Duke is supportive of the comprehensive response provided by *National Association for Biomedical Research ("NABR")*. Specific comments related to the NABR response and impact to our institution is provided below.

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Requirement for semiannual inspections of animal care and use facilities. Animal Welfare Act (AWA) Section §2143(b)(3). Duke University supports the allowance of more flexibility in meeting the inspection requirements of the AWA and Animal Welfare Regulations (AWR). This could be accomplished by one or more of the following: (1) Amend 2143(b)(3) of the AWA to require only an annual inspection by the Institutional Animal Care and Use Committee (IACUC) as supported in NABRs response and/or (2) Revise 2.31(c)(3) which requires at least two Committee members to conduct the evaluations. A proposed revision is to make the requirement more consistent with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) which allows the *IACUC…, at its discretion, (to) determine the best means of conducting an evaluation of the institution's programs and facilities.*

In general semiannual inspections require a substantial time commitment of the IACUC, which is primarily composed of faculty members. The conservative labor cost by IACUC members, IACUC administrative staff, and laboratory personnel to complete these inspections at Duke to meet the AWA, AWA-Regulations, and PHS Policy requirements is $122,880/year.

Changing to annual inspections and/or allowing the IACUC to determine the best method to conduct the evaluations would eliminate significant administrative burden to investigators and allow for IACUC members to perform more qualitative evaluations. Furthermore, this would allow staff to better focus their efforts on the daily oversight and welfare of animals.

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Requirement of annual inspection by the Secretary of research facilities at least once a year. Animal Welfare Act Section §2146(a). Research facilities are the only USDA-regulated category mandated to be inspected annually in the AWA. Dealers, exhibitors, intermediate handlers, carriers, and operators of auction sales have no such annual requirement. An amendment to this language would give the USDA more flexibility to determine where it should place its enforcement efforts, as opposed to continually inspecting institutions that maintain a clean record year after year. Further, it would help them fully embrace the Risk Based Inspection System currently employed for other regulated entities. Additionally, a cost savings for both research entities and the USDA would be realized. It is estimated that the conservative cost of a USDA inspection at Duke University is between $6,500-$8,000 / year. Allowing a more risk-based approach to research facility inspections based on compliance history would decrease administrative cost to the USDA/APHIS/AC by requiring fewer Veterinary Medical Officer inspections of research facilities, reduce the administrative cost to research facilities, and would match the frequency of inspection to match the need.

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Requirement of IACUC review of proposed activities. Revisions to Section 2.31(d)(2) of the AWR to allow for a risk based tiered level of IACUC review of proposed activities. Duke University supports the model of greater oversight in areas having a higher potential for risk that would both ensure animal welfare and allow investigators to devote more time to research. The response from the NABR provides more conceptual information that proposes such a risk-based approach used in the human research arena, where exempt research and expedited review of low risk animal activities could be processed more

expeditiously. Such a risk-based approach would be more administratively efficient than the current animal regulatory framework and permit veterinarians and IACUC members to spend more time on studies with a higher risk potential. Thus, the National Institutes of Health (NIH) and USDA is encouraged to expeditiously establish a risk-based process for review of animal research protocols and to harmonize the process for continuing review of activities.

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Requirement of the IACUC to conduct continuing reviews of animal activities at least annually. It is recommended that Section 2.31(d)(5) of the AWR be amended to be consistent with Section IV. C. 5 of the PHS Policy. The PHS Policy requires continuing review of previously approved activities at least once every three years. Furthermore, the AWA does not require annual review of approved activities and the review considerations indicated in the USDA Animal Welfare Inspection Guide 7.4.1.6. primarily outlines items for which a process is already established and described in the Animal Welfare Act Regulations under section 2.31(c)(7) IACUC approval of proposed significant changes regarding the care and use of animals in ongoing activities.

The administrative cost for both faculty and IACUC support staff to achieve this regulatory requirement is conservatively estimated at $8,064/year. Consistent with the approach taken in the PHS Policy which is described in the Guide for the Care and Use of Laboratory Animals, eighth edition (NRC, 2011), this objective could be accomplished by establishing an internal process that monitors those activities (e.g., postapproval monitoring).

