0.

23. AAALAC International was founded in 1965 by animal research trade associations that sought to prevent the passage of the 1966 Laboratory Animal Welfare Act. **Garner, R. (2007)**. *Political animals: Animal protection politics in Britain and the United States*. Macmillan Press, Ltd., at 205 (noting that AAALAC International's establishment by industry was intended to "show that animal welfare was being voluntarily upheld"). Since its inception, AAALAC International's existence as an animal research industry trade group has been widely known and even recognized by Congress itself: in considering a proposal to have AAALAC International, instead of the United States Department of Agriculture, regulate AWA compliance, Senator Joseph Clark stated: "I never saw a situation more inclined to the cliche that you are setting a fox to watch the chicken coop". **Animal Welfare Act: Hearing on S. 2322, S. 3059, and S. 3138 Before the S. Comm. on Commerce. 89th Cong. 263 (1966)** (documenting also Senator Clark's description of AAALAC International as operating a "self-policing coverup of conditions in experimental laboratories").

24. **Carbone, L. (2021).** *Estimating mouse and rat use in American laboratories by extrapolation from Animal Welfare Act-regulated species.* Sci Rep 11, 493. https://doi.org/10.1038/s41598-020-79961-0. ("AAALAC's confidentiality policies do not allow release of individual or aggregate statistics....").

25. **Goodman JR, Chandna A, Borch C. (2014).** Does accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) ensure greater compliance with animal welfare laws? J Appl Anim Welf Sci. 2015;18(1):82-91. doi: 10.1080/10888705.2014.948625. PMID: 25174609 ("AAALAC-accredited facilities . . . are actually more likely to violate animal welfare laws compared with nonaccredited facilities."); see **Congressional Research Service. (2022).** *The Animal Welfare Act: Background and Selected Issues* (CRS Report No. R47179). Library of Congress. https://crsreports.congress.gov/product/pdf/R/R47179/3 (citing research findings that, "on a per-animal basis", "facilities with AAALAC accreditation" have been found to receive "more AWA noncompliance citations from APHIS than facilities without AAALAC accreditation").

26. **U.S. Department of Agriculture. (2024).** *Animal welfare enforcement actions and horse protection activity reports.* Animal and Plant Health Inspection Service. https://www.aphis.usda.gov/animal-care/awa-services/animal-welfare-horse-protection-actions (accessed September 11, 2024).

27. Of the 139 enforcement actions listed by the USDA, four belong to Virginia-based, state-funded animal research institutions. See **U.S. Department of Agriculture. (2024).** Animal welfare enforcement actions and horse protection activity reports. Animal and Plant Health Inspection Service. https://www.aphis.usda.gov/animal-care/awa-services/ animal-welfare-horse-protection-actions (accessed September 11, 2024).

28. For 2023, APHIS has posted 1,047 annual reports supplied by animal research institutions; and, of these, only nine were proffered by Virginia-based, state-funded animal research institutions: Blue Ridge Community College, Christopher Newport University, Eastern Virginia Medical School, George Mason University, Northern Virginia Community College, Old Dominion University, University of Virginia, Virginia Commonwealth University, and Virginia Polytechnic Institute & State University. *See* **U.S. Department of Agriculture. (n.d.).** *Annual reports public search tool.* Animal and Plant Health Inspection Service. https://aphis.my.site.com/PublicSearchTool/s/annual-reports (accessed September 11, 2024).

29. Virginia Tech Office of Research and Innovation. (2024). About animal care compliance. Virginia Tech. https://www.research.vt.edu/animal-care/about.html. ("The Virginia-Maryland College of Veterinary Medicine, the College of Science, College of Engineering, College of Natural Resources and Environment, the Fralin Biomedical Research Institute, and the Fralin Life Sciences Institute are accredited by AAALAC International.").

30. U.S. Department of Agriculture. (2024). Virginia Polytechnic Institute & State University Official Warning. Animal and Plant Health Inspection Service. https://www.aphis.usda.gov/sites/default/files/vapolytech.pdf.

31. **U.S. Department of Agriculture. (2024).** *Virginia Polytechnic Institute & State University Settlement Agreement.* Animal and Plant Health Inspection Service. https://www.aphis.usda.gov/sites/default/files/virginiapolytechnicinstitute.pdf.

32. Virginia Polytechnic Institute & State University. (2023). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/ entity/virginia-polytechnic-institute-state-university-1733/records/32649 (documenting that a calf died after not having an IV catheter placed, as required by the research protocol; and that a gerbil died after being inappropriately restrained); Virginia Polytechnic Institute & State University. (2023). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/ entity/virginia-polytechnic-institute-state-university-1733/records/32650 (documenting that inadequate staff training resulted in the deaths of gerbils); Virginia Polytechnic Institute & State University. (2022). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/ 32645 (documenting the veterinarian's inability to humanely euthanize animals in "a timely manner" due to "lack of access" to necessary resources, and the transport of bats in "enclosures" with "insufficient ventilation openings"); Virginia Polytechnic Institute & State University. (2022). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-stateuniversity-1733/records/32646 (documenting that a piglet removed from his/her mother died "from starvation and emaciation due the facility's failure to ensure it received a sufficient amount of food"); Virginia Polytechnic Institute & State University. (2021). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-stateuniversity-1733/records/32643 (documenting that a cow experienced "heat stress", and that sheep and cows were unable to "protect themselves from direct sunlight" and "were seen seeking shade in the narrow path" of "an electrical power line" that "cast[] a thin line of shade").

33. Virginia Polytechnic Institute & State University. (2021). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/ entity/virginia-polytechnic-institute-state-university-1733/records/32643 (documenting that the attending veterinarian was not advised of the unexpected deaths and injuries of piglets involved in a traumatic brain injury experiment); Virginia Polytechnic Institute & State University. (2016). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/ virginia-polytechnic-institute-state-university-1733/records/32633 (documenting that a cow with observed lameness was not evaluated by a veterinarian for 27 days; that a cow who was limping was not seen by a veterinary for three days and, then, was not provided with the recommended hoof care; and that a cow with a swollen third eyelid did not receive veterinary evaluation or treatment); Virginia Polytechnic Institute & State University. (2015). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/32632 (documenting a five-day delay between research staff observing a cow's lameness and contacting a veterinarian, who diagnosed the cow with a cruciate tear; a "several week[]" delay between observing a bear's "decreased appetite and foot pad ulcers on both front paws due to pacing (stereotypical behavior)" and consulting with the attending veterinarian; and a failure to report to the attending veterinarian a pig's "obvious[] limping" and "bright red abraded area of skin").

34. Virginia Polytechnic Institute & State University. (2022). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/ entity/virginia-polytechnic-institute-state-university-1733/records/32645; Virginia Polytechnic Institute & State University. (2022). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-stateuniversity-1733/records/32646; Virginia Polytechnic Institute & State University. (2022). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-stateuniversity-1733/records/32649; Virginia Polytechnic-institute-state-university-1733/records/32649; Virginia Polytechnic Institute & State University. (2021). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/32649; Virginia Polytechnic Institute & State University. (2021). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/ virginia-polytechnic-institute-state-university-1733/records/32643.

35. Virginia Polytechnic Institute & State University. (2023). United States Department of Agriculture - Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/ entity/virginia-polytechnic-institute-state-university-1733/records/32647; Virginia Polytechnic Institute & State

**University.** (2021). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/32643; **Virginia Polytechnic Institute & State University.** (2016). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/32633; **Virginia Polytechnic Institute & State University.** (2015). United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/

virginia-polytechnic-institute-state-university-1733/records/32632.
36. See, e.g., Virginia Polytechnic Institute & State University. (2023). National Institutes of Health Office of Laboratory Animal Welfare, RE: Animal Welfare Assurance A3208-01 [OLAW Case 1M]. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/28541 (documenting that a bird died after being held in a holding crate); Virginia Polytechnic Institute & State University. (2023). National Institutes of Health Office of Laboratory Animal Welfare, RE: Animal Welfare of Laboratory Animal Welfare, RE: Animal Welfare Assurance A3208-01 [OLAW Case 1L].

Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/28540 (documenting that, in a bat study, "adequate veterinary care was unavailable", "humane endpoints were not followed", and "the euthanasia method was not listed on the protocol and was not an American Veterinary Medical Association approved method"). Virginia Polytechnic Institute & State University. (2022). National Institutes of Health Office of Laboratory Animal Welfare, RE: Animal Welfare Assurance A3208-01 [OLAW Case 1]]. Animal Research Laboratorv Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/ 25944 (documenting that "a bird was found dead after being mistakenly returned to its cage without food or water rather than euthanized"); Virginia Polytechnic Institute & State University. (2020). National Institutes of Health Office of Laboratory Animal Welfare, RE: Animal Welfare Assurance A3208-01 [OLAW Case 1H]. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/virginia-polytechnic-institute-state-university-1733/records/18922 (reporting that mice were found dead after research staff "failed to euthanize" them at their "humane endpoints"); Virginia Polytechnic Institute & State University. (2019). National Institutes of Health Office of Laboratory Animal Welfare, RE: Animal Welfare Assurance A3208-01 [OLAW Case 1E]. Animal Research Laboratory Overview. https://arlo.risefor animals.org/entity/virginia-polytechnic-institute-state-university-1733/records/5127 (documenting that "mice undergoing euthanasia survived due to failure to ensure death").

