THE HUMANE SOCIETY OF THE UNITED STATES

HUMANE SOCIETY LEGISLATIVE FUND™

January 8, 2018

Patricia A. Brown, VMD, MS
Director
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: Animal Welfare Regulations Must Not Be Compromised to Comply with the Goals of the 21st Century Cures Act

Dear Dr. Brown:

In response to a recent workshop report, organized by the Federation of American Societies for Experimental Biology (FASEB), Association of American Medical Colleges (AAMC), Council on Government Relations (COGR) and National Association for Biomedical Research (NABR), I am reaching out to you, on behalf of The Humane Society of the United States (HSUS), and the Humane Society Legislative Fund (HSLF) to express our concern regarding many of the recommendations issued and request a meeting to discuss these concerns.

The 21st Century Cures Act (Pub. Law 114-255) calls for examining ways to reduce regulatory burdens on biomedical research "while maintaining the integrity and credibility of research findings and protection of research animals" (Section 2034(d)). FASEB, AAMC, COGR, and NABR are attempting to use this opportunity for modernization to severely weaken the regulations and policies currently in place to protect animals used for biomedical research, testing and education.[1] However, any proposals to reduce oversight of, and decrease minimal standards for, institutions engaged in animal research pose a great risk to animal welfare and undermine the integrity and credibility of research findings derived from such animal testing. Therefore, HSUS and HSLF offer the attached comments on the research community's recommendations and our ideas for simplifying regulations related to animal welfare such as prohibiting random source Class B dealers, requiring the use of non-animal alternative test methods when available, and ensuring that any

[1] http://www.faseb.org/Portals/2/PDFs/opa/2017/FASEB-Animal-Regulatory-Report-October2017.pdf

harmonization of animal welfare regulations follows the highest standards of care and oversight, including amending the definition of animal in the Animal Welfare Act.

The 21st Century Cures Act also calls for creation of a Research Policy Board (Pub. Law 114-255, Section 2034(f)), which would fall under the Federal Advisory Committee Act, to make recommendations for improving regulations and policy related to research. The Act directs the Office of Management and Budget (OMB) to establish the Board and include non-federal members from "nonprofit organizations with relevant expertise." Section 2034(f)(2)(B). We strongly urge OMB to include members of the animal protection and ethics communities as members of the Board, Further, we recommend that the Board solicit public input on its recommendations in order to improve transparency, public trust and accountability, consistent with the Federal Advisory Committee Act (5 U.S.C. App. 2 § 10). Included with this letter is our recommendations for individuals to serve on the Research Policy Board or any expert subcommittee created to assist the Research Policy Board.

The HSUS and HSLF looks forward to meeting with you to discuss any efforts to streamline animal welfare regulations and will be in touch with your office to set up a meeting at your earliest convenience.

Sincerely,

Kathleen Conlee
Vice President, Animal Research Issues

Tracie Letterman
Vice President, Federal Affairs

Recommendations for the Research Policy Board mandated by the 21st Century Cures Act

Andrew N. Rowan, PhD is the Chief Scientific Officer for The Humane Society of the United States (HSUS), the President of The HSUS Wildlife Land Trust's board of directors and Executive Director of The Humane Society Veterinary Medical Association. He has served in numerous advisory and consultative roles, including as a member of the advisory committee on alternative methods in toxicology for the National Institute of Environmental Health Sciences and of the National Research Council committee on the use of animals and alternatives in the generation of monoclonal antibodies. Read more: http://www.humanesociety.org/about/leadership/executive_staff/andrew_rowan.html

Jeffrey Khan, PhD, MPH, is the Director of the Johns Hopkins Berman Institute of Bioethics and a Professor in the Dept. of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health. Read more: http://www.bioethicsinstitute.org/people/jeffrey-kahn-4

John P. Gluck, PhD is a Professor Emeritus of psychology at the University of New Mexico and a research professor at the Kennedy Institute of Ethics at Georgetown University. Read more: https://www.psychologytoday.com/blog/animal-emotions/201610/voracious-science-journey-animal-user-advocate

David DeGrazia, PhD is a Professor of Philosophy at George Washington University and a Senior Research Fellow in the Department of Bioethics at NIH. Read more: https://www.bioethics.nih.gov/people/degrazia-bio.shtml

Larry Carbone, DVM, PhD, is the director of the Animal Care and Use Program and senior veterinarian at the Laboratory Animal Resource Center at University of California, San Francisco. Read more: http://wcsj2017.org/speaker/larry-carbone/