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Duke University supports NABR's comment regarding clarification to the Animal Care Policy by eliminating mandatory language and codify that this document contains non-binding recommendations and that an alternative approach is acceptable if the approach satisfies the requirements of the applicable statutes and regulations.

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Duke University supports NABR's comment regarding revisions to Animal Care Policy #12 with respect to literature searches to be consistent with Section 2.31(d)(1)(ii) of the AWR. The language in USDA's Animal Care Policy #12 (issued March 25, 2011) is currently inconsistent with that in the Animal Welfare regulations section 2.31(d)(1)(ii). The former recommends a database search as the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures, while the later requires the principle investigator to provide the IACUC with a written assurance that alternatives were considered. Rarely has the database searches led to a meaningful review of alternatives for animal procedures and is viewed generally as administrative burden.

National Association *for* Biomedical Research

February 12, 2018

Sent via Electronic and U.S. Mail

Michael Poe
Office of Budget and Program Analysis
United States Department of Agriculture
Jamie L. Whitten Building
Room 101–A, 1400
Independence Ave. SW.
Washington, DC 20250

Re: RFI: Identifying Regulatory Reform Initiatives

Dear Mr. Poe:

This letter is in response to the United States Department of Agriculture's (USDA) Request for Information (RFI) Pursuant to Executive Order 13777- Enforcing the Regulatory Reform Agenda, which appeared in the Federal Register on July 17, 2017. The National Association for Biomedical Research ("NABR") represents more than 360 public and private universities, medical and veterinary schools, teaching hospitals, voluntary health organizations, professional societies, pharmaceutical and biotechnology companies advocating sound public policy for the humane care and use of laboratory animals in biomedical research.

On behalf of its institutional membership, NABR appreciates the opportunity to provide the Regulatory Reform Task Force comments and suggestions to improve and reduce the regulatory burden of the regulations and guidance and policy documents used in the enforcement of the Animal Welfare Act (AWA) by the Animal Plant Health Inspection Service's (APHIS) division of Animal Care (AC). Our comments address separately the Animal Welfare Act, the Animal Welfare Regulations and the policy or guidance documents that should be repealed, replaced or modified.

I. Animal Welfare Act

A. Amend Section 2143(b)(3) of the AWA to require only an annual inspection by the IACUC. Currently, section 2143(b)(3) of the AWA requires semiannual inspections of animal facilities and study areas and does not prescribe how this should be accomplished. The Animal Welfare Regulations require more extensive program review requirements that exceed the requirements of the AWA. In general, semiannual inspections/program reviews rarely identify

"programmatic" concerns that would not have already been identified by animal care or veterinary staff during routine daily checks. A review of the NIH's Office of Laboratory Animal Welfare (OLAW) 19-page checklist used by most institutions shows how onerous this task is. Semiannual inspections require a considerable time commitment for Institutional Animal Care and Use Committee (IACUC) members, the majority of whom are faculty; they are required to visit all animal study areas and animal facilities as part of the inspection. For some large research institutions, weeks are invested to schedule and complete the inspections, and significant hours of effort to review the program and finalize the report-typically with minimal findings.

As required by the AWA, reports are then reviewed at a committee meeting, approved, and issued as a final report. The process then starts over again. This process is carried out for multiple entities, including funding agencies and accreditors, contributing to the sense that institutions are incessantly undergoing inspection. Changing to annual inspections would eliminate significant administrative work and allow staff to better focus their efforts on the daily oversight and welfare of animals.