37. **Eastern Virginia Medical School. (2024).** *Nonhuman primate research resources.* Eastern Virginia Medical School. https://www.evms.edu/research/research\_administration/evms\_research/nhp/ (accessed September 11, 2024).

38. **U.S. Department of Agriculture. (2024).** *Eastern Virginia Medical School Official Warning*. Animal and Plant Health Inspection Service. https://www.aphis.usda.gov/sites/default/files/eastvamed.pdf.

39. **Eastern Virginia Medical School. (2023).** United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/ eastern-virginia-medical-school-1729/records/31783; *see also* **Eastern Virginia Medical School. (2023).** United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/ Overview. https://arlo.riseforanimals.org/entity/ eastern-virginia-medical-school-1729/records/31783; *see also* **Eastern Virginia Medical School. (2023).** United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/ eastern-virginia-medical-school-1729/records/31777.

40. **Eastern Virginia Medical School. (2023).** United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/ eastern-virginia-medical-school-1729/records/31777 ("The facility failed to utilize appropriate methods to prevent, control, and diagnose medical issues that arose from the administration of IV insulin, ultimately leading to the death of a[] [primate] and hours of unresolved, low blood glucose levels in others.").

41. **Eastern Virginia Medical School. (2021).** United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/ eastern-virginia-medical-school-1729/records/31780.

42. **Eastern Virginia Medical School. (2014).** United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/ eastern-virginia-medical-school-1729/records/31770.

43. **Old Dominion University. (n.d.).** *Animal care and use compliance.* Old Dominion University. https://ww1.odu.edu/impact/compliance/animals (accessed September 11, 2024) (displaying a circular, gold, red, and black icon that reads: "PROUDLY, AN aaalac INTERNATIONAL ACCREDITED PROGRAM").

44. **U.S. Department of Agriculture. (2024).** *Old Dominion University Official Warning.* Animal and Plant Health Inspection Service. https://www.aphis.usda.gov/sites/default/files/olddominionu.pdf.

45. **Old Dominion University. (2021).** United States Department of Agriculture Animal and Plant Health Inspection Service, Inspection Report. Animal Research Laboratory Overview. https://arlo.riseforanimals.org/entity/old-dominion-university-1731/records/32665 (documenting the absence of animal care and monitoring records, inadequate animal care (including the death of an animal "in distress" after failing to receive "timely veterinary care"), inconsistencies in a research protocol, and inadequate training and review of personnel qualifications that placed animals" "health and welfare at risk").

46. Lee, C. G. (2016). The Animal Welfare Act at Fifty: Problems and Possibilities in Animal Testing Regulation, 95 Neb. L. Rev. 194. http://digitalcommons.unl.edu/nlr/vol95/iss1/6 (citing findings by the United States Department of Agriculture's Office of Inspector General).

47. See U.S. Department of Agriculture. (n.d.). Annual reports public search tool. Animal and Plant Health Inspection Service. https://aphis.my.site.com/PublicSearchTool/s/annual-reports (accessed September 11, 2024); see a/so National Institutes of Health. (2024). Domestic institutions with PHS-approved Animal Welfare Assurances. Office of Laboratory Animal Welfare. https://olaw.nih.gov/ assured/app/index.html (accessed September 11, 2024).

48. See National Institutes of Health. (2024). Domestic institutions with PHS-approved Animal Welfare Assurances. Office of Laboratory Animal Welfare. https://olaw.nih.gov/assured/app/index.html (accessed September 11, 2024) (listing as "assured" Christopher Newport University, the College of William and Mary, Virginia State University, and the Virginia-Maryland College of Veterinary Medicine); U.S. Department of Agriculture. (n.d.). Annual reports public search tool. Animal and Plant Health Inspection Service. https://aphis.my.site.com/PublicSearchTool/s/annual-reports (accessed September 11, 2024) (listing the "Certificate Status[es]" of Christopher Newport University and the College of William & Mary as "Cancelled", and not listing Virginia State University or the Virginia-Maryland College of Veterinary Medicine at all). As of 2024, James Madison University should be added to this list because its APHIS registration displays as "[C]ancelled" as of "12/20/2023", while it remains listed as assured by OLAW. See National Institutes of Health. (2024). Domestic institutions with PHS-approved Animal Welfare Assurances. Office of Laboratory Animal Welfare. https://olaw.nih.gov/assured/app/index.html (accessed September 11, 2024); U.S. Department of Agriculture. (n.d.). Annual reports public search tool. Animal and Plant Health Inspection Service. https://aphis.my.site.com/PublicSearchTool /s/annual-reports (accessed September 11, 2024).

49. Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, July 26). [Video]. Virginia Department of Agriculture and Consumer Services; National Association for Biomedical Research. (2024). [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services; States United for Biomedical Research. (2024). [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services; States United for Biomedical Research. (2024). [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services.

50. **States United for Biomedical Research. (2024).** [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services.

51. Per Task Force member Sharon Adams of the Virginia Alliance for Animal Shelters, "[w]e are talking about animals purchased with taxpayer funds, in the care of a publicly-funded institution." **Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, August 30).** [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency- task-force.shtml.

52. Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, July 26). [Video]. Virginia Department of Agriculture and Consumer Services; Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, August 30). [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency-task-force.shtml; Americans for Medical Progress. (2024). [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services; National Association for Biomedical Research. (2024). [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services; States United for Biomedical Research. (2024). [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services; States United for Biomedical Research. (2024). [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services; States United for Biomedical Research. (2024). [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services; States United for Biomedical Research. (2024). [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services.]

53. See also **Miller, R. J. (2023).** The Rise and Fall of Animal Experimentation: Empathy, Science, and the Future of Research. Oxford University Press (describing an "alarming trend . . . in which universities have just become gigantic self-serving corporations that have abandoned the role they might once have had in promoting academic excellence or ethical behavior. As a result, we are left with a piece of legislative nonsense like the AWA.").

54. **National Association for Biomedical Research. (2024).** [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services.

55. **Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, August 30).** [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency-task-force.shtml (quoting Sharon Adams of the Virginia Alliance for Animal Shelters).

56. **Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, July 26).** [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency-task-force.shtml.

57. **Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, July 26).** [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency-task-force.shtml.

58. **Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, July 26).** [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency-task-force.shtml.

59. **Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, July 26).** [Video]. Virginia Department of Agriculture and Consumer Services. https://www.vdacs.virginia.gov/food-transparency-task-force.shtml.

60. **Americans for Medical Progress. (2024).** [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services.

61. **States United for Biomedical Research. (2024).** [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services.

62. **States United for Biomedical Research. (2024).** [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services.

63. **National Association for Biomedical Research. (2024).** [Written comments]. Task Force on Transparency in Publicly Funded Animal Testing Facilities, Virginia Department of Agriculture and Consumer Services.

64. Both the National Association for Biomedical Research ("NABR") and States United for Biomedical Research ("SUBR") are, ironically, two of the animal research industry's leading *special interest groups*. NABR is a membership and lobbying organization that identifies itself as "the leading public policy organization in support of animal research" and boasts of being responsible for the exclusion of mice, rats, and birds from the AWA. **National Association for Biomedical Research**. (2020). *About. NABR*. https://www.nabr.org/about (accessed September 11, 2024). SUBR is a membership organization "committed" to promoting "support for biomedical research, including . . . the use of research animals" and is affiliated with and funded by some of the largest players in the animal research industry. **States United for Biomedical Research (n.d.)**. *Mission*. https://statesforbiomed.org/about-us/ (accessed September 11, 2024); **States United for Biomedical Research (n.d.)**. *Members & Funders*. https://statesforbiomed.org/about-us/members-funders/ (accessed September 11, 2024).

65. **Faunalytics. (2024).** *Fundamentals: Research animals.* Faunalytics. https://faunalytics.org/ fundamentals-research-animals/.



We keep medical advances moving ahead.

August 28, 2024

Task Force on Transparency in Publicly Funded Animal Testing Facilities Virginia Department of Agriculture and Consumer Services 102 Governor Street Richmond, VA 23219

Re: Public Comments for August 30 Meeting

Dear Task Force Members,

Americans for Medical Progress (AMP) appreciates the opportunity to provide comments to the Task Force on Transparency in Publicly Funded Animal Testing Facilities, established through Virginia Senate Bill 411. AMP is a nonprofit health research advocacy group that supports the advancement of human and animal medicine through responsible and highly-regulated research in animals across the United States, including Virginia. We recognize that transparency is essential for fulfilling proper stewardship of taxpayer funds. More importantly, we support improving transparency in animal research to strengthen scientific collaboration, enhance research rigor and reproducibility, and bolster public trust in science.

While we support initiatives that advance transparency goals, we have concerns about recommendations that would create unnecessary and duplicative burdens that hinder Virginia's world-class research institutions without improving laboratory animal welfare.

In particular, we respectfully suggest the Task Force avoid recommendations that:

- Create unintended consequences for biomedical research;
- Jeopardize the ability to explore future scientific questions;
- Impede the training of the next generation of researchers and;
- Adversely impact Virginia's academic, biomedical, and biotechnology market sectors.