Margaret Landi, DVM, DACLAM is Chief of Animal Welfare and Veterinary Medicine and the Vice President of Global Laboratory Animal Sciences at Glaxo Smith Kline. Read more: http://www.chimphaven.org/about-us/board-of-directors/

Alicia Karas, DVM is a veterinary anesthesiologist and pain specialist at the Cummings School of Veterinary Medicine at Tufts University. Read more: http://tuftsvets.org/staff/dr-karas.php

Frans B. M. de Waal, PhD is a primatologist and Professor in the Psychology Department of Emory University and Director of the Living Links Center at the Yerkes National Primate Research Center. Read more: http://www.emory.edu/LIVING_LINKS/people/dewaal.shtml

Joseph Garner, DPhil, is an Associate Professor at the Department of Comparative Medicine at Stanford University. Read more: http://med.stanford.edu/compmed/faculty-postdocs/garner.html

Tory Hampshire, DVM is the President of Capital Preclinical Scientific Consultants, LLC. Dr. Hampshire served 27 years as a United States Public Service Veterinary Officer. Read more: http://www.cardiomedllc.com/consultant/victoria-hampshire/

Executive Summary

In December 2016, Congress passed the 21st Century Cures Act, legislation to speed the drug and device approval process and included a requirement to review all regulations and policies concerning laboratory animal care. In October 2017, several organizations within the research community released a report of 20 recommendations to limit statutory and regulatory oversight of laboratory animals, undermining agency responsibility to ensure minimum standards of animal welfare at our nation's laboratories. The Humane Society of the United States (HSUS) and Humane Society Legislative Fund (HSLF) dispute the research community's assessment that accounting for animal welfare is a burden and has responded to their claims below.

Instead, HSUS and HSLF put forth four proposals for harmonizing and simplifying oversight requirements of United States Department of Agriculture (USDA) and National Institutes of Health (NIH).

1. Amend the definition of animal in 7 U.S.C. § 2132 of the Animal Welfare Act (AWA) to include all vertebrates. This change would not only align USDA and NIH regulations but would also harmonize U.S. policy with other countries and industry standards.

2. Amend 7 U.S.C. § 2137 and §2138 of the AWA to prohibit the use of random source[1] dogs and cats in research. Due to a history of violations related to both standards of care for the animals and obtaining animals illegally, USDA Animal and Plant Health Inspection Service (APHIS) has been inspecting random source Class B dog and cat dealers quarterly as opposed to other dealers which are supposed to be inspected annually. The agency must also perform tracebacks to determine whether animals were obtained from legal sources.[2] Despite the additional oversight, continued concerns about random sources dealers led to an NIH decision to end the use of cats and dogs from random sources in federally funded research in 2012[3] and 2014[4] respectively. There is no reason to continue to waste resources regulating random source Class B dealers.

3. Amend 7 U.S.C. § 2143 to require the use of alternative test methods and strategies whenever available. 21st century science is moving away from animal tests. Many effective alternatives to animal testing exist, including 3-D printing, construction of artificial human tissue, and the generation of sophisticated computer programs that can make accurate predictions about chemical safety. Research facilities should be required to use any available methods that replace, reduce, or refine animal use.

4. Harmonize all NIH and USDA requirements on animal welfare to the highest possible standard. Harmonization of regulations, guidance and policies will help alleviate confusion and make it easier for research facilities to adhere to animal welfare requirements. It is important that

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[1] 9 CFR § 1.1, *Random source* means dogs and cats obtained from animal pounds or shelters, auction sales, or from any person who did not breed and raise them on his or her premises.

[2] US Government Accountability Office. (September 2010). *USDA's Oversight of Dealers of Random Source Dogs and Cats Would Benefit from Additional Management Information and Analysis.* Retrieved from: http://www.gao.gov/assets/320/310004.pdf

[3] National Institutes of Health. (February 2012). Notice Regarding NIH plan to Transition from use of USDA Class B Cats to Other Legal Sources. NOT-OD-12-049. Retrieved from: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-049.html

[4] National Institutes of Health. (December 2014). Notice Regarding NIH Plan to Transition from Use of USDA Class B Dogs to Other Legal Sources. NOT-OD-14-034. Retrieved from: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-034.html

any efforts to standardize agency requirements ensure following the best practices as it pertains to animal welfare.