B. Amend Section 2146 of the AWA to remove the requirement for annual USDA inspections of research facilities and allow for an inspection frequency based on compliance history, as part of the agency's Risk Based Inspection System process. Section 2146 of the AWA requires the Secretary to "inspect each research facility at least once a year," and more often if necessary, until all deficiencies or deviations from the standards are corrected. Since the enactment of this legislation, the research community has demonstrated a consistent, continued commitment to compliance with the AWA requirements. In fact, in FY 2016, of the 1,339 inspection reports posted in the Animal Care Inspection Service database, only 21 percent of the research facility inspections resulted in any citations, and almost two-thirds of those had only one citation. The majority of citations issued to research facilities involve administrative issues and not issues involving animal care. A comparison of the FY 2006 inspection results with those for FY 2016 show the number of citations for research facility-specific issues has declined by 87 percent. A review of FY 2016 citations also finds that 1.5 percent of facilities accounted for 30 percent of total citations, suggesting that a data-driven risk-based inspection process incorporating compliance history would significantly improve the inspection process efficiency and overall compliance with the AWA. This trend continues with the number of citations issued in FY 2017 down another 19 percent from FY 2016, with the number of facilities cited down 10 percent. These positive achievements by the research community present an opportunity to transition from a one-size-fits-all regulatory approach to a risk-based inspection process that allows the frequency of inspections to match the need.

II. Animal Welfare Act Regulations

A. Revise Section 1.1 of the Animal Welfare Regulations (AWR) (Definition of Terms) to make the definition of "Activity" and "Animal" consistent with definition of "animal" in Section 2132 of the AWA to read:

i. ***Activity*** means, for purposes of part 2, subpart C of this subchapter, those elements of research, testing, or ~~teaching~~ experimentation procedures that involve the care and use of animals.

ii. ***Animal*** means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, ~~teaching~~, testing, experimentation, or exhibition purposes, or as a pet. This term excludes birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research; horses not used for research purposes; and 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.

The inclusion of the word teaching in the regulatory definition of animal has been used to require schools which teach animal care and husbandry to register as a research facility and thus be subject to the requirements of Subparts B and C of the AWR, even though they do not conduct activities that would meet the definition of a research facility as defined in either the AWA or AWR. Inclusion of these facilities in the inspection process is not only inconsistent with the intent of Congress, it places an unwarranted regulatory burden on such facilities not engaged in research or experimentation and requires APHIS Animal Care personnel to conduct annual inspection of facilities that they have no statutory authority to regulate.

B. Revise Section 2.25(a) & 2.30 (a) of the AWR to eliminate the requirement for updating registration forms every three years. Section 2136 of the AWA requires each carrier and intermediate handler, and each exhibitor not required to be licensed under section 3 of the Act and the regulations of this subchapter and research facilities to register with the USDA. The Act says nothing about renewals or updated registrations. The requirement to update the registration also appears unnecessary and redundant because Sections 2.27(a) and 2.30(c) of the AWR requires notifications about changes in operations. It also imposes extra burdens on every registrant and APHIS.

C. Revise Section 2.31(c)(3) of the AWR to reflect the language contained in Section 2143(b)(4)(A)(i) of the AWA to permit the IACUC to determine the best means of conducting evaluations. Currently, the AWR requires that the reports of facility inspections be signed by a majority of the members of the IACUC, which exceeds the requirements of the AWA. The AWA requires that the reports be signed by a majority of the "...Committee members involved in the inspection." This could be accomplished by revising subsection (3) to read "The IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; *Provided* That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. Reports of these evaluations shall be submitted to the IACUC, signed by a majority of the Committee members involved in the evaluations for review and endorsement at a convened meeting of a quorum of the IACUC." A new subsection (4) would read as follows, and all subsequent subsections would be renumbered to reflect this addition: "The IACUC remains responsible for the evaluations and reports as required by the Act and regulations and shall review the reports submitted per (3) to determine the nature and extent of the research facility's adherence to this subchapter. The IACUC must identify specifically any departures from the provisions of title 9, chapter I, subchapter A – Animal Welfare, and must state the reasons for each departure and they must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. The IACUC must submit their findings as to the facility's adherence to the provisions of title 9, chapter I, subchapter A – Animal Welfare to the Institutional Official of the research facility. Their findings shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports and the IACUC's review of those findings shall be updated at least once a year upon completion of the required annual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity."