As detailed below, AMP has significant concerns that gathering animal numbers and statistics without proper context results in unintended consequences; the Task Force's efforts duplicate already ongoing research transparency efforts at the national level; and newly implemented research transparency requirements in Virginia should be reviewed for effectiveness before additional administrative requirements are added.

#### Animal Numbers and Statistics Without Proper Context Results in Unintended Consequences

Sharing animal numbers can lead to the misinterpretation and misuse of these facts in a manner that could negatively impact scientific research by furthering the public's distrust in science and losing scientific talent. Numbers without context are ambiguous, particularly in biomedical research settings. Scientific studies are meticulously designed and encompass a wide range of variables that differ from study to study based on the research question. For animal studies, these include, but are not limited to, animal species and strain, weight, age,





genetic composition, extrinsic treatments, immune status, and environmental conditions, among many others. Each of these variables plays a vital role in achieving the study objectives and, therefore, influences the total number of animals researchers include in their studies. However, without relevant knowledge of these complex scientific variables or the research question at hand, reported animal numbers can be manipulated and incorporated into incorrect messaging.

Without proper context, animal numbers will be analyzed, used, and promoted with a biased perspective that harms the future of research and may make Virginia unattractive to scientific endeavors. Practices such as data cherry-picking, confirmation bias, and outlier bias will become especially common and exaggerated through media channels. A recent example<sup>1</sup> involved several organizations perpetuating false information to the public about critical health research on leishmaniasis—a dangerous parasitic disease that threatens both canines and humans—by accusing NIH of "medieval torture." However, the study and viral photo used and criticized by these groups was never funded by NIH<sup>2</sup>. Unfortunately, as seen in this example and several others, once inaccurate information is published on websites, brochures, blogs, and social media, it persists even after errors are identified. Taken together, these practices undermine the scientific community's strong commitment to research rigor and integrity.

Additionally, **AMP remains concerned about the effect misinterpreted data and associated messaging could have on the scientific workforce**. If animal research is disparaged and misrepresented, students and early career investigators may be discouraged from locating their work in Virginia and pursuing science altogether, jeopardizing Virginia's ability to remain at the forefront of biomedical research progress. Ultimately, this will result in Virgina losing out on millions of dollars in grant, philanthropic, and venture capital funding for vital research. While strengthening transparency is essential, AMP encourages the Task Force to ensure these efforts do not inadvertently compromise the community's commitment to cultivating public trust in science and nurturing the future scientific workforce.

#### The Task Force's Efforts Duplicate Ongoing Research Transparency Efforts at the National Level

The animal research community has consistently demonstrated its longstanding commitment to transparency and animal welfare. Various federal and volunteer initiatives continue to expand and actively support this important work. For example, in 2019 the National Institutes of Health (NIH) established a <u>working group</u><sup>3</sup> within its Advisory Committee to the Director (ACD) specifically focused on enhancing rigor, transparency, and translatability in animal research. The working group's <u>final report</u><sup>4</sup> shared numerous recommendations for achieving this goal. Importantly, it is worth noting that the 54-page report (and its accompanying recommendations) do not propose disclosing animal research numbers as a means to facilitate improved transparency. Rather, the report emphasizes the importance of policymakers and researchers coalescing around a shared mission focused on improving the *conduct* of science. Examples include strengthening study design, enhancing methods and results reporting, and training the workforce to adopt such practices and guide the next generation of researchers. AMP concurs with this approach and believes this fulfills the current Task Force's charge more effectively.

<sup>&</sup>lt;sup>1</sup> Americans for Medical Progress Statement on Ongoing Misinformation Campaign Targeting the National Institute of Allergy and Infectious Diseases. (n.d.). Retrieved from https://www.amprogress.org/wp-content/uploads/2021/10/Dog-research-statement-10.28.2021-.pdf <sup>2</sup> Chelbi, I., Maghraoui, K., Zhioua, S., Cherni, S., Labidi, I., Satoskar, A., Hamilton, J. G. C., & Zhioua, E. (2021). Enhanced attraction of sand fly vectors of Leishmania infantum to dogs infected with zoonotic visceral leishmaniasis. PLOS Neglected Tropical Diseases, 15(7), e0009647. https://doi.org/10.1371/journal.pntd.0009647

<sup>&</sup>lt;sup>3</sup> ACD Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research (n.d.). Retrieved from: https://acd.od.nih.gov/working-groups/eprar.html

<sup>&</sup>lt;sup>4</sup> ACD Working Group Final Report on Enhancing Rigor, Transparency, and Translatability in Animal Research (n.d.). Retrieved from: https://acd.od.nih.gov/documents/presentations/06112021\_AGP\_WorkingGroup\_FinalReport.pdf

**With NIH's leadership, several of the ACD working group's recommendations are underway**. For instance, recent NIH guidance (<u>NOT-OD-23-057</u>)<sup>5</sup> encourages researchers to include the <u>ARRIVE</u><sup>6</sup> (Animal Research: Reporting of In Vivo Experiments) Essential 10 checklist in all NIH-supported publications using vertebrates and cephalopods. This checklist standardizes methods reporting by outlining the minimum information researchers should include in a manuscript, including sample sizes, animals used, statistical analyses, inclusion and exclusion criteria, randomization, etc.

Finally, another example that illustrates researchers' dedication to improving transparency is the very broad institutional participation in the <u>U.S. Animal Research Openness</u><sup>7</sup> (USARO) initiative. Predicated on building public trust and understanding of animal research, USARO's mission is to increase the availability of information about how, when, and why animals are needed to advance scientific knowledge. By empowering individuals and institutions with expanded resources and strategies for transparency, the community can reduce the knowledge gap between researchers and public stakeholders. *AMP encourages the Task Force to endorse this initiative and facilitate conversations with Virginia institutional leaders and USARO's steering group regarding participation so as not to duplicate ongoing efforts on this topic.* 

#### Newly Implemented Research Transparency Requirements in Virginia Should be Reviewed for Effectiveness

Policy review and assessment play a pivotal role in the legislative process and stewardship of taxpayer funds. AMP recognizes the Virginia General Assembly's previous efforts focusing on animal research transparency and recordkeeping of research institutions using animals that receive state support. Accordingly, before mandating new requirements, we strongly advise the Task Force first focus on collecting data and outcome metrics from recent legislative actions to assess their effectiveness in achieving intended goals. Two laws that are particularly relevant to the current Task Force's charge and could benefit from such analysis are Senate Bills (SB) 88 (Va. Code Ann. §3.2-6592.1)<sup>8</sup>, and 1271 (Va. Code Ann. §3.2-6593.2)<sup>9</sup> passed in 2022 and 2023, respectively. This will minimize duplication and enable the Task Force to identify the true policy gaps that must be addressed, conserving valuable time and resources for policymakers and institutions alike.

SB 88 (Va. Code Ann. §3.2-6592.1) requires dog and cat breeders selling animals to research facilities to maintain records of all animals for five years and submit quarterly summaries of these records to the state veterinarian. The second statute, SB 1271 (Va. Code Ann. §3.2-6593.2), requires entities to make annual reports and inspection reports publicly available; additionally, institutions must notify institutional leadership when critical noncompliance is reported. Based on these requirements, it may be presumed that relevant stakeholders, including the public, already have increased access to the number of animals housed in research facilities and included in research studies, making the current efforts duplicative.

### As part of the Task Force's efforts, AMP encourages a thorough review of the following questions as they relate to SB 88 (Va. Code Ann. §3.2-6592.1) and 1271 (Va. Code Ann. §3.2-6593.2):

- Are the statutes being implemented as intended?
- Are the statutes having the desired effect? (e.g., enhanced public transparency)
- Is the public seeking out this new information? If so, how is the information used?

Answers to these and other related questions are necessary before imposing new requirements that could be counterproductive to the overarching goals. Moreover, such assessments may spur important discussions about

<sup>&</sup>lt;sup>5</sup> NOT-OD-23-057: NIH Encourages the Use of the ARRIVE Essential 10 Checklist in All Publications Reporting on the Results of Vertebrate Animal and Cephalopod Research". Nih.gov. Retrieved from: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-057.html <sup>6</sup> The ARRIVE guidelines 2.0. (2020, April 3). ARRIVE Guidelines. Retrieved from: https://arriveguidelines.org/arrive-guidelines

<sup>&</sup>lt;sup>7</sup> About | USARO Main Site. (n.d.). USARO Main Site. Retrieved from https://www.usaro.org/about

<sup>&</sup>lt;sup>8</sup> § 3.2-6592.1. Breeding cats and dogs for experimental purposes. (2024). Virginia.gov. https://law.lis.virginia.gov/vacode/3.2-6592.1/

<sup>&</sup>lt;sup>9</sup> § 3.2-6593.2. Animal testing facilities; public notification. (2024) Virginia.gov. https://law.lis.virginia.gov/vacode/3.2-6593.2/

how to effectively measure, evaluate, and advance research transparency, as the word transparency holds different meanings for different stakeholders. AMP strongly encourages these conversations and believes active public engagement—through requests for information, listening sessions, public forums, etc.—ensures all perspectives are represented in the policymaking process.

