

AAU Association of American Universities
COGR Council on Governmental Relations

May 15, 2014

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

Office of Laboratory Animal Welfare, National Institutes of Health

SUBJECT: NOT-OD-14-063: RFI: Invitation to Comment on Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities

The Council on Governmental Relations (COGR) is an association of 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. The Association of American Universities (AAU) represents 60 leading public and private U.S. research institutions. AAU focuses on issues important to research intensive universities, such as funding for research, research policy issues, and graduate education. We appreciate the opportunity to comment on the National Institutes of Health's (NIH) Office of Laboratory Animal Welfare (OLAW) guidance concerning significant changes in an approved animal protocol.

We recognize and understand the delineation of significant changes as outlined in Sections A and B of the proposed guidance. These sections are consistent, as noted, with guidance offered in response to Frequently Asked Questions (FAQs) in 1995, as modified concerning personnel in 2003. It is equally important to acknowledge that the PHS Policy on Humane Care and Use of Laboratory Animals affords the Institutional Animal Care and Use Committee (IACUC) the discretion to determine the meaning of significance in all cases and the changes outlined in Sections A and B are to be used as a guide in making that determination. The PHS Policy does not define significance and OLAW cannot use the mechanism of guidance to establish new policy requirements.

In line with the Office of Management and Budget (OMB) 2007 *Final Bulletin for Agency Good Guidance Practices*, we interpret Sections A and B as offering OLAW's current thinking on the meaning of significant changes and acknowledge the advice of establishing a mechanism that determines significance and communicating that mechanism to our investigators. One of the principal goals of the OMB Bulletin was to ensure that guidance documents – whether presented as FAQs or notices – do not impose new legally binding requirements. Thus, this OLAW Guidance should not set a requirement but, rather, offer useful advice and counsel to grantees.

We object, however, to Section C concerning changes that are not significant and we strongly recommend the elimination of Section C. If the changes are not significant, they do not require action on the part of the IACUC. Such changes do not need to be reported to the IACUC, a "requirement" that exceeds the PHS Policy. There is no regulatory requirement for the IACUC to consider the stock, strain, or genetic modifications in animals used in research. There is no regulatory requirement for the IACUC to consider changes in the housing of animals currently approved for the activity within facilities overseen by the IACUC. As previous guidance noted, there is no requirement for the IACUC to review changes in personnel other than the principal investigator. And it would be entirely unnecessary and a

burden with absolutely no benefit to notify the IACUC of corrections of typographical or grammatical errors or changes in contact information.

In issuing guidance on the meaning of significance changes in on-going animal activities, we urge OLAW to make clear the purpose of the guidance – to offer its current thinking on the topic – and to address the specific issue in the guidance – the meaning of significant changes as described in Sections A and B – and to eliminate Section C from the guidance document.

Sincerely,

The image shows two handwritten signatures in black ink. The signature on the left is for Anthony P. DeCrappeo, and the signature on the right is for Hunter R. Rawlings. Both signatures are written in a cursive, flowing style.

Anthony P. DeCrappeo
President
COGR

Hunter R. Rawlings
President
AAU