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**Harry W. Orf, Ph.D.**

*Senior Vice President for Research  
Massachusetts General Hospital  
Principal Associate in Genetics  
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Office of Laboratory Animal Welfare  
National Institutes of Health

Dear Madam/Sir:

Thank you very much for providing the grantee community with an opportunity to comment on revisions to the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) as it pertains to significant changes. I am writing on behalf of the Massachusetts General Hospital (MGH) a principal teaching affiliate of Harvard Medical School with a substantial portfolio of federally-funded research that includes animal activities.

My colleagues and I appreciate the intent of the NIH to reduce the burden on investigators and their institutions; however, as written, we respectfully suggest that some aspects of NOT-OD-14-063, specifically, Section C, would greatly increase rather than decrease the administrative burden on the IACUC staff and committee. For the reasons noted below, we recommend that OLAW not revise the Policy to include Section C requirements.

- Total increase in animal number for animals not regulated by USDA that does not exceed 10% of the number reviewed and approved by the IACUC.
  - Reporting a 10% or less increase in animal number for non-regulated animals adds no value to an institution's animal welfare program. It would only increase the administrative burden on IACUC staff to prepare information for the meetings.
- Change that would result in less discomfort or invasiveness to the animal, except the changes described in section A.
  - As stated above, this activity would add no value to the animal welfare program and would increase the administrative burden.
- Change to house or use animals in a location that is currently used for the same purpose and is part of the animal program overseen by the IACUC.
  - Currently there is no requirement for the IACUC to review the details of changes in housing location that are part of the centralized animal housing program. Transfers of animals from approved centralized managed housing location A to approved centralized managed housing location B are not required to be submitted to, or reviewed by, the IACUC. These are insignificant changes that not only do not need to be reported to the IACUC when handled as minor changes by IACUC staff, neither the Principal Investigator (PI) nor animal facility manager is required to report these changes to the IACUC. Requiring reporting would only add an administrative burden at no value to the program.
- Change in personnel other than the PI (An appropriate administrative review must be conducted to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by the IACUC. The IACUC should have a procedure in place to ensure that the review is conducted.)
  - As indicated in the guidance, changes in personnel must have an appropriate administrative review "conducted to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by the IACUC." As long as that process is in place, we believe the added value of reporting compared to the associated administrative burden would be infinitely small.
- Correction of typographical errors, grammar, and contact information.
  - We believe the added value of reporting would be insignificant compared to the associated administrative burden.

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Overall, my colleagues and I are concerned that required notification of minor administrative changes would, in fact, create unnecessary workload and distraction from the substantive issues at hand.

We appreciate the opportunity to comment on the proposed revision. Please do not hesitate to contact me if you need any additional information.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'H. Orf', written over a horizontal line.

Harry W. Orf, Ph.D.  
Senior Vice President for Research