#### Conclusion

AMP appreciates the opportunity to provide comments to the Task Force on Transparency in Publicly Funded Animal Testing Facilities. As the Task Force reviews these comments, AMP welcomes the opportunity to collaborate with members and other experts to explore alternative approaches to improve research transparency and strengthen animal health and welfare.

Sincerely,

Paula Clifford, MLA, CVT, RLATG Executive Director Americans for Medical Progress paula@amprogress.org, 202-624-8812

**RECEIVED** By Stacy E. Metz at 2:31 pm, Aug 28, 2024



August 29, 2024

The Honorable Commissioner Joseph Guthrie Virginia Department of Agricultural and Consumer Services 102 Governor Street Richmond, Virginia 23219

Dear Commissioner Guthrie:

The National Association for Biomedical Research (NABR) writes concerning the Task Force on Transparency in Publicly Funded Animal Testing Facilities.

The task force consists of legislators and stakeholders tasked with identifying potential deficiencies in publicly funded animal testing facilities in the Commonwealth and recommending methods and context for making certain information about such animal testing facilities publicly available.

For more than 45 years, NABR has been the nation's only organization solely dedicated to advocating for sound public policy in support of ethical and essential laboratory animal research and the lifesaving discoveries they produce. NABR's diverse and unified membership includes more than 320 universities, medical and veterinary schools, teaching hospitals, pharmaceutical and biotechnology companies, patient groups and academic and professional societies that rely on the humane and responsible use of research animals to advance global human and animal health.

Animal research remains vital to our mission to understand disease, discover targeted therapies, alleviate suffering, and improve and increase the quality of life. Biomedical research projects involving animals, governed by a strict structure of laws, regulations, and guidelines, continue to yield invaluable data in the process of discovering new therapies to treat, cure, and prevent disease. Cancer therapies, immunizations, organ transplants, reconstructive surgeries, and many other innovations have been brought to fruition through research conducted at our member institutions.

NABR is concerned that the true intent of this study, mandated by  $(\underline{8.411})$  and backed by special interest groups, may have negative impacts on life-saving research and scientific innovation in the Commonwealth. Therefore, we encourage the task force to review our concerns below and take them into consideration.

- 1. It is unclear what problem or goal the legislation attempts to address. The goal of the study appears punitive rather than constructive. It will merely institute an unnecessary administrative burden, through additional paperwork and time, and will set overly stringent reporting requirements for publicly funded research facilities and the State of Virginia.<sup>1</sup>
- 2. The proposed state reporting requirements are duplicative and unnecessary. Such reporting would add to the already substantially high administrative burden of bioscience research institutions. In fact, there are currently more regulations surrounding animal research than human clinical trials. The information sought for the number of covered species animals used in research and testing, is already shared with the United States Department of

<sup>&</sup>lt;sup>1</sup> <u>https://thefdp.org/wp-content/uploads/FDP-FWS-2018-Primary-Report.pdf</u>



Agriculture as part of required filings and reviews, and readily available on the USDA website. It is unclear what the purpose or impact such additional and duplicative reporting will achieve. Additionally, the penalties noted are particularly punitive given the intent for mere administrative filing. Additional costs in time and fees for compliance only serve to decrease the value of federal grants, as well as Virginia tax funds, when researchers should be spending the majority of their time and funds actually conducting research to save both human and animals lives. According to the Federal Demonstration Partnership Faculty's 2018 Workload Survey, federally-funded principal investigators in research labs are spending an estimated 44.3% of their time on administrative requirements rather than conducting research – an increase in time spent on activities other than research compared to previous FDP survey years. Functionally, this means researchers are only spending a little over half their time conducting bench work – the rest is spent complying with an evergrowing web of complex regulatory requirements. The proposed state reporting requirements will only exacerbate this problem.

- 3. Increased animal reporting requirements for publicly funded institutions in the Commonwealth are unlikely to benefit a public that doesn't know what lab animal medicine is. (According to FBR and Johns Hopkins University's 2022 public opinion poll, 67% of Americans are unaware of the existence of full-time veterinary specialists for the care of animals in biomedical research). History suggests animal rights groups are far more interested in such information, for the purposes of targeting, rather than the average Virginia taxpayer. Some effort should be made to determine the true demand for such information by citizens who are not attempting to advance the agenda of animal rights groups, which primarily consists of eliminating animal models from research.
- 4. Instituting onerous and impractical regulations covering animals in research is likely to send a chilling message to publicly funded research institutions that Virginia is not supportive of its life sciences industry. Researchers will go where they are treated best. Yet the state's research institutions are already experiencing a shortage of scientists and veterinarians, and this legislation will worsen the problem. The legislation will ultimately hamper discovery and innovation at Virginia's world-class research institutions, and the economic impact will be felt across the state. Excessive regulatory and reporting requirements are entirely at odds with the Commonwealth's stated goal of creating a Virginia Research Triangle.

Sincerely,

Matter RISing

Matthew R. Bailey President

cc: Senator William Stanley, Jr. Senator Jennifer Boysco House of Delegate Hillary Pugh Kent House of Delegate Shelly Simonds



 From:
 Schmidt, Kevin (VDACS)

 To:
 Robichaud, Nicolas (VDACS)

 Subject:
 FW: Public Comment Received: RE: Physicians Committee Letter Received 8/29

 Date:
 Wednesday, October 2, 2024 1:41:19 PM

 Attachments:
 Outlook-31 piy00r.png image001.png PHYSIC~1.PDF

**Kevin Schmidt** 

WC12 Poster - Animal Numbers.pdf

Director, Office of Policy, Planning, and Research Virginia Department of Agriculture and Consumer Services

Phone: 804.786.1346 Website: <u>www.vdacs.virginia.gov</u> E-mail: <u>Kevin.Schmidt@vdacs.virginia.gov</u> Address: <u>102 Governor Street, Richmond, Virginia 23219</u>

From: rr-VDACS.Commissioner <vdacs.commissioner@vdacs.virginia.gov>
Sent: Monday, September 16, 2024 11:38 AM

To: Suzanne Griffin <srgriffin@vt.edu>; Hildabrand, Annette - hildabak <hildabak@jmu.edu>; Robert N. Corley <RCORLEY@VSU.EDU>; Daphna Nachminovitch <daphnan@peta.org>; Sharon Adams <sharonadams980@gmail.com>; Will Lowrey <wlowrey@animalpartisan.org>; D. Joshua Cohen <djcohen@vcu.edu>; raphael.malbrue@virginia.edu; Steve Weddle <stevew@vpa.net>; Megan Rhyne <mrhyne@opengovva.org>; Louden, Corrine (OSIG) <Corrine.Louden@osig.virginia.gov>; senatorstanley@senate.virginia.gov; senatorboysko@senate.virginia.gov; Aimee Perron Seibert <aimee@commonwealthstrategy.net>; Bell, Justin I. <jbell@oag.state.va.us>;

delhkent@house.virginia.gov; Smith, Paul (SCHEV) <PaulSmith@schev.edu>; Schmidt, Kevin (VDACS) <Kevin.Schmidt@vdacs.virginia.gov>; Joseph, Isaac (VDACS) <Isaac.Joseph@vdacs.virginia.gov>; Pantazis, Kirstin (SCHEV) <KirstinPantazis@schev.edu>; Kirstin (SCHEV) <KirstinPantazis@schev.edu> <DelSSimonds@house.virginia.gov>

Cc: Office Contact <contact@simondsfordelegate.com>

Subject: Public Comment Received: RE: Physicians Committee Letter Received 8/29

Good morning,

?

The Commissioner's Office received this public comment and is making the task force members aware of it as we will with any written comment we receive for the task force. This refers to the Physicians Committee Letter received 8/29/2024. I have attached both.

"I am now writing to share the results of an analysis (second attachment) that we presented at a scientific conference in 2023 regarding the number of animals used in

#### laboratories funded by the federal government.

#### I expect this analysis will be of interest to you and members of the Task Force." Ryan Merkley

Sincerely,

Joe



Joseph W. Guthrie Commissioner Virginia Department of Agriculture and Consumer Services

Phone: 804.786.3501 Website: <u>www.vdacs.virginia.gov</u> E-mail: <u>vdacs.commissioner@vdacs.virginia.gov</u> Address: 102 Governor Street, Richmond, Virginia 23219

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### PhysiciansCommittee

PCRM.ORG

5100 Wisconsin Ave. NW, Suite 400 • Washington, DC 20016 • Tel: 202-686-2210 • Fax: 202-686-2216 • pcrm@pcrm.org

August 29, 2024

Joseph Guthrie Chair, Task Force on Transparency in Publicly Funded Animal Testing Facilities Virginia Department of Agriculture and Consumer Services 102 Governor St. Richmond, VA 23219

*Sent via email (<u>vdacs.commissioner@vdacs.virginia.gov</u>; <u>kevin.schmidt@vdacs.virginia.gov</u>; <u>stacy.metz@vdacs.virginia.gov</u>; <u>isaac.joseph@vdacs.virginia.gov</u>; <u>acarolynn.bissett@vdacs.virginia.gov</u>)* 

Dear Chair Guthrie and Members of the Task Force:

I am writing as a former faculty member and director of the cardiology fellowship program at the Medical College of Virginia (now named the Virginia Commonwealth University School of Medicine) and as a former animal researcher at the University of Texas Southwestern Medical School. On behalf of the global nonprofit Physicians Committee for Responsible Medicine and our more than 17,000 physician members and 900,000 supporters, I am writing to provide public comments in advance of your August 30 meeting.

