Reforming Animal Research Regulations:

Workshop Recommendations to Reduce Regulatory Burden

Report of an April 17, 2017 workshop organized by FASEB, AAMC, and COGR, with assistance from NABR

FASEB
Federation of American Societies for Experimental Biology

AAMC
"Tomorrow's Doctors. Tomorrow's Cures"®

COGR
Council On Governmental Relations

nabr National Association for Biomedical Research

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Workshop on Reforming Animal Research Regulations, April 17, 2017

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Executive Office of the President & Congress					
Corresponding Recommendation			Statutory or Regulatory Action Required	Reduction of Burden for	Report Page
2		The Executive Office of the President (EOP) and the Office of Management and Budget (OMB) should explore whether regulatory efficiencies could be gained, and burden reduced, by consolidating animal research oversight under a single Federal office or entity with one primary set of regulations and guidance documents.	EOP and OMB should perform exploratory study using an advisory group of experts engaged in animal research from the regulated community	• Investigator • IACUC • Institution	10–11
		• An advisory group of experts engaged in animal research from entities that receive federal research awards should be invited to assist with this effort.			
	2a	– Harmonize existing federal requirements for those species currently covered by USDA and those covered by the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) to conform to the least burdensome standard while maintaining animal welfare.		• Investigator • IACUC • Institution	10–11
	2b	– Pilot new models and structures through the Federal Demonstration Partnership (FDP), as appropriate.		• Investigator • IACUC	10–11
3		The EOP and OMB should consider requiring at least a 60-day comment period on the merits and impact of any proposed policies, guidance documents, frequently asked questions (FAQs), or interpretive rules before they are issued.	EOP and OMB should institute policy		11–12
		• Final policies and guidance should include material changes that reflect germane comments received from the regulated community.			
	3a	– Near-final documents should be reviewed by an external advisory committee of experts engaged in animal research from the regulated community before they are disseminated for public comment or final agency review.	The advisory group mentioned above (2) could assist with this review	• Investigator • IACUC • Institution	11–12
	3b	– All guidance documents should state clearly that they do not carry legal or regulatory force.	State on all guidance documents	• Investigator • IACUC	11–12
	3c	– Guidance documents should not be accompanied by a requirement to obtain agency approval for alternative methods and/or processes.	State on all guidance documents	• Investigator • IACUC	11–12
14		Congress should amend §2143(b)(3) of the Animal Welfare Act (AWA) and §495(b)(3) of the Health Research Extension Act (HREA) to require only annual inspection by the IACUC.	Amend §2143(b)(3) of the AWA and §495(b)(3) of the HREA	• Investigator • IACUC	20
16		Congress should amend §2146 of the AWA to remove the requirement for annual USDA inspection of research facilities and allow for an inspection frequency based on compliance history, as part of the agency's Risk Based Inspection System process.	Amend §2146 of the AWA	• Investigator • IACUC • Institution	21–22

National Institutes of Health & United States Department of Agriculture					
Corresponding Recommendation			Statutory or Regulatory Action Required	Reduction of Burden for	Report Page
1		NIH and other federal agencies involved in the review of regulations and policies for the care and use of laboratory animals mandated by the 21st Century Cures Act (Cures) should appoint an external advisory group of experts engaged in animal research from entities that receive federal research awards to serve as advisors. The advisory group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, IACUC members, veterinarians, and investigators engaged in animal research.	Establish a review committee of experts engaged in animal research from the regulated community to assist with implementation of Cures mandates		9
		• This will foster progress and impartiality in the conduct of this review, which should take into account relevant regulations, policies, and guidance, along with the recommendations of this and other reports that have addressed regulatory burden associated with animal research.			
	1a	– The committee could be designated an "expert subcommittee" of the Research Policy Board mandated by Cures. Agencies might also consider a permanent animal research advisory group modeled after the Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections.	Designate the review committee as an "expert subcommittee" of the Research Policy Board mandated by Cures		9
4		As part of the review mandated by Cures, all current Public Health Service (PHS) and USDA regulations, policies, guidance documents, FAQs, and interpretive rules, as well as the process for generating them, should be reviewed by an external advisory group of experts engaged in animal research from entities that receive federal research awards. The advisory group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, IACUC members, veterinarians, and investigators engaged in animal research.	The advisory group mentioned above (1a) could assist with this review	• Investigator • IACUC • Institution	12
		• This review would ensure that these documents emphasize matters of core importance to animal welfare identified in the statutory language of the HREA and AWA, and are consistent with current scientific and technological knowledge and approaches.			
9		NIH and USDA should establish a risk-based process for review of animal research protocols similar to that for human subjects research under 45 CFR 56; §46.110. Studies deemed low-risk, noninvasive, or minimally invasive could be exempt from full IACUC review or eligible for administrative review without concurrence by the full IACUC.	NIH and USDA should issue a Notice in the Federal Register amending protocol review requirements to define types of studies involving low-risk, noninvasive, or minimally invasive procedures	• Investigator • IACUC • Institution	16

National Institutes of Health				
Corresponding Recommendation		Statutory or Regulatory Action Required	Reduction of Burden for	Report Page
5	The *Guide for the Care and Use of Laboratory Animals (Guide)* is not a regulatory document. Given that, OLAW should use the *Guide* as it was intended, namely, "to assist institutions in caring for and using laboratory animals in ways judged to be professionally and humanely appropriate." The *Guide* allows facilities to produce welfare outcomes for animals in diverse and innovative ways by permitting alternative strategies to "should" statements upon approval by the IACUC.	Amend NIH FAQ C7, PHS Policy IV.B.3.c, and NIH website: https://grants.nih.gov/grants/olaw/departures.htm	• Investigator • IACUC • Institution	13–14
	• OLAW should not consider IACUC-approved alternative strategies from "should" statements in the *Guide* as departures or deviations nor should they be required to