Background

The 21st Century Cures Act, legislation that seeks to facilitate Food and Drug Administration (FDA) approval of drugs and devices, was signed into law in December 2016. One provision of the Cures Act tasked NIH, USDA, and FDA to review all regulations and policies on the care of laboratory animals in an effort to reduce administrative burden on researchers. The law states:

"Not later than 2 years after the date of enactment of this Act, the Director of National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, shall complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. In carrying out this effort, the Director of the National Institutes of Health shall seek the input of experts, as appropriate. The Director of the National Institutes of Health shall--

(1) identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative, including with respect to inspection and review requirements by Federal agencies and accrediting associations;

(2) take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and

(3) take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals."[5]

The law also calls for the creation of a Research Policy Board and allows for the creation of expert subcommittees. The law states:

"(f) Research Policy Board.--

(1) Establishment.--Not later than 1 year after the date of enactment of this Act, the Director of the Office of Management and Budget shall establish an advisory committee, to be known as the ``Research Policy Board'' (referred to in this subsection as the ``Board''), to provide Federal Government officials with information on the effects of regulations related to Federal research requirements.

(2) Membership.--

(A) In general.--The Board shall include not more than 10 Federal members, including each of the following Federal members or their designees:

(i) The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget.

(ii) The Director of the Office of Science and Technology Policy.

(iii) The Secretary of Health and Human Services.

(iv) The Director of the National Science Foundation.

(v) The secretaries and directors of other departments and agencies that support or regulate scientific research, as determined by the Director of the Office of Management and Budget.

(B) Non-federal members.--The Board shall be comprised of not less than 9 and not more than 12 representatives of academic research institutions, other private, nonprofit research institutions, or other nonprofit organizations with relevant expertise. Such members shall be

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[5] 21st Century Cures Act. Public Law No. 114-255 (2016).

appointed by a formal process, to be established by the Director of the Office of Management and Budget, in consultation with the Federal membership, and that incorporates--

(i) nomination by members of the nonprofit scientific research community, including academic research institutions; and

(ii) procedures to fill membership positions vacated before the end of a member's term.

(3) Purpose and responsibilities.--The Board shall make recommendations regarding the modification and harmonization of regulations and policies having similar purposes across research funding agencies to ensure that the administrative burden of such research policy and regulation is minimized to the greatest extent possible and consistent with maintaining responsible oversight of federally funded research. Activities of the Board may include--

(A) providing thorough and informed analysis of regulations and policies;

(B) identifying negative or adverse consequences of existing policies and making actionable recommendations regarding possible improvement of such policies;

(C) making recommendations with respect to efforts within the Federal Government to improve coordination of regulation and policy related to research;

(D) creating a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices; and

(E) conducting ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes.

(4) Expert subcommittees.--The Board may form temporary expert subcommittees, as appropriate, to develop timely analysis on pressing issues and assist the Board in anticipating future regulatory challenges, including challenges emerging from new scientific advances."[6]

In response, the Federation of American Societies for Experimental Biology (FASEB), the Association of American Medical Colleges (AAMC), the Council on Governmental Relations (COGR) and the National Association for Biomedical Research (NABR) drafted a report detailing the groups' 20 major recommendations. A number of these recommendations would have deleterious effects on animal welfare. These include weakening regulations/policies that govern Institutional Animal Care and Use Committees (IACUCs), removing annual APHIS inspections, and removing USDA policy suggesting the completion of literature searches for alternative test methods. Below is a list of the recommendations along with any HSUS response.

Research community recommendations and HSUS/HSLF response

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

[6] 21st Century Cures Act. Public Law No. 114-255 (2016).

a) *The committee could be designated an "expert subcommittee" of the RPB mandated by Cures. Agencies might also consider a permanent animal research advisory group modeled after the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Human Research Protections.*

HSUS/HSLF Response: Members of animal protection organizations and the ethics community should be included as members of any advisory group or expert subcommittee. In establishing the Research Policy Board, at least one representative from the animal welfare community should sit on the board. Unlike research facilities and researchers that have a biased interest in allowing research protocols to continue with minimal oversight, the animal welfare community is solely focused on ensuring any changes to regulations or guidance maintain protection for laboratory animals. It would also be advisable to hear from alternative test method developers as the best way to protect animals used in research is to replace their use with non-animal methods. Further, public input should be sought on any committee membership to help improve transparency as well as public trust and accountability. See the enclosed list of recommendations for the Research Policy Board or any associated advisory groups or expert subcommittees.