Our organization operates a health clinic; conducts clinical research; and advances research, testing, and training methods that improve human health while reducing and replacing animals. We believe it is crucial that our publicly funded institutions, universities, and research and testing facilities are transparent and open about how they pursue science, including the use of animals, and whether they are in compliance with federal laws and standards of practice.

Data are a cornerstone of science and research, and the scientific community must be committed to the reduction and replacement of animals in labs. Yet scientists everywhere and the public especially are woefully in the dark when it comes to information about how many animals are used in laboratories. Fewer than 5% of all animals used in labs in the United States are accurately reported. This is in stark contrast to our research partners in the European Union, United Kingdom, Canada, and elsewhere—where accurate reporting is a routine and publicly transparent process. Only by understanding how the institutions we entrust to advance public health use animals can we measure scientific progress and research ethics.

In addition, the public is increasingly concerned about whether research and testing facilities are working expeditiously to modernize and humanize their work when nonhuman animals so often fail to accurately model human diseases. There is ample reason for that concern. For example, a 2013 review documented that 96% of drugs successfully tested in animals failed in human clinical trials,<sup>1</sup> and this was confirmed by the director of the National Institutes of Health (NIH).<sup>2</sup> Rather than improving over time, the failure rate for these drugs worsened from 86% in 1985 to 92% in 2003 and to 96% by 2013.<sup>3</sup> In 2014, Cleveland Clinic researchers found an abysmal 99.6% failure rate for Alzheimer disease drugs undergoing clinical trials between 2002 and 2012, noting a "translational gap" between humans and animal experiments.<sup>4</sup> There remains no treatment that meaningfully impacts outcome for Alzheimer disease.<sup>5</sup>

In a landmark 2013 study, researchers from Stanford University, Harvard University, and elsewhere found that when it comes to serious inflammatory conditions such as sepsis, burns, and trauma, results from mice cannot be applied to humans because of their vastly different genetic responses.<sup>6</sup> Even the director of NIH acknowledged the time and resources wasted on sepsis experiments on mice. He called the catastrophe—in which 150 drugs successfully treated sepsis in mice but failed in human trials—a "heartbreaking loss of decades of research and billions of dollars."<sup>7</sup>

Yale University School of Public Health epidemiologist Dr. Michael Bracken co-authored a 2014 *BMJ* analysis that questioned whether animal experimentation is sufficiently evidence-based, writing:

The current situation is unethical. Poorly designed studies and lack of methodological rigour in preclinical research may result in expensive but ultimately fruitless clinical trials that needlessly expose humans to potentially harmful drugs or may result in other potentially beneficial therapies being withheld. Moreover, if poorly conducted studies produce unreliable findings, any suffering endured by animals loses its moral justification because their use cannot possibly contribute towards clinical benefit.<sup>8</sup>

The analysis concluded that due to the continued failures by researchers to conduct rigorous studies and by the studies to predict outcomes in humans, "the public's continuing endorsement and funding of preclinical animal research seems misplaced."<sup>9</sup>

The kind of transparency that Virginia residents are seeking through your task force would be a benefit to public health and the pursuit of medical treatments—without burdening researchers. Any research or testing facility should already know how many animals it has purchased or bred and how it conducts research—whether with animals or nonanimal methods. While on faculty at universities that used animals in research, I would have been certain that my laboratory could easily compile such information. Indeed, it is our duty—to the animals and the public—to know how many animals we use and what impact such use has on patient outcomes.

As Dr. Larry Carbone, a research veterinarian with more than 40 years of experience at Cornell University and the University of California, San Francisco, stated, "How can you measure your progress ... if you're not even counting the animals?"<sup>10</sup>

We see your work as critical to improving public health and ensuring animal welfare.

Thank you for your attention and time.

Very truly,

sprin us

John J. Pippin, MD, FACC Director of Academic Affairs Phone: 972-407-9396 Email: jpippin@pcrm.org

#### References

<sup>1</sup> Pippin, J.J. (2013). Animal Research in Medical Sciences: Seeking a Convergence of Science, Medicine, and Animal Law. South Texas Law Review, 54(3).

<sup>2</sup> Collins, F.S. (2011). Reengineering Translational Science: The Time Is Right. Science Translational Medicine, 3(90):1.

<sup>4</sup> Cummings, J.L., Morstorf, T. & Zhong K. (2014). Alzheimer's Disease Drug-Development Pipeline: Few Candidates, Frequent Failures. Alzheimer's Research & Therapy, 6(37).

<sup>5</sup> Pippin, J.J. (2019). Animal Research for Alzheimer Disease: Failures of Science and Ethics. In K. Hermann & K. Jayne (Eds.), Animal Experimentation: Working Toward a Paradigm Shift (pp. 489-490).

<sup>6</sup> Junhee, S. et al. (2013). Genomic Responses in Mouse Models Poorly Mimic Human Inflammatory Diseases. PNAS, 110(9).

<sup>7</sup> Collins, F. (2013, Feb. 19). Of Mice, Men, and Medicine. NIH Director's Blog.

<sup>8</sup> Pound, P., Bracken, M.B., & Bliss, S.D. (2014). Is Animal Research Sufficiently Evidence Based to Be a Cornerstone of Biomedical Research? The BMJ, 348.

9 Ibid.

<sup>10</sup> Grimm, D. (2021, Jan. 12) How Many Mice and Rats Are Used in U.S. Labs? Controversial Study Says More Than 100 Million. Science.

<sup>&</sup>lt;sup>3</sup> Pippin, J.J. (2013).

# Groundbreaking Analysis of Research Animal Numbers at U.S. Government-Funded Laboratories

Ryan W. Merkley; Bethany J. Beauregard; Catharine E. Krebs, PhD Physicians Committee for Responsible Medicine, Washington, DC, USA

# THE PROBLEM

The U.S. government does not collect accurate numbers of vertebrate animals used in experiments or publish the limited data it gathers. The U.S. Department of Agriculture (USDA) only collects data on species covered by the Animal Welfare Act, which excludes most rats and mice, many birds, and all cold-blooded animals. U.S. National Institutes of Health (NIH) animal welfare policies apply to all vertebrates, but NIH collects only an "approximate average daily inventory" of animals every four years. Without accurate numbers, the U.S. cannot measure national progress toward reduction and replacement.

## RESULTS

- 19,700,425\* vertebrates being used or housed in U.S. government-funded facilities at any given time
- 1,056 unique physical laboratories from 822 registrations with NIH

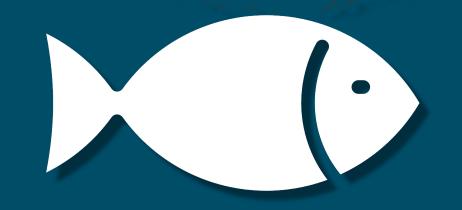
# METHODS

Using the federal Freedom of Information Act, copies of all "Facility and Species Inventory" records for domestic research institutions registered with NIH as of Nov. 2019 were obtained over 13 months ending in Dec. 2020. Data were manually entered from PDFs provided by NIH into a spreadsheet and analyzed.



**10,803,194 mice** and **304,739** "cages" \*(cages conservatively extrapolated = 914,217 additional mice)





5,821,804 fish, 17,465 zebrafish "tanks," and 248 zebrafish "racks"



## 856,144 rats and 6,246 rat "cages"

of animals reported to NIH are covered by the Animal Welfare Act

(source: USDA FY19 compiled data = 934,771 animals)



62,953 birds and 80,515 bird "cages"

## TROUBLING FIGURES



412,489 cages, tanks, and racks were reported for various species, making an accurate calculation impossible

**Ryan Merkley** Director of Research Advocacy Phone: +1-202-527-7336 • Email: rmerkley@pcrm.org • Twitter: @RyanWMerkley

From: To:	<u>rr-VDACS.Commissioner</u> Suzanne Griffin; Hildabrand, Annette - hildabak; Robert N. Corley; Daphna Nachminovitch; Sharon Adams; Will Lowrey; D. Joshua Cohen; raphael.malbrue@virginia.edu; Steve Weddle; Megan Rhyne; Louden, Corrine (OSIG);
	senatorstanley@senate.virginia.gov; senatorboysko@senate.virginia.gov; Aimee Perron Seibert; Bell, Justin I.; delhkent@house.virginia.gov; Smith, Paul (SCHEV); Schmidt, Kevin (VDACS); Joseph, Isaac (VDACS); Pantazis, Kirstin (SCHEV); Kirstin (SCHEV) < KirstinPantazis@schev.edu>
Cc:	Office Contact
Subject:	Public Comment Received: Fw: Senate Bill (SB) 411
Date:	Monday, September 16, 2024 4:58:34 PM
Attachments:	<u>Outlook-hwr0ikgf.png</u>

#### Good afternoon,

The Commissioner's Office received this public comment and is making the task force members aware of it as we will with any written comment we receive for the task force.

