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Sent via Regulations.gov and U.S. Mail

Michael Poe
Office of Budget and Program Analysis, USDA
Jamie L. Whitten Building, Room 101-A
1400 Independence Ave, SW
Washington, DC 20250

Re: Retrospective Review: Identifying and Reducing Regulatory Burdens; 81 FR 4213

Dear Mr. Poe:

This letter is in response to the United States Department of Agriculture's (USDA) Request for Information (RFI) that appeared in the Federal Register on January 26, 2016. The notice requests comment on regulations that should be modified, expanded, streamlined, or repealed to make the USDA's regulatory program more effective or less burdensome and measures that can be taken to increase flexibility.

The Association of American Universities (AAU) is an association of 60 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization with a membership of 235 public research universities, land-grant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico, that is dedicated to strengthening and advancing the work of public universities. The Council on Governmental Relations (COGR) is an association of over 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.

On behalf of member institutions, AAU, APLU and COGR appreciate the opportunity to respond to this RFI on Identifying and Reducing Regulatory Burdens in accordance with Executive Orders 13563, "Improving Regulation and Regulatory Review," and 13610, "Identifying and Reducing Regulatory Burdens."

A number of reports and articles have documented the growth in the level of administrative work associated with federally funded research.^{1,2,3,4} This administrative "burden" results from the accretion over time of

¹ Schneider, S, Ness, K, Rockwell, S, Shaver, K, Brutkiewicz, R. Federal Demonstration Partnership 2012 Faculty Workload Survey Research Report. Retrieved from: http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf

² Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century: Part 1. 2015. The National Academies Press. Retrieved from: <http://www.nap.edu/catalog/21803/optimizing-the-nations-investment-in-academic-research-a-new-regulatory>

³ Reducing Investigators' Administrative Workload for Federally Funded Research. 2014. National Science Board. Retrieved from: <http://www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf>

regulations, policies, guidance documents and other requirements associated with receipt of federal funding. Regulations and policies are necessary for the safe and proper conduct of research, but as these reports suggest, some regulations could be eliminated or modified to reduce the level of administrative work without compromising the intent of the rules and the proper conduct of research. The Federal Demonstration Partnership's (FDP) 2012 Faculty Workload Survey results suggest that administrative burdens associated with Federal research funding are consuming roughly 42% of a principal investigator's available research time. A significant proportion of this time spent on administration can be attributed to increasing regulatory requirements. This and other reports³ also find that animal research is among the areas with the highest administrative workloads. AAU, APLU and COGR member institutions support regulations that are necessary for the safety and well-being of lab animals and appreciate this opportunity to address areas where the level of work might be reduced while maintaining high standards for safety and conduct.

Modify Requirements for Continuing Review

Currently the USDA requires annual review of research protocols for USDA-covered species (per section 2.31(d)(5) of the Animal Welfare Regulations) while the Public Health Services (PHS) requires only triennial review of species subject to the PHS Policy on the Care and Use of Laboratory Animals (PHS Policy, section IV, C, 5). The National Science Board (NSB), in its report *Reducing Investigators' Administrative Workload for Federally Funded Research*, recommended as part of an evaluation of current regulations, policies, and guidance documents, the possible alignment of USDA requirements for continuing review with PHS regulations; that is, review at least every three years.

A survey of AAU, APLU and COGR member institutions conducted last year identified significant effort in reviewing animal research projects subject to USDA regulations. Faculty and staff at 42 schools reported spending 11,447 hours reviewing 4,322 research protocols subject to USDA oversight in FY14. In light of the FDP and NSB findings and recommendations and the results of our own survey, we propose the following options for reducing the level of administrative work while maintaining necessary protections:

- Align USDA requirements for continuing review with the PHS policy, allowing for review every three years or with greater frequency as deemed necessary by the IACUC.
- Limit annual reviews to Category E; that is research in which animals are subjected to procedures involving more than slight or momentary accompanying pain or distress in which appropriate anesthetics, analgesics, or tranquilizing drugs are withheld because their use would have adversely affected the teaching, testing, or experiments.

These options are consistent with a proposal made by the National Association for Biomedical Research (NABR), in its comment letter, that the USDA establish a risk-based, tiered level of oversight for animal research that does not pose more than minimal risk. This would mirror regulations for human subjects research and could include exempt and expedited categories. AAU, APLU and COGR support this proposal and the NABR comment letter generally.

Inspections

³ Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Nation's Prosperity and Security. 2012. The National Academies Press. Retrieved from: <http://www.nap.edu/catalog/13396/research-universities-and-the-future-of-america-ten-breakthrough-actions>

We also propose that USDA take a more risk-based approach to inspection to better harmonize with the PHS Policy which does not require an annual agency site visit. To the extent allowed by statute, USDA might consider inspections every 2 – 3 years for institutions that have been fully compliant or those with only indirect non-compliance items: those items that do not directly impact animal welfare. Institutions would still report any animal welfare concerns in the interim period.

With further regard to inspections, institutions have expressed concern about USDA inspectors second-guessing IACUC review and approval of items such as species and numbers justifications and key words used for compliance with Policy 12 (Literature Search for Alternatives for Pain/Distress). Concerns have also been expressed about consistency among inspectors and inspector training.

Alternatives to Literature Searches

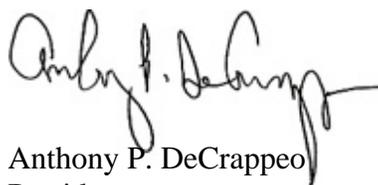
Investigators responding to the NSB report suggested that the USDA's policies and guidance, which require a literature search as a means to identify alternatives to animal models, create considerable administrative work but are ineffective – offering little tangible benefit for animal welfare. It was further suggested that failure to adequately perform the search is one of the top USDA citations. We recommend that the USDA identify alternatives to the literature search that would reduce unnecessary administrative work while meeting the intent of the regulations. We note that in the NSB report, a representative from the USDA's Animal and Plant Health Inspection Service indicated that the USDA supports efforts "to explore options that address the respondents concerns" regarding this and other USDA requirements and "look forward to working with the research community to ensure regulatory compliance, reduced administrative burdens, and humane animal treatment and care." AAU, APLU and COGR would appreciate the opportunity to work with the USDA and other stakeholder groups to explore potential alternatives to the literature search and to address additional areas of compliance burden.

We appreciate the opportunity to comment on USDA regulatory requirements and remain available for questions or additional discussion on the comments and recommendations included in this response.

Sincerely,



Hunter R. Rawlings III
President
Association of American Universities



Anthony P. DeCrappeo
President
Council on Governmental
Relations



Peter McPherson
President
Association of Public and Land-grant Universities