D. Revise Section 2.31(d)(2) of the Animal Welfare Regulations (AWR) to allow for a risk based tiered level of IACUC review of proposed activities. Section 2143(a)(3) of the AWA addresses the requirements "for animal care, treatment, and practices in experimental procedures to ensure that animal pain and distress are minimized". Currently, with the exception of veterinary consultation, the review of all use of animals is conducted by either a designated member review or by the full IACUC at a convened meeting. In contrast, in the human subjects protection field, the Office for Human Research Protections (OHRP) regulations found at 45 CFR § 46 provides more flexibility in reviewing human subjects research. This flexibility allows institutions to determine the appropriate level of review for a proposed research activity. For example, an item that qualifies for an

exempt determination is not classified as an expedited item. Similarly, an item that qualifies for expedited review is not assigned to a convened IRB meeting. This risk-based approach is a more administratively efficient approach than the current animal regulatory framework.

Human subject research activities that are considered exempt are reviewed by at least one member of the IRB Committee or other IRB staff or individual, as defined by institutional policy. Exempt determinations can be made by other qualified individuals (including the PI), although OHRP strongly discourages the PI from making such determinations due to the inherent conflict of interest. OHRP, once again, provides flexibility to institutions to define the individuals at the institution who can make exempt determinations. To be considered exempt, the research must not pose more than minimal risk and all of the study's procedures must meet defined exempt categories. Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests (45 CFR § 102(i)).

Human subjects research activities that are considered eligible for expedited review are also reviewed by at least one experienced member of the IRB. To be considered as expedited, the research must pose no greater than minimal risk and all of the study's procedures must meet defined expedited categories. Examples of these expedited categories are as follows:

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts;
2. Prospective collection of biological specimens for research purposes by noninvasive means;
3. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice;
4. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes; and
5. Collection of data from voice, video, digital, or image recordings made for research purposes.

If the same regulatory framework described above were applied to animal research, a list of study procedures could be defined. Proposals using only those procedures could then be reviewed and approved by one IACUC member without requiring concurrence by the members of the IACUC. Adoption of this approach in the AWR would expedite important research activities, reduce regulatory burden and decrease costs.

E. Amend Section 2.31(d)(5) of the AWR to be consistent with Section IV, C, 5 of the PHS Policy. This section of the Public Health Service (PHS) Policy requires, "The IACUC shall conduct continuing review of each previously approved,

ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1-4. at least **once every three years**" (emphasis added). In contrast, Section 2.31(d)(5) of the AWR requires, "The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, *but **not less than annually***" (emphasis added). Revising Section 2.31(d)(5) of the AWR to state, "The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, including a complete review as required in Section 2.31(d)(1-4) at least **once every three years**;" would significantly reduce the regulatory burden on many of those involved in animal care and use programs, especially investigators.

The AWA does not require an annual review of approved activities. In fact, the only place that the word annually appears in the AWA is in Section 2143(a)(7)(A), which outlines the responsibility of the research facility to report annually and to show upon inspection, that the provisions of this chapter are being followed and that professionally acceptable standards governing the care, treatment, and use of animals are being followed by the research facility during actual research or experimentation. Consistent with the approach taken in the PHS Policy, this objective could be accomplished without mandating the annual review of each approved activity, but by establishing an internal process that monitors those activities posing the greatest risk to the animals. This could be accomplished by establishing a risk based tiered level of oversight.

The current requirement for an annual review imposes cost on the institution and more importantly on the investigators that exceed any benefits in terms of compliance with the requirement or intent of the AWA.

F. Revise Section 2.36(a) of the AWR to be consistent with the definition of research facility contained in the AWA and AWR to read as follows: "(a) The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, or experiments~~, or for teaching~~." Those facilities that are currently registered whose activity does not involve research, tests or experiments, do not meet the definition of research facility and thus should not be required to comply with the requirement for research facilities in subpart C.

G. Revise Section 2.38 of the AWR by deleting subsection (a). The requirements in this section to furnish information about the business of the research facility are not authorized by the enabling legislation and thus exceed the authority of Secretary in promulgating regulations and standards. The overly broad nature of the language in (a) does not represent sound public policy and thus could lead to inconsistent interpretation of the requirements imposed by this language and subsequent inconsistent implementation of the requirements.

III. Animal Care Policy Manual

A. Style and Format - The Animal Care Policy Manual should include a Preface containing the following language, "This guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the USDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."

