

MICHIGAN STATE UNIVERSITY

May 15, 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:

Please accept this letter from representatives of the animal care program at Michigan State University, a PHS-assured and USDA-registered institution with campus-wide AAALAC accreditation of our extensive research, teaching, testing, and outreach activities involving animals.



Office for Regulatory Affairs

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Olds Hall, Room 204C
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Our IACUC already considers the items listed in parts A & B in the Proposed Guidance NOT-OD-14-063 because they directly impact the health and well-being of the animals plus they are contained in other OLAW guidance, notably FAQ D9. Our qualified and trained IACUC and vivaria staff, including 3 CPIAs and 1 CM, manage the items in part C. Although the stated Purpose of NOT-OD-14-063 is to reduce the burden, we believe NOT-OD-14-063 does, through part C, 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.

As noted in the collective response from representatives of the animal care programs of the Big 10 Conference universities, "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."

NOT-OD-14-063 goes a step further in increasing burden by requiring a process not required by PHS Policy. NOT-OD-14-063 contains a very clear statement of changes that are considered significant and we agree that the examples given have or may have a direct impact on animal welfare and should be carefully considered by the IACUC. We take issue with part C which does not include any items that are significant. As written, part 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. The focus of our IACUC is the health and welfare of the animals and they should not be distracted from that to review administrative actions taken by the staff. Establishing processes and policies to manage such activities should be the institution's prerogative without a specific directive from OLAW on how to do this. Requiring an activity that is not required by the PHS Policy and does not help the animals 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. We hope you will reconsider the need for NOT-OD-14-063.

With best regards,

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph R. Haywood". The signature is fluid and cursive, with a large, stylized initial "J" and "H".

Joseph R. Haywood, PhD
Professor, Department of Pharmacology & Toxicology
Assistant Vice President for Regulatory Affairs