2. *Animal research community request: The Executive Office of the President (EOP) and OMB should explore whether regulatory efficiencies could be gained, and burden reduced, by consolidating animal research oversight under a single Federal office or entity with one primary set of regulations and guidance documents. A committee of experts engaged in animal research from entities that receive federal research awards should be invited to assist with this effort. The group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, IACUC members, veterinarians, and investigators engaged in animal research.*

    a) *Harmonize existing federal requirements for those species currently covered by USDA and those covered by PHS Policy to conform to the least burdensome standard while maintaining animal welfare.*
    b) *Pilot new models and structures through the FDP as appropriate.*

HSUS/HSLF Response: While there may be some benefit to consolidating all animal welfare oversight activities under one federal agency, it is vital that any harmonization of regulations requires facilities to uphold the highest standards of care and protection for animals, not the lowest. There is no doubt that animal welfare will be negatively impacted by pushing all facilities to the lowest common denominator. The HSUS and HSLF strongly support, as part of any effort toward consolidation, that all research facilities provide requirements for minimum standards of care for all vertebrate animals and make US law consistent not only within the country (agency to agency) but also with industry standards and international laws and regulations. It is also critical that unannounced inspections by a government agency be maintained, as this is an extremely important oversight tool.

In the AWA, "the term "animal" means any live or dead dog, cat, monkey (nonhuman primate

mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet; but such term excludes (1) birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes."[7]

In contrast, the Public Health Service Policy on Humane Care and Use of Laboratory Animals defines animal as "Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes."[8]

AAALAC International, a private nonprofit organization that offers voluntary accreditation and assessment programs to animal research facilities, defines laboratory animals as "any live vertebrate animal (and any other animal designated by applicable legislation) used or intended for use in research, testing, or teaching."[9] AAALAC is currently seeking public comment on expanding its definition of animal to include cephalopods.[10] The Council for International Organization of Medical Sciences and International Council for Laboratory Animal Science created guiding principles for the responsible use of vertebrate animals in scientific and educational activities.[11]

Amending the definition of animal to include all vertebrates under the AWA would also aid the US as it works toward harmonization with other countries. For instance, the US is part of the International Cooperation on Cosmetics Regulations, which seeks to align cosmetics laws among its member countries, Canada, European Union, and Japan. All of these countries provide protection to a greater number of species than the AWA. In the EU, animal is defined as live non-human vertebrate animals and live cephalopods.[12] Similarly, the Canadian Council on Animal Care provides certification for research involving vertebrates or

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[7] 7 U.S.C §2132(g)

[8] Office of Laboratory Animal Welfare. (2015). *Public Health Service Policy on Humane Care and Use of Laboratory Animals*. Retrieved from: https://grants.nih.gov/grants/olaw/references/phspol.htm#PublicHealthServicePolicyonHumaneCareandUseofLaboratory

[9]AAALAC International. (n.d.) Definition of "Laboratory Animals." *Position statements*. Retrieved from: https://www.aaalac.org/accreditation/positionstatements.cfm#labanimals

[10] AAALAC International. (2017). *Public Comment Period*. Retrieved from: https://aaalac.wufoo.com/forms/aaalac-international-public-comment-period/

[11]Council for International Organization of Medical Sciences and the International Council for Laboratory Animal Science. (2012). *International Guiding Principles for Biomedical Research Involving Animals.* Retrieved from: https://grants.nih.gov/grants/olaw/Guiding_Principles_2012.pdf

[12] Directive 2010/63/EU. (2010). Retrieved from: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063

cephalopods.[13] The Scientific Council of Japan's *Guidelines for Proper Conduct of Animal Experiments*, defines a laboratory animal as "an animal of mammalian, avian or reptilian species used in animal experiments."[14]

The US is not only an outlier among other countries, but also contradicts itself in determining which species should receive protection in laboratory settings. Harmonizing the definition of animal will not only ensure that those animals are covered under minimum standards of care, but will also enable stakeholders to accurately determine the number of animals used in research and testing and ensure that research facilities are utilizing alternatives to either minimize pain and distress for these animals or limit or end their use. By accounting for all animals used in research, appropriate stakeholders can have access to important trend data that can guide specific needs and narrow priorities for the development and implementation of alternatives. As additional non-animal test methods are developed, this information will become more relevant to ensuring facilities are utilizing the best scientific methods while also limiting the number of animals used. And since animal use is generally more expensive and takes more time to complete than newer alternative methods, it will likely bring about savings that will enable researchers to invest more time and money in developing groundbreaking and effective research.