Best Regards,

Joe



Joseph W. Guthrie Commissioner Virginia Department of Agriculture and Consumer Services

Phone: 804.786.3501 Website: <u>www.vdacs.virginia.gov</u> E-mail: <u>vdacs.commissioner@vdacs.virginia.gov</u> Address: <u>102 Governor Street, Richmond, Virginia 23219</u>

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From: John Gluck <jgluck@unm.edu>
Sent: Monday, September 16, 2024 4:23 PM
To: Metz, Stacy (VDACS) <stacy.metz@vdacs.virginia.gov>; rr-VDACS.Commissioner
<vdacs.commissioner@vdacs.virginia.gov>
Subject: Senate Bill (SB) 411

#### Transparency

Dear Commissioner, Guthrie: I am aware of the State of Virginia task force created by Senate Bill 411 to elaborate and extend the public's awareness of research activities that utilize nonhuman animals as subjects of study and are publicly funded. As a retired academic researcher that utilized rodents and nonhuman primates in my studies for many years, I support the process and purpose of this task force and your leadership. During my university service I was a member and chair of the University of New Mexico IACUC (10+ years) and research ethics advisor to the former UNM President – Robert G. Frank (5 years). I also directed The Research Ethics Service Project that offered ethical guidance to researchers, technicians, and students, anonymously (if asked) with earnest questions about the appropriateness of research practices, with humans and/or animals, that they had become aware of.

When I started conducting biomedical and behavioral research with animals, first as graduate student at the University of Wisconsin Primate Laboratory in 1968 and then as a university faculty member in 1971, what was happening in animal research labs was in the furtherest state from transparency. Laboratory doors were mostly closed to the public and at times to other faculty as well. It was also a rarity for a university animal facility to have continual access to veterinary expertise either on staff or available on call. Instead, each laboratory director was seen as the main source of the methods of animal care as well as the methods necessary to realize experimental goals. Not surprisingly, there was significant variability in the capabilities of researchers in that trusted position. Techniques were too frequently passed on to the next generation of students by the "Watch one, Do one, Teach one" method. No longer (never) an acceptable way to conduct science and train students.

Change in this untenable situation began due to reporting in public venues of cases of improper methods of animal acquisition and treatment in the laboratory (e.g., Life Magazine, 2/4/1966, Testimony of Prof. Bernard Rollin, Colorado State University). The result was the passage of the Animal Welfare Act in 1966 that focused on lab animal health and appropriation. Oversight of activities inside the laboratory remained untouched. Then again, in the 1980s reports of research animal mistreatment like the University of Pennsylvania primate head injury studies (e.g., 1984, NBC Nightly News, the film: "Unnecessary Fuss") led to the passage of the 1985 requirement of expansion of research oversight by review committees (IACUCs) at each university (Robert Dole and George Brown modification of 1985 Farm Bill). More currently, the difficulty in repeating research findings by other researchers, and the repeated difficulty in translating animal research into useful and effective human interventions is another signal that research activities need fresh evaluative eyes.

My point to the Task Force is that each time oversight of animal and human research has been responsibly increased, the treatment of the subjects of research is improved and the validity of the relevant science is increased. The wisdom of the Task Force's work has great potential value.

John P. Gluck Ph.D. Emeritus Professor University of New Mexico Faculty Affiliate Kennedy Institute of Ethics Georgetown University http://press.uchicago.edu/ucp/books/book/chicago/V/bo23671366.html



August 29, 2024

#### VIA EMAIL

The Honorable Joseph Guthrie Chair Task Force on Transparency in Publicly Funded Animal Testing Facilities Virginia Department of Agriculture and Consumer Services 102 Governor Street Richmond, Virginia 23219

Dear Chairman Guthrie and Task Force Members:

On behalf of States United for Biomedical Research (SUBR), whose members represent the nation's leading life sciences companies and research universities, including multiple institutions located in Virginia, thank you for the opportunity to comment on issues related to institutional transparency regarding laboratory animal research. SUBR and its members are committed to transparency and support initiatives that promote an informed public regarding medical innovation made possible through laboratory animal research. Nearly every vaccine, treatment, cure, diagnostic and surgical procedure available today has been made possible through studies with animals. As more fully detailed below, we respectfully ask that the Task Force avoid recommendations that create unnecessary and duplicative reporting burdens that fail to advance laboratory animal welfare and simply provide a mechanism for animal rights organizations to attack Virginia's research institutions.

The availability and use of animals in biomedical research is critical and without which the progress we all demand for ourselves and our loved ones, including our pets, would not be possible. It is with this reality in mind that we urge the Task Force members to be diligent in your review and avoid recommendations that create "transparency" without context. Existing reporting requirements within Virginia and the federal government already create opportunities for those who knowingly seek to end lifesaving research with animals before science allows to disparage researchers and animal care staff for their own benefit.

Far too often activist groups opposed to laboratory animal research misrepresent clerical errors and create false claims of animal welfare failures, missing animals, and wasted funds. In no uncertain terms, well-funded activist groups will utilize every opportunity to take data out of context to promote anti-research positions. This is unnecessary and would make Virginia a less desirable location to conduct life-saving biomedical research. The public record contains far too many examples where this occurred. To note just two examples, one well-known anti-research organization directed false animal welfare claims at Dr. Anthony Fauci and life-saving research into Leishmaniasis.<sup>1</sup> Another organization continues to wage a years-long attack on a bird researcher now based at Louisiana State University.<sup>2</sup> In that particular case, the FBI had to be called in after activists associated with an animal extremist organization threatened physical harm against the researcher, her husband and young child while they resided in Connecticut, where she conducted post-doctoral studies at Yale University.

<sup>&</sup>lt;sup>1</sup> https://www.factcheck.org/2021/11/answering-questions-about-beaglegate/

<sup>&</sup>lt;sup>2</sup> https://www.insidehighered.com/news/2017/09/22/peta-goes-after-postdoc-her-research-birds-and-academics-cry-foul States United for Biomedical Research • PO Box 1163, Camp Hill, Pennsylvania 17001

Equally important, Virginia enacted multiple laws related to laboratory animals in 2022 and 2023 – SB 87, SB 88, SB 90, SB 604, and SB 1271. Collectively, these laws provide Virginia with comprehensive restrictions and detailed reporting requirements for laboratory animal research. In particular, SB 88 requires dog and cat breeders selling animals to research facilities to maintain records of all animals for five years and submit quarterly summaries of these records to the state veterinarian and SB1271 requires entities to make annual reports and inspection reports publicly available. We recommend a thorough review of the impact these existing laws continue to have on the transparency goals the General Assembly seeks to advance through this Task Force prior to new recommendations being made.

Finally, we must note that legislators in Colorado recently rejected similar reporting and transparency requirements to those that are under consideration in Virginia after a non-partisan fiscal note detailed the anticipated annual costs of \$5.7 million for the Colorado Department of Public Health and just three public institutions.<sup>3</sup> The cost of compliance is indeed significant and should be considered alongside the fact that it is typically well-funded, international animal activist organizations that demand access to laboratory animal research records, not the general public.

In summary, we ask the Task Force to avoid recommendations that propose to unnecessarily regulate an already highly regulated research community, which could increase the cost, both in time and resources, of advancing research and science in Virginia. Existing laws in Virginia already include some of the strictest laboratory animal provisions, including reporting requirements, in the country. We ask that these laws be reviewed for their effectiveness in providing transparency before additional burdens are placed on the Commonwealth's world-class research institutions. Research locates itself where it is welcomed, and we ask that the Task Force avoid any recommendations that make the Commonwealth a less desirable destination for researchers and institutions alike.

Thank you for reviewing our concerns. If you have any questions, please do not hesitate to contact us.

Sincerely,

SUBR Board of Directors

If Leach

By: Tom Leach President leach@njabr.org

> **RECEIVED** By Stacy E. Metz at 5:37 pm, Aug 29, 2024

<sup>&</sup>lt;sup>3</sup> See the Fiscal Note for Senate Bill 67 - <u>https://leg.colorado.gov/sites/default/files/documents/2024A/bills/fn/2024a\_sb067\_f1.pdf</u>



### Animal Welfare Institute

900 PENNSYLVANIA AVENUE, SE, WASHINGTON, DC 20003 · 202-337-2332 · AWIONLINE.ORG

September 18, 2024

Mr. Joseph Guthrie Co-Chair, Task Force on Transparency in Publicly Funded Animal Testing Facilities Virginia Department of Agriculture and Consumer Services 102 Governor Street Richmond, Virginia 23219 Delivered via email: vdacs.commissioner@vdacs.virginia.gov

Mr. Paul Smith Co-Chair, Task Force on Transparency in Publicly Funded Animal Testing Facilities State Council of Higher Education for Virginia (SCHEV) 101 North 14th Street, 10th Floor James Monroe Building Richmond, Virginia 23219 Delivered via email: <u>PaulSmith@schev.edu</u>

Dear Chair Guthrie, Chair Smith, and Members of the Task Force:

On behalf of its many members and supporters in Virginia, the Animal Welfare Institute welcomes the mission of the Task Force on Transparency in Publicly Funded Animal Testing Facilities to ensure that the public has access to important information about the use of animals by facilities funded by tax dollars. We would first like to offer our thoughts regarding the information that should be provided, and then address why it is necessary to instruct facilities to provide this information.