Each Policy document should include the following language, "USDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, the guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited."

Each page of the Animal Care Policy Manual should contain the following header, "CONTAINS NON-BINDING RECOMMENDATIONS."

Each existing Policy should be reviewed in accordance with Section II, h of the OMB's Final Bulletin for Agency Good Guidance to eliminate any use of "mandatory language such as ''shall,'' ''must,'' ''required'' or ''requirement,'' unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties."

B. Revise Policy # 3 (Pharmaceutical-Grade Substances) to contain the language in the previous policy prior to the Agency change in 2014. In a May 14, 2014 Stakeholder's announcement, the agency announced that it had clarified its position on pharmaceutical-grade substances.[1] This change resulted in the USDA's position matching the position of the National Institutes of Health's (NIH) Office of Laboratory Animal Welfare (OLAW) as a result of its adoption of the 8th Edition of the *Guide for the Care and Use of Laboratory Animal Care* (*Guide*). OLAW changed its previous position based upon language that appears on page 31 of the 8th Edition of the *Guide* which states, "The use of pharmaceutical-grade chemicals and other substances ensures that toxic or unwanted side effects are not introduced into studies conducted with experimental animals. They should therefore be used, when available, for all animal-related procedures (USDA 1997b). The use of non-pharmaceutical-grade chemicals or substances should be described and justified in the animal use protocol and be approved by the IACUC (Wolff et al. 2003); for example, the use of a non-pharmaceutical-grade chemical or substance may be necessary to meet the scientific goals of a project or when a veterinary or human pharmaceutical-grade product is unavailable. In such instances, consideration should be given to the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of

[1] *Available at:* http://content.govdelivery.com/accounts/USDAAPHIS/bulletins/aafd1c

administration, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues relating to its use (NIH 2008)."

The key reference for this statement was listed as USDA 1997b, which refers to USDA's Policy # 3 "Veterinary Care" accessed on July 9, 2010. The language in that policy stated "Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures. Non-pharmaceutical-grade chemical compounds should only be used in regulated animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone are not an adequate justification for using non-pharmaceutical-grade compounds in regulated animals."
The overarching statement in the *Guide,* which apparently led OLAW to revise its position and with which the USDA has concurred, and thus changed its existing policy, is not supported by the reference. Specifically, the statement "...should therefore be used, when available, for all animal-related procedures..." is not supported by the reference which in fact only refers to their use as *medications*. The current section of policy should be replaced by the previous policy.

C. Revise Animal Care Policy #12 with respect to literature searches to be consistent with Section 2.31(d)(1)(ii) of the AWR, 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...".

Section 2143(a)(3)(B) of the AWA states that the principal investigator must consider "alternatives to any procedure likely to produce pain to or distress in an experimental animal." Section 2143(e)(3) authorizes the establishment of information services at the National Agricultural Library to provide (inter alia) "information on improved methods of experimentation which could reduce or replace animal use; and minimize pain and distress to animals." Section 2.31(d)(1)(ii) of the AWR requires the IACUC to determine whether proposed animal use activities meet various requirements, including verification 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, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available."

In 1989 when the final rule on Section 2.31 of the AWR was published, USDA explained it as follows:

"We have modified the requirement concerning consideration of alternative procedures to allow research facilities greater flexibility in devising internal procedures for their principal investigators to follow, which simplify their task of

indicating what sources were consulted. The principal investigator must provide a written narrative of the sources consulted, such as biological abstracts, *Index Medicus*, the Current Research Information Service (CRIS), and the Animal Welfare Information Center that is operated by the National Agricultural Library. We believe that in fulfilling this requirement, Committee members will discuss these efforts with the principal investigator in reviewing the proposed activity. We also believe that consideration of alternatives will be discussed during Committee meetings where proposed activities are presented for approval, and made part of the meeting minutes. If the Committee determines that the written narrative prepared by the principal investigator provides adequate assurance that alternatives were considered, the Committee's meeting minutes need only reflect this determination."