3. *Animal research community request: The EOP and OMB should consider requiring at least a 60-day comment period on the merits and impact of any proposed policies, guidance documents, FAQs, or interpretive rules before they are issued. Final policies and guidance should include material changes that reflect germane comments received from the regulated community.*

    a) *Near-final documents should be reviewed by an external advisory committee of experts engaged in animal research from the regulated community before they are disseminated for public comment or final agency review. This would help ensure that policies and guidance meet their intended objectives while maintaining or improving animal welfare without creating unnecessary administrative work and cost.*
    b) *All guidance documents should state clearly that they do not carry legal or regulatory force.*
    c) *Guidance documents should not be accompanied by a requirement to obtain agency approval for alternative methods and/or processes.*

HSUS/HSLF Response: The rulemaking process is notoriously slow and leaves many pressing issues on hold for years. For example, the AWA was amended in 2002 to exclude, birds, rats and mice used in research from the law's protection. This created a need to develop

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[13] Canadian Institutes of Health (n.d.) *Agreement on the Administration of Agency Grants and Awards by Research Institutions.* Retrieved from: http://science.gc.ca/eic/site/063.nsf/eng/h_56B87BE5.html?OpenDocument

[14] Science Council of Japan. (June 2016). *Guidelines for Proper Conduct of Animal Experiments.* Retrieved from: http://www.scj.go.jp/ja/info/kohyo/pdf/kohyo-20-k16-2e.pdf

standards for birds, rats and mice not used in research, such as in the pet trade.[15] Fifteen years later and regulations to ensure the proper care and treatment of these animals still have not been finalized. The issuance of guidance documents and policy statements is an important tool to allow agencies to clarify expectations and prevent animal suffering without going through the expense and time of creating new rules. The report's suggestion that the regulated industry should be given prior approval of any proposed guidance runs counter to the oversight role that the agencies are supposed to occupy. Just as with any comment period, industry would have an opportunity to weigh in as would other stakeholders. It would be deleterious to protecting animals to allow the research community to be the only voice shared with regulators early in the process.

4. *Animal research community request: As part of the review mandated by Cures, all current PHS and USDA regulations, policies, guidance documents, FAQs, and interpretive rules, as well as the process for generating them, should be reviewed by an external advisory group of experts engaged in animal research from entities that receive federal research awards. This group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, IACUC members, veterinarians, and investigators engaged in animal research. The purpose of this review should be to ensure that these documents emphasize matters of core importance to animal welfare identified in HREA and AWA statutory language and are consistent with current scientific and technological knowledge and approaches.*

HSUS/HSLF Response: Any external advisory group of experts tasked with reviewing current PHS and USDA regulations regarding animal use must include members of both the animal protection and ethics communities. This is vital not only to ensuring that animal welfare remains a top concern, but also for encouraging the implementation of newer, non-animal approaches. Further, public input should be sought on any advisory group to help improve transparency as well as public trust and accountability.

5. *Animal research community request: The Guide is not a regulatory document. Given that, OLAW should use the Guide as it was intended, namely, "to assist institutions in caring for and using laboratory animals in ways judged to be professionally and humanely appropriate." The Guide allows facilities to produce welfare outcomes for animals in diverse and innovative ways by permitting alternative strategies to "should" statements upon approval by the IACUC. Thus, OLAW should revise FAQ C7 and PHS Policy IV.B.3.c to ensure that IACUC-approved alternative strategies from "should" statements in the Guide are not deemed departures or deviations and are not required to be included in the semiannual report to the Institutional Official. This would be consistent with OMB's Agency Good Guidance Practices Bulletin and would significantly reduce administrative burden without compromising animal welfare.*

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[15] *Animal Welfare; Regulations and Standards for Birds, Rats, and Mice; Proposed Rule*. Federal Register 69 (4 June 2004): 31537-31541. Retrieved from: https://www.federalregister.gov/documents/2004/06/04/04-12692/animal-welfare-regulations-and-standards-for-birds-rats-and-mice

HSUS/HSLF Response: It should not be a regulatory burden to inform the Institutional Official (IO) about a facility's decision to depart from any "should" statements in the *Guide*. Since the Institutional Animal Care and Use Committee (IACUC) would have to go through the process of reviewing any departures, they should already have all the information needed to fill out the semi-annual report[16], which would need to take place regardless. The *Guide* was created to ensure that animals used in research are given appropriate and humane care. Even if there is some scientific justification for departing from these recommendations, it is important that these differences are brought to the IO's attention. Additionally, facilities with PHS assurance receive federal funding; these institutions should be held to a higher standard and accountable to the public.