#### I. Recommendations

Based on our many years of experience with the use of animals in research and the many failures to comply with humane care standards and to operate transparently, we would ask that the Task Force recommend that publicly funded research facilities submit the following information to the State Veterinarian annually:

- 1. The total number of animals (on hand both at the beginning of the reporting period and at the end of the reporting period) used or held, for research, education, testing, or experimental, scientific, or biomedical purposes with such animals identified and grouped according to use and species;
- 2. The number of animals purchased and/or acquired from, including via transfer or trade with, other animal testing facilities or suppliers, during the preceding calendar year, with

such animals identified and grouped according to species, and including the names and locations of the facilities supplying the animals, and identifying the numbers of each species supplied by each such facility;

- 3. The number of animals born at the facility during the preceding calendar year, with such animals identified and grouped according to species;
- 4. The number of animals euthanized, lost, adopted, transferred, traded or sold to other facilities during the preceding calendar year, with such animals identified and grouped according to disposition outcome and species;
- 5. The number of animals who died unassisted during the preceding calendar year, identified and grouped according to species;
- 6. The number of animals who experienced adverse events during the preceding calendar year, identified and grouped according to species; where the term "adverse events" means "those unexpected incidents that lead to harm, or endanger the well-being of animals or humans at a research facility."

For the number of animals experiencing adverse events, it would be a further show of good faith for institutions to post the following on their websites:

- a) their Inspection Reports, which are produced by USDA and therefore don't require facilities to write their own, and
- b) any adverse-event-related communication between institutions and OLAW, e.g., self-reports to OLAW, OLAW's responses, and any other letters of complaint or concern from OLAW to institutions.
- 7. The dollar amount expended by such facility during the preceding calendar year on activities that involved the use of animals in research, education, testing, experimental, scientific, or biomedical purposes where such dollar amount shall include amounts spent to procure and maintain the animals (including food, housing, veterinary care, administrative costs, animal care technicians, and other related costs) as well as amounts spent during the course of use of the animal.

### II. The need for directing publicly funded research facilities to provide such information has been questioned. We would like to assure the Task Force that such direction is needed.

1. There is a lack of transparency at the federal level. Contrary to claims otherwise, federal requirements are not sufficient to ensure full transparency: (a) approximately 95 percent of the animals used in research—birds, rats, mice, and cold-blooded species—are not covered by the Animal Welfare Act. (b) Although the PHS Policy on Humane Care and use of Laboratory Animals covers all vertebrate species, the numbers reported under PHS rules are only an "approximate average daily inventory," and that information can be acquired only through a costly and time-consuming FOIA process. (c) Canada and

members of the EU report the total number of animals used, the purpose for which they are used, and the severity of the experiments to which they are subjected. This is not the case in the U.S.

- 2. Recent changes in reporting were not designed to increase transparency. For example, the NIH's Advisory Committee to the Director Working Group on enhancing Rigor, Transparency, and Translatability in Animal Research did not, according to its own 2021 report, "propose disclosing animal research numbers a means to facilitate improved transparency."
- 3. The public supports—in fact, expects—greater transparency. In a 2022 public opinion poll, 56 percent of respondents stated they supported state legislation to require laboratories to disclose the number of animals used in research, and testing, the purpose of the experiments, and whether the animals experienced pain and distress. Only 26 percent opposed such legislation.
- 4. Contrary to suggestions otherwise, like those put forward by Americans for Medical Progress, enhanced transparency will not "create unintended consequences for biomedical research" nor "jeopardize the ability to explore future scientific questions." Transparency is just that...It is not a directive to do one thing or another, merely to allow those who are funding the research—taxpayers—access to information. Similarly, enhanced transparency will not "impede the training of the next generation of researchers" nor "adversely impact Virginia's academic, biomedical and biotechnology market sectors." Rather, Virginia will be seen to be on the cutting edge of science and accountability, concepts with which the rising generation of scientists is more in tune, and can become a hub for more forward-thinking research.

Further, contrary to suggestions made by States United for Biomedical Research (SUBR), increased transparency is not likely to cause "well-funded activist groups [to] utilize every opportunity to take data out of context to promote anti-research positions." Firstly, some of those data are already available for those species the public cares about the most (dogs, nonhuman primates) and for all species in many other Western countries. Secondly, while AWI is firmly against any type of violence or attacks against individual researchers, the victim of the second example cited by SUBR admitted that a *lack* of transparency is what led to being targeted and that she has "gotten much better at communicating clearly about the importance of my work, ... We can't expect the public to understand why this work matters, and why it has to be done this way, unless we tell them." Indeed, if the industry is concerned that the Task Force will make "recommendations that create "transparency" without context," then they are welcome to provide the needed context.

We very much appreciate the work of the Task Force and its efforts to engage with the public in that work. Please let me know if we can be of any further assistance.

Sincerely,

J. Mahourt.

Joanna Makowska, PhD Director & Senior Scientist, Applied Animal Behavior Animals in Laboratories Program

**RECEIVED** 

By Stacy E. Metz at 1:16 pm, Sep 18, 2024



September 9, 2024

Task Force on Transparency in Publicly Funded Animal Testing Facilities Virginia Department of Agriculture and Consumer Services 102 Governor Street Richmond, VA 23219

Dear Task Force Members,

On behalf of the Humane Society of the United States (HSUS) and our members and supporters in Virginia, I thank you for the important work you are doing to ensure that Virginia's publicly funded animal testing facilities are operating with transparency. HSUS has previously provided recommendations on what information should be made available to the public. However, we would now like to address concerns raised by other organizations about the important work being done by the Task Force on Transparency in Publicly Funded Animal Testing Facilities (Task Force).

#### There is a clear lack of federal transparency.

Despite claims that state-level transparency on animal research is not needed due to current federal requirements, there are severe limitations in the amount of information that is currently available. It is estimated that approximately 95% of animals used in research are exempt from being counted through the Animal Welfare Act (AWA) since the law excludes mice, rats, and birds bred for use in research, along with cold-blood species including fish, reptiles, and amphibians.<sup>1</sup>

Unlike the AWA, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals covers all vertebrate species. Research facilities getting grants from the National Institutes of Health (NIH) must follow PHS policy. Unfortunately, the number of animals used is reported only as an "approximate average daily inventory."<sup>2</sup> Furthermore, this information can only be accessed through submission of Freedom of Information Act (FOIA) requests, which can be costly and time-consuming for the public.

The Unites States lags behind other countries in reporting information about animal use. In the European Union, all member countries report the total number of animals used, the purpose of their use, and the severity of the experiments. In 2021, "the European Commission launched two open access databases, available for all interested stakeholders, to facilitate identification of areas where

<sup>1</sup> 7 U.S.C. § 2132(g) (2018).

<sup>&</sup>lt;sup>2</sup> Office of Laboratory Animal Welfare (n.d.) Domestic Assurance Sample Document. Retrieved from: <u>https://olaw.nih.gov/sites/default/files/assursmp.htm</u>

replacement and refinement efforts are most urgently needed."<sup>3</sup> Without full transparency, it is difficult to assess the areas where available alternatives should be implemented, and where new non-animal method development should be prioritized.

#### Recent national efforts on transparency are not adequate.

While HSUS supports any efforts to improve research outcomes and translatability, the efforts cited by Americans for Medical Progress (AMP) in their August 28 letter are not intended to provide transparency to the public about the use of animals in research. By their own admission, the NIH Advisory Committee to the Director Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research did not "propose disclosing animal research numbers as a means to facilitate improved transparency" in their 2021 report.<sup>4</sup> As for the ARRIVE (Animal Research: Reporting of In Vivo Experiments) Guidelines, "the primary purpose of the guidelines is to improve the quality of manuscripts" and "can also be used during the planning and conduct of animal studies to help make sure that experiments are robustly designed and properly recorded, preparing the way for future publication."<sup>5</sup> While following these guidelines may be important for researchers hoping to get their work published, it is not meant to provide public transparency and is therefore not applicable to the efforts of the Task Force. Finally, the United States Animal Research Openness Initiative (USARO) advocates for research facilities to commit to being open about their animal use; however, the stated aim of this organization is "to increase the number of institutions that are engaging in meaningful public conversations about the importance of animal contributions to science."<sup>6</sup> AMP raised concerns about "confirmation bias" with animal use data being made available to the public in its letter to the Task Force. Similar concerns could be raised with groups like USARO.<sup>7</sup>

#### The public supports efforts to increase transparency.

In a 2022 public opinion poll of more than 1,500 likely general election voters conducted by Remington Research Group, 56% of respondents would support state legislation to require laboratories in their state to disclose the number of animals used in research and testing, the purpose of those experiments, and whether the animals experienced pain and distress while only 26% opposed. This demonstrates "the true demand for such information by citizens," which was questioned by the National Association of Biomedical Research in their August 29 letter to the Task Force.<sup>8</sup>

<sup>&</sup>lt;sup>3</sup> European Commission (2023). Commission Staff Working Document: Summary Report on the statistics on the use of animals for scientific purposes in the Member States of the European Union and Norway in 2020. Retrieved from: <u>https://circabc.europa.eu/ui/group/8ee3c69a-bccb-4f22-89ca-277e35de7c63/library/10ad28d6-e17e-4367-b459-20883402cfcc/details</u>

<sup>&</sup>lt;sup>4</sup> Clifford, Paula. Letter to Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, August 28).

