

May 12, 2014

Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6750 Rockledge Drive
Bethesda, MD 20892

RE: Invitation to Comment on Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities (NOT-OD-14-063)

Submitted online at <http://grants.nih.gov/grants/rfi/rfi.cfm?ID=36>

Dear Dr. Brown:

This letter is from representatives of the animal care programs of the Big 10 Conference universities (see below). All signatory universities are PHS-assured and USDA-registered research and teaching facilities, with AAALAC accredited components, committed to quality animal care programs. As research intensive universities, the use of animals is critical to our missions and we strongly support efforts to ensure we are allowed to continue these activities.

We appreciate the opportunity to comment on NOT-OD-14-063 - *Request for Information: Invitation to Comment on Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities*.

It can be argued that most IACUCs already fulfill all the points outlined in the Proposed Guidance, but there is concern that the proposal may lead some IACUCs to increase the workload unnecessarily. Although the stated Purpose of NOT-OD-14-063 is to reduce the burden, we believe NOT-OD-14-063 does, in fact, increase the burden to IACUCs and their staff. Further, it is unclear how NOT-OD-14-063 improves upon the guidance already provided in OLAW's FAQ D9.

OLAW has stated several places that the *IACUC has some discretion to define what it considers a significant change, or to establish a mechanism for determining significance on a case-by-case basis* (see FAQ D9 and other commentary by OPRR/OLAW staff as referenced in D9). In that it includes more than 14 specific items, NOT-OD-14-063 does not allow much room for IACUCs *to define what it considers a significant change*.

In providing detailed, itemized lists of what is and is not significant, NOT-OD-14-063 effectively moves OLAW away from supporting performance standards and professional judgment towards the more stringent engineering standards. This is in direct contrast to numerous OLAW statements supporting both performance standards and professional judgment as described on pages 6-7 of the Guide for the Care and Use of Laboratory Animals. This action reminds us of findings of the 1999 NIH study of regulatory burden: "This type of regulatory burden is the inevitable consequence of regulatory systems that are designed to control outcome by defining the process that the research institution is to follow. While each of these restrictions undoubtedly has a well-intended purpose, the programs are too complex and the universe of research institutions is too varied to have rigid rules that limit adaptation to changing and variable conditions, and that stifle creativity." [1999 Report of the NIH review of regulatory burden](#)

NOT-OD-14-063 goes a step further in increasing burden by requiring a process not required by PHS Policy. According to NOT-OD-14-063, *Significant changes are those changes that have or may have a direct impact on animal welfare including but not limited to changes that have the potential to increase the level of pain or distress of the animal and includes all changes that involve anesthesia, analgesia, sedation, or euthanasia; in frequency, interval, type, number, or anatomical location of: procedures; and substances delivered to the animal.*"

PHS Policy Section IV.B.7. requires the IACUC to *review and approve, require modifications of proposed significant changes regarding the use of animals* and Sections IV.E.1 & 2. require "*records of significant changes in the care and use of animals* .

Item C of NOT-OD-14-063 does not include any items that are significant, those *that have the potential to increase the level of pain or distress of the animal*. As written, **Item C** of NOT-OD-14-063 exceeds the PHS Policy requirements in that it requires action by the IACUC on changes that are not significant: "*the IACUC is to be informed of changes handled by the IACUC staff.*" It is unclear why the IACUC needs this information or what it is supposed to do with the information. Several IACUC Chairs have noted that their focus is the health and welfare of the animals and they should not be distracted from that to review administrative actions taken by the staff. Requiring an activity that is not required by the PHS Policy is regulatory burden.

In closing, NOT-OD-14-063 does not identify the need for, nor the justification for, its issuance. Neither the problem nor why it is a problem are addressed. Furthermore, rather than supporting performance standards, professional judgment, and reduction of burden, the requirements of NOT-OD-14-063 are in direct conflict with its stated Purpose.

Thank you for the opportunity to comment,

University of Illinois at Urbana-Champaign
Indiana University
University of Iowa
University of Maryland
University of Michigan
Michigan State University
University of Minnesota
University of Nebraska-Lincoln
University of Nebraska Medical Center
Northwestern University
The Ohio State University
Penn State University
Purdue University
Rutgers, the State University of New Jersey
University of Wisconsin-Madison