6. *Animal research community request: OLAW should cease using the word "deviation" in their guidance documents when referring to IACUC-approved alternative strategies to "should" statements in the Guide. As with USDA regulations, the meaning of words used in OLAW guidance documents not defined in legislation or the PHS Policy should be that of a standard dictionary.*

HSUS/HSLF Response: As noted above, any departures from "should" statements in the *Guide* must be identified. The terminology used is less important than the intent to ensure best animal welfare practices are being used.

7. *Animal research community request: The Guide should be a "living" document that continuously incorporates changes in the scientific literature. Consideration should be given to an online version of the Guide with periodic updates provided in partnership with an independent group such as the American Association for Laboratory Animal Science.*

HSUS/HSLF Response: We agree that the *Guide* should be updated regularly to incorporate the latest knowledge about animal welfare and humane care of animals in laboratories. However, any updates should be opened up to a public comment period. In addition, we disagree with the premise that American Association for Laboratory Animal Science (AALAS) is entirely independent since it identifies itself as an "association of professionals that advances responsible laboratory animal care and use to benefit people and animals."[17] While AALAS could certainly provide the Office of Laboratory Animal Welfare (OLAW) with information regarding advances in laboratory animal welfare, updates to the *Guide* should encompass the best available ideas from many sources internationally, including the animal protection community.

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[16] National Institutes of Health. (n.d.) *Sample Semiannual Report to the Institutional Official.* Retrieved from: https://grants.nih.gov/grants/olaw/sampledoc/docdlass60.pdf

[17] American Association of Laboratory Animal Science. (n.d.) *Mission statement.* Retrieved from: https://www.aalas.org/about-aalas

8. *Animal research community request: Revise §2.31(d)(5) of the AWR as follows: "The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, including a review as required in §2.31(d)(1-4) at least once every three years" (emphasis added). This would make review frequency consistent with the PHS Policy.*

HSUS/HSLF Response: The suggestion that IACUCs should have less oversight of research protocols and facilities is in direct contrast with a 2014 audit from the USDA Office of Inspector General (OIG). This review of animal care at research facilities found that IACUCs "did not adequately approve, monitor, or report on experimental procedures on animals."[18] OIG reviewed AWA violations from FYs 2009 – 2011 and found that 531 of 1,117 research facilities were cited for 1,379 IACUC oversight violations. It would be unwise to remove any oversight requirements and would be more useful to see these IACUCs expand their membership to include animal protection representatives and ethicists. In an effort to harmonize PHS Policy with the AWR, all facilities should be subject to annual IACUC protocol reviews as well as increase IACUC membership from 3 persons to 5.

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

HSUS/HSLF Response: The IACUC, though flawed, is an important safeguard against animal welfare problems under the current regulatory system. We would support the idea of not requiring protocol review of truly noninvasive research only if the USDA pain/distress categorization system is changed to reflect levels of pain/distress associated with the animal use instead of a system focused on whether or not anesthetics/analgesics were used. Facilities would have to be vigilant not to mischaracterize some animal studies as "noninvasive."

10. *Animal research community request: Revise USDA Animal Care Policy #14 to reflect the language in AWA §2143 and AWR §2.31(d)(1)(x)(A-C), allowing approval of multiple survival operative procedures at the discretion of the IACUC and as justified for scientific and animal welfare reasons. This will enhance the community's efforts to reduce the number of animals involved in research.*

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[18] USDA Office of the Inspector General. (December 2014). *APHIS Oversight of Research Facilities.* Retrieved from: https://www.usda.gov/oig/webdocs/33601-0001-41.pdf

HSUS/HSLF Response: USDA Animal Care Policy #14 already allows for exemptions to policy against multiple survival operations. It states: "Under special circumstances, the AWA allows for exemptions to the limitation that only one major operative procedure be performed on an animal."[19] Furthermore, while using the same animals to complete multiple studies may limit the number of animals that are used in research, it will negatively affect the wellbeing of those animals. That is why Policy #14 puts restrictions on the ability to get an exemption. Efforts to reduce the number of animals used in research and testing should instead focus on new test methods and strategies that eliminate or reduce the need for live animals.

11. *Animal research community recommendation: Amend the third bullet in section 8.1.2.5 of NIH Grants Policy to read "Change from the approved use of live vertebrate animals that would result in an increased risk."*

HSUS/HSLF Response: NIH should be kept informed of any changes in approved use of animals. We hope that more and more NIH grants will include a strong emphasis on eliminating or limiting animal use or at least ensuring that the best possible protections for animals are being followed. Eliminating the requirement that "the recipient must obtain prior approval from the NIH"[20] if s/he wishes to change plans for the use of animals will discourage following approved animal care protocols. Further, this wording appears to leave it up to the institution to determine the definition of an "increased risk," which could result in the use of animals that may not have been necessary or approved by NIH.

12. *Animal research community request: Amend the language in USDA Animal Care Policy #12 with respect to literature searches to be consistent with AWR §2.31(d)(1)(ii), which charges the IACUC to determine "that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...".*

HSUS/HSLF Response: This seems to be an unnecessary change to USDA Animal Care Policy #12. The current text of the policy recommends literature searches via database as "the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures."[21] The policy goes on to state that there may be situations in which other types of searches for alternatives may be acceptable. In this situation, the policy is simply providing information to help researchers comply with the requirements of the AWA and corresponding regulations. HSUS and HSLF believe 7 U.S.C.

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[19] APHIS. (October 2017). *Animal Care Policy Manual.* Retrieved from: https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Policy%20Manual.pdf

[20] National Institutes of Health. (October 2017). *NIH Grants Policy Statement.* Retrieved from: https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.1_changes_in_project_and_budget.htm?tocpath=8%20Administrative%20Requirements%7C8.1%20Changes%20in%20Project%20and%20Budget%7C8.1.2%20Prior%20Approval%20Requirements%7C_____5#8.1.2.5_Change_in_Scope

[21] APHIS. (October 2017). *Animal Care Policy Manual.* Retrieved from: https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Policy%20Manual.pdf

§ 2143 of the AWA should be amended to require the use of available alternative test methods that replace, reduce, or refine the use of animals when they are available.

13. *Animal research community request: Eliminate the requirement for verification of protocol and grant congruency in NIH Grants Policy 4.1.1.2 to allow for reasonable advances, discoveries, and other developments in the overall research objectives.*

HSUS/HSLF Response: It is an important assurance that research grant approval is based upon review of an IACUC. It is not a large burden to provide information about any changes based on new scientific developments. And the research community's report even states that "differences appear to rarely occur."[22] Removing the requirement that any changes be explained from the grant application to IACUC approval seems to remove an important aspect of assuring that grant applications provide for animal care oversight. In addition, it is not unreasonable to expect that NIH should be kept apprised of any changes in the research it is funding.

14. *Animal research community request: Congress should amend §2143(b)(3) of the AWA and §495(b)(3) of the HREA to require only an annual inspection by the IACUC. This will eliminate significant administrative work for investigators and IACUC members and allow staff to better focus their efforts on the daily oversight and welfare of animals. Such a change is not intended to negate or minimize the expectation for IACUCs to assess and assure compliance with federal requirements regarding the welfare of animals used in research, teaching, and testing.*

HSUS/HSLF Response: See response in #8

15. *Animal research community request: Revise § 2.31(c)(3) of the AWR to state: "The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities that includes all members wishing to participate in the process. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report."*

HSUS/HSLF Response: While it appears that the purpose of this recommended change is only to eliminate the requirement that at least two IACUC members participate in the inspection of a research facility, the regulation cited actually contains many provisions important for ensuring animal welfare including reporting deficiencies and reviewing modification in protocols. Even if this change were made in relation to number of IACUC members present during inspections, the rest of § 2.31(c)(3) must remain unchanged.

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[22]Federation of American Societies for Experimental Biology, et al. (2017). *Reforming Animal Regulations: Workshop Recommendations to Reduce Regulatory Burden.* Retrieved from: http://www.faseb.org/Resources-for-the-Public/News-Room/Article-Detail-View/tabid/1014/ArticleId/1579/New-Report-Promoting-Regulatory-Efficiency-in-Animal-Research.aspx

16. *Animal research community request: Congress should amend §2146 of the AWA to remove the requirement for annual USDA inspection of research facilities and allow for an inspection frequency based on compliance history, as part of the agency's Risk Based Inspection System process.*

HSUS/HSLF Response: The HSUS has conducted a number of undercover investigations at laboratories, unveiling AWA violations; these same facilities are often cited for AWA violations in subsequent inspections by USDA. Further, a 2014 audit report by the USDA OIG found that 45 percent of research facilities that were reviewed (13 of 29) misreported animal use. The report stated: "The facilities either reported animals in the wrong pain category or could not provide us with documentation to reconcile their annual report. Despite these errors, VMOs did not cite any of our sampled facilities for misreporting animals. Further, they cited less than 6 percent of facilities nationwide for the same violations over our 3-year scope period."[23]

The report went on to explain that Veterinary Medical Officers (VMO) do not necessarily cite facilities even when they admit to inaccuracies in their reports. It references an example of a facility in Texas whose staff admitted to the VMO that its annual report was not completed correctly, but "the VMO did not cite the facility for submitting an inaccurate annual report and did not require the facility to submit a corrected one."

Another problem pointed out in the OIG audit was that VMOs were not always completing the required reviews of research protocols. OIG emphasized the importance of completing these reviews writing that not doing so "reduced assurance that the research is conducted in accordance with AWA requirements, which could affect the health, safety, and humane treatment of the animals used in research."[24]

If AWA violations are not routinely cited on inspection documents by USDA, there is no adequate way to create a risk-based approach to annual inspections. In addition, it is conceivable that facilities that are not prone to AWA violations may become lax in their adherence to animal welfare standards if they are assured that no USDA inspector will be visiting.

17. *Animal research community request: USDA should consider including AAALAC International accreditation as a factor in their risk assessment.*

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[23] USDA Office of the Inspector General. (December 2014). *APHIS Oversight of Research Facilities.* Retrieved from: https://www.usda.gov/oig/webdocs/33601-0001-41.pdf

[24] USDA Office of the Inspector General. (December 2014). *APHIS Oversight of Research Facilities.* Retrieved from: https://www.usda.gov/oig/webdocs/33601-0001-41.pdf

HSUS/HSLF Response: As stated in #16, we do not agree with using a risk-based approach to determine whether facilities receive annual USDA inspection. Each facility should be inspected by the USDA at least annually, with additional inspections conducted at those facilities with repeat problems, and this should not be changed. It is important to emphasize that AAALAC accreditation does not mean that an institution has not been cited for AWA violations by USDA. AAALAC is an independent body for which there is no public accountability and information about AAALAC inspections at individual institutions is not available to the public, unlike USDA inspection reports. In addition, AAALAC only inspects research facilities every three years making their accreditation a wholly unreliable and insufficient gauge of current animal welfare concerns.

18. *Animal research community request: Revise the NIH guidance in NOT-OD-05-034 regarding prompt reporting to include only those incidents that jeopardized the health or well-being of animals.*

HSUS/HSLF Response: Currently, prompt reporting to OLAW is required for a variety of situations including failure to follow IACUC protocol, receive IACUC approval for animal use, or maintain proper records of animals.[25] Deviations of any kind should be a concern to NIH. IACUC protocols are reviewed and approved to address issues of animal welfare. It may not be obvious during an inspection that animals are negatively affected by deviations from the protocol or a deviation may not immediately result in the jeopardized health or well-being of animals but may do so at a later time. It is important that these differences are quickly reported to OLAW in order to ensure the problem is addressed before it becomes a larger issue resulting in animal welfare problems.

19. *Animal research community request: OLAW specifies that the grant number be included in these reports[26], but this is not required in PHS Policy (IV.F.3). Grant numbers should not be required on noncompliance reports in order to protect investigators and study teams from harassment by parties seeking to disrupt animal research.*

HSUS/HSLF Response: Including grant numbers helps to identify if a particular research project has repeated problems with maintaining animal welfare standards. Further, the studies and institutions are being supported by the public through taxpayer dollars and should therefore have increased transparency, especially if problems are being identified. There is no reason to remove this information.

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[25] OLAW. (2005). *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals* . NOT-OD-05-034. Retrieved from: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html

[26] https://grants.nih.gov/grants/olaw/reporting_noncompliance.htm

20. *Animal research community request: Streamline the assurance for animal research. In addition, for Category 1 institutions, allow proof of accreditation in lieu of the detailed program description.*

HSUS/HSLF Response: AAALAC accreditation should not be allowed to replace a description of the institution's animal care and use program. Animal Welfare Assurances are documents that are subject to FOIA and therefore an important part of public oversight of animal research.