



Animal Welfare Institute

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Comments on the draft document, Reducing Administrative Burden for Researchers:
Animal Care and Use in Research, A Report by the 21st Century Cures Act
Sec. 2034(d) Working Group dated November 2018.

Submitted to OLAW on February 20, 2019

Thank you for the opportunity to comment on this document. The Animal Welfare Institute finds that contrary to its mandate, the Working Group's draft document describes both proposed and even changes that have already been implemented that we anticipate will reduce the protection afforded animals in research. A major flaw of the document is that while each change that is discussed explains how the administrative burden would be lessened, there is nothing on how it will or will not impact animals. A stated goal is to eliminate duplicative processes while safeguarding animal welfare, but the impact to animals is scarcely mentioned.

Under the guise of reducing regulatory burden, USDA and NIH are weakening oversight of the housing, handling and care of animals in research. And since NIH and USDA (and FDA) intend to keep at this "in the coming years," it is clear that they hope to keep whittling away at 1) the modest requirements adopted more than thirty-three years ago and 2) the broader implementation of the laws. While we believe enforcement should be strengthened, for decades the Improved Standards for Laboratory Animals Amendment and the Health Research Extension Act have done a decent job of helping animals *without* impeding research.

It is important to keep in mind that despite industry's mantra about the regulatory burden it is carrying, many research facilities actually elect to go beyond the legally required minimum. We understand, however, that this process is geared towards facilitating laboratories' ability to do the minimum possible. It would seem appropriate that as USDA and NIH identify new ways to scale back, they make clear their support of and provide encouragement for those facilities that elect to do more than is required under the law. For example, having a majority of IACUC members engaged in the semi-annual inspections or choosing to have more than one community member so as to ensure the involvement of at least one of the two in all IACUC activities. Shouldn't all laboratories seek to maintain the highest possible standards?

Additional concerns identified in the draft document are outlined below.

Semi-Annual Inspection

AWA regulations do state that the "IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations", further underscoring the importance of IACUC inspections and going into detail regarding this, but does not go into detail regarding flexibility ("*Provided, however, That*

the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities;").

The IACUC is "an agent of the facility." Shuttling out this incredibly important IACUC function, enshrined in the Animal Welfare Act itself, to a third-party accreditor paid for by the research industry, and which does not have a public member, violates both the spirit and the letter of the Act itself. What this proposal would result in is the IACUC simply signing off on a third-party accreditor's opinion, with that third party not being constituted as the Act requires. How could a minority report be filed by the Committee under these circumstances? Enshrining this in any kind of policy, guidance, regulation, etc. serves to weaken IACUCs, which both NIH and USDA rely on and which are a key component of both the AWA and the HREA. What has become of the all-important public member of the IACUC, who under the AWA is "to provide representation for general community interests in the proper care and treatment of animals"? The intent was to have the non-affiliated member serve as the public eye, such that the public need not feel in the dark about what is going on behind the laboratory door.

Section 2.31 of the AWA regulations state: "*Provided, further*, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded." If AAALAC is conducting a site visit, it must permit any member of the committee, including the public member, to participate.

The draft report vaguely refers to USDA allowing "flexibility in how and by whom the semiannual inspections are conducted" and "The PHS Policy allows flexibility in how and by whom the inspections are conducted." Further, "NIH in coordination with USDA will develop guidance to address existing flexibilities while fulfilling the purposes of the Acts." It appears that NIH and USDA will see how many loopholes they can find, and the public will learn of it via a guidance document.

Animal Activities (Protocol) Review

The draft report is opting for the lowest common denominator in seeking to have USDA reduce the protocol reviews from annual to once every three years as NIH does.

Perhaps consideration might be given to the manner in which protocols are "renewed" on an annual basis in Canada following a full review. Every year, the protocol must be "renewed" if the work is to continue. A renewal does not entail another full review. For a renewal, the PI receives an automatically generated email that the protocol is up for renewal, and the renewal process must be undertaken or the protocol will expire automatically. The renewal process is fairly simple: the PI fills out a form by answering several questions. These questions ask about any unintended outcomes with regards to animal welfare, and progress with regards to the 3Rs (e.g., can any refinements be made in light of what was learned so far while undertaking this work), and a short explanation for why the work must continue. This renewal request is reviewed by the Animal Care Committee (IACUC) before the protocol is renewed. Up to 3 renewals are allowed; after this, the protocol is terminated and a new protocol must be created if the PI wishes to continue with this line of research.

Institutional Reporting

We do not object to streamlining data submission processes as long as priority is given to the ability to ensure timeliness and ease in providing public access to data/documents.

Guidance on Federal Standards

We object strongly to USDA's decision to remove its Animal Care policy manual from its website in July 2018. This has a negative effect on animal welfare. For example, Policy 12 describes the requirement that researchers conduct a search for alternatives and recommends a database search as the most effective and efficient method for demonstrating compliance with the legal mandate to consider alternatives to procedures that may cause more than momentary or slight pain or distress. For those who don't believe literature searches are useful or that simply don't know how to conduct effective ones, the staff of the Animal Welfare Information Center at the National Agricultural Library are well versed at such searches and available to help. Another example is Policy 14 which provides guidance to PIs to help prevent them from conducting more than one invasive surgical procedure on an animal. These two policies cover critical aspects from the 1985 amendment to the AWA and are intended to prevent needless animal suffering.

This section is among the most troublesome as weakening of guidance by both USDA and NIH will undermine sound compliance with the law. We remain skeptical about "alternative approaches" as shortcuts to this compliance. We are disturbed to see that there may be "new interpretations" of the PHS Policy, the NAS Guide, or the AVMA euthanasia guidelines.

Agency Harmonization

We are surprised to see a recommendation made "outside the scope" of the 21st Century Cures Act as a number of suggestions made by animal welfare advocates were rejected on the grounds that they, too, were "outside the scope."

Training and Resources

We recommend that you not narrow the source of your training and resources to industry alone.

Noncompliance and Reporting

We strongly object to USDA's attempt to "incentivize registrants to self-identify, self-correct, and voluntarily report serious noncompliances." The requirements under the AWA are modest and rewarding certain facilities when they fail to comply is simply unacceptable.