USDA's Animal Care Policy #12 (Issued March 25, 2011) states that "APHIS continues to recommend *a database search* as the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures" (emphasis added). This is not consistent with USDA language in the final rule, which states, "If the [IACUC] determines that the written narrative prepared by the principal investigator provides adequate assurance that alternatives were considered, the Committee's meeting minutes need only reflect this determination."

Policy #12 is problematic for four reasons. First, keyword/literature searches ***are not required*** by either the AWA or AWR. Second, such searches have been shown to be ineffective. Third, the requirement to perform unproductive literature searches represents unnecessary regulatory burden. Finally, USDA admits, when pressed, that its Animal Care Policies have no regulatory standing but continues to refer to those policies as enforceable.

D.

Revise USDA Animal Care Policy #14 to reflect the language in Section 2143 of the AWA and Section 2.31(d)(1)(x)(A-C) of the AWR 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. Currently researchers cannot perform major multiple survival operative procedures on the same animal in an unrelated study, even when multiple years have elapsed between procedures or when multiple protocols are involved. This limitation, which is specific to the United States, conflicts with efforts to replace, reduce, and refine animal research; it increases the number of animals used.

As written, USDA Animal Care Policy #14—Major Survival Procedures—prohibits the use of animals in more than one proposal involving a major operative procedure. This prohibition exceeds the statutory authority provided in AWA and AWR. The current regulations in Sections 2.31(d)(1)(x)(A-C) of the AWR, leave approval of multiple survival surgery at the discretion of the IACUC

if justified for scientific and animal welfare reasons, with a provision that the Secretary may approve that usage for other special circumstances.

Section 2143(a)(6) of the AWA prohibits the Secretary from promulgating "rules, regulations, or orders with regard to the design, outlines, or guidelines of actual research or experimentation by a research facility as determined by such research facility" with certain exceptions as provided in subparagraphs (C)(ii)-(v) and (7). Therefore, this guidance document should be revised to be consistent with existing statutory and regulatory authority. Both the AWA and the AWR require that such usage be scientifically justified, but there is no requirement limiting that use to one activity. As currently written, Policy #14 would appear to be in violation of the requirements in Section 2143 of the AWA.

IV. Animal Care Inspection Guide

A. Style and Format – While the purpose of the Inspection Guide states that it "does not rise to the level of policy", it does contain definitions for the words, "May", "Should" and "Must" as used in the document. The definition of "Must" is "…when the referenced action is required by an Animal Care Procedure or by the 9CFR regulations/standards" would appear to require that this document be reviewed in accordance with Section II, h of the OMB's Final Bulletin for Agency Good Guidance to eliminate any use of "mandatory language such as ''shall,'' ''must,'' ''required'' or ''requirement,'' unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties."

Conclusion - We have provided multiple recommendations for repealing, replacing or modifying the Animal Welfare Regulations as well as several of the Animal Plant Health Inspection Service's policies and guidance documents. These recommendations address requirements that are outdated, unnecessary and/or ineffective and impose cost on both the regulated community and the Agency that exceed any benefits derived. Implementation of these recommendations will provide better customer service and provide the least interference with the regulated community while allowing the agency to accomplish its mission. The modifications we propose will allow research staff to be more productive and the animal care staff to have more time to improve the welfare of those animals that must be used in research. In preparing these recommendations, we were unable to determine, with the information that is currently available, whether jobs would be eliminated or whether job creation would be inhibited, but are certain that these changes would provide for more efficient and effective oversight process for the use of animals in biomedical research. We have also provided input on USDA requirements that would eliminate any conflict with another Federal agency. We also were unable to provide the compliance costs for our 360 members, but are confident that the modifications we recommend will reduce those costs and allow those resources to be shifted to increased research productivity without compromising the oversight of the animal care and use program. The research community has demonstrated through its record of compliance that it is committed to both the letter and the spirit of the Animal Welfare Act. In the face of this commitment these recommendations will reform the

current regulatory requirements and increase the research productivity of the regulated community while ensuring the welfare of laboratory animals.

NABR appreciates the opportunity to comment on Identifying Regulatory Reform Initiatives

Respectfully,

Matthew R. Bailey
President