<sup>&</sup>lt;sup>5</sup> National Centre for the Replacement, Refinement, and Reduction of Animals in Research. (2020). New ARRIVE Guidelines 2.0 Released. Retrieved from: <u>https://arriveguidelines.org/news/new-arrive-guidelines-20-released</u>

<sup>&</sup>lt;sup>6</sup> United States Animal Research Openness Initiative (n.d.) About Us. Retrieved from: <u>https://www.usaro.org/about</u>
<sup>7</sup> Clifford, Paula. Letter to Task Force on Transparency in Publicly Funded Animal Testing Facilities. (2024, August 28).

<sup>&</sup>lt;sup>8</sup> Bailey, Matthew. Letter to Commissioner Joseph Guthrie. (2024, August 29).

#### Increased transparency should not represent an overwhelming administrative burden.

Efforts to oppose transparency at animal research facilities have often focused on the idea that any new reporting will create an undue burden on facilities. HSUS feels strongly that the purpose of the Task Force is to create recommendations that will not only provide transparency but also specifically address these concerns. Research facilities already have processes in place for accounting annually for certain animals that are used. These same procedures could be put in place for all animals without the need to create new systems. The University of Washington has their animal use statistics clearly available on their website. This includes species not covered by the AWA including mice and fish which represent 48.67% and 48.2% of the animals used respectively in their most recent reporting.<sup>9</sup> In addition, facilities must keep careful records of animal purchases for accounting purposes making it easy to track where animals are acquired. Finally, by proactively publishing information about animal use, Virginia research facilities can eliminate the time and effort it takes to respond to FOIA requests from the public. All of the information will be readily available and will not need to be redacted.

### Transparency could help Virginia's publicly funded facilities acquire and maintain talented researchers.

NABR states (without any evidence to support its assertion) that passage of a law to require transparency will "ultimately hamper discovery and innovation at Virginia's world-class research institutions, and the economic impact will be felt across the state." However, on its website, USARO, which aims to educate the public about the value of animal research, includes exemplars from research institutions that have embraced transparency including from the University of Washington. Contrary to NABR's claim, University of Washington identified three major benefits of being more forthcoming on animal use. The first is an increase in staff morale declaring that the "institution's confidence and consistent reaffirmation of commitment to animal welfare serves as a rallying point for passionate members of the UW research community." The other benefits highlighted were limiting the burden of responding to records requests as discussed in the point above and being able to provide pushback against misinformation.<sup>10</sup>

21st century science is rapidly moving away from outdated animal tests and toward human-based technologies. According to NIH's National Institute for Environmental Health Sciences, "improved technological capabilities enable scientists to reduce their reliance on animal models for specific types of studies. These advances are important because testing in animals can pose ethical issues, takes significant time and resources, and the relevance to human health is not always certain."<sup>11</sup> It would not be surprising that many young researchers would be looking to learn about, use, and develop modern testing approaches that do not rely on animals. Virginia facilities, by also reporting on their use of non-animal research could attract additional interest in their facilities.

<sup>11</sup> National Institute of Environmental Health Sciences. (2024). Alternatives to Animal Testing. Retrieved from: <u>https://www.niehs.nih.gov/health/topics/science/sya-iccvam</u>

<sup>&</sup>lt;sup>9</sup> University of Washington. (2024). Metrics and Reports: Animal Census. Retrieved from: <u>https://www.washington.edu/aco3rs/metrics-and-reports/</u>

<sup>&</sup>lt;sup>10</sup> United States Animal Research Openness Initiative (n.d.) University of Washington. <u>https://www.usaro.org/post/exemplar-univwashington</u>

We thank the Task Force for the work it is doing to ensure transparency at publicly funded Virginia research institutions and would be happy to answer any questions or provide additional information.

Sincerely,

rowe

Virginia State Director, State Affairs <u>ccrowe@humanesociety.org</u> P 571-648-7951 <u>humanesociety.org</u>

**RECEIVED** By Stacy E. Metz at 1:43 pm, Sep 09, 2024 Delcianna Winders Associate Professor of Law Animal Law and Policy Institute Director Vermont Law and Graduate School 802-831-1107 · dwinders@vermontlaw.edu

September 16, 2024

Task Force on Transparency in Publicly Funded Animal Testing Facilities Virginia Department of Agriculture and Consumer Services

Via email: stacy.metz@vdacs.virginia.gov; vdacs.commissioner@vdacs.virginia.gov

#### Re: Written Comments for the Task Force on Transparency in Publicly Funded Animal Testing Facilities

Dear Members of the Task Force on Transparency in Publicly Funded Animal Testing Facilities,

I am writing to provide written comments and recommendations as the task force works to identify deficiencies in publicly funded animal testing facilities and to recommend methods to provide public transparency and accountability, in accordance with Chapters 675 and 693 of the 2024 Acts of Assembly. As background I begin with information about the federal Animal Welfare Act (AWA) to underscore the critical importance of the taskforce's work. I then turn to specific recommendations of data to collect and make publicly available.

#### I. <u>AWA Implementation and Enforcement Failures and Limitations</u>

As a preliminary matter, I want to underscore the critical importance of the taskforce's work and ultimate recommendations, given the extensive and longstanding failures in implementation of the AWA and—something on which I have published extensive scholarship—and the limitations of that law.

#### A. Implementation and Enforcement Failures

When Congress was considering the law that would become the AWA in 1966, the U.S. Department of Agriculture (USDA) implored the legislature that it not be the agency tasked with implementing this law, noting its lack of expertise in the area of animal experimentation. Congress nevertheless delegated AWA responsibility to the USDA, an agency whose focus is promoting American agriculture. When Congress amended the AWA several years later, the USDA again urged that responsibility for animal experimentation be assigned to a different agency, to no

avail. Thus, from the beginning, the USDA was disinterested in enforcing the AWA, particularly as to animal research facilities—a disinterest that has persisted across decades and across presidential administrations, as made clear by a series of damning audit reports from the USDA Office of Inspector General finding that, even in the rare instances where the USDA seeks enforcement, the agency reduces penalties so greatly that they are treated as a cost of doing business.

Because of these ongoing implementation and enforcement failures, transparency has been critical—but far from guaranteed. Over the years, certain administrations have removed thousands of AWA records from public access—most recently in February 2017—making it impossible for the public to monitor AWA compliance.

#### **B. AWA Limitations**

In addition to these enforcement failures, the AWA's scope is limited—particularly when it comes to research facilities. First, the act applies to "warm-blooded" animals only, despite the lack of any scientific basis for such a distinction. It is well documented that sentience is not tied to "warm bloodedness." In addition, the AWA excludes from the very definition of "animal" rats, mice, and birds bred for experimentation—by far the largest category of warm-blooded animals used for experimentation.

Moreover, the AWA treats research facilities differently—with a much lighter touch—than it does other types of entities regulated under the act. Most AWAregulated facilities—including those that breed animals for research—must obtain and maintain a license, which is conditioned on compliance with minimum animal welfare standards. Disregard of those standards can result in suspension, revocation, or non-renewal of the license. Research facilities, on the other hand, need only "register"—that is, alert the USDA of their intent to experiment on animals. No matter how egregiously a research facility violates the AWA, and no matter how many animals may endure ongoing suffering as a result of these violations, the USDA will not halt their operations. Indeed, the agency is unable to even confiscate such animals unless the facility deems them no longer necessary for research. In addition, numerous AWA enforcement mechanisms—including criminal penalties and injunctive relief—do not apply to research facilities.

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For these reasons, state oversight of animal experimentation—which the AWA makes absolutely clear is permissible and can go further than the AWA—is imperative.

#### II. <u>Recommendations</u>

For the reasons discussed above, I suggest that the taskforce recommend that the following information be collected from research facilities on at least an annual basis, and be timely disclosed to the public online in an easily navigable format:

#### A. Numerical Data

- 1. The total number of animals held by the facility at both the beginning and end of the reporting period , broken down by species and use;
- 2. The number of animals acquired during the reporting period and where they were acquired from, broken down by species;
- 3. The number of animals born at the facility during the reporting period, broken down by species;
- 4. The number of animals disposed of, categorized by both species and disposition method (e.g., death other than euthanasia, euthanasia, adoption, sale, etc.), sorted by species;
- 5. The number of animals who experienced unexpected events that endangered their well-being, sorted by species; and
- 6. The number of unexpected events that endangered the wellbeing of humans at the research facility.

#### B. Financial Data

The amount of money the research facility spent during the reporting period on animals used for research, including to acquire and care for animals as well as to conduct experiments on them.

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Thank you very much for considering these comments, and for your work to ensure transparency and accountability regarding publicly funded animal experimentation. Please do not hesitate to reach out if I can be of any assistance.

Sincerely,

Onlineer

Delcianna J. Winders

**RECEIVED** By Stacy E. Metz at 11:30 am, Sep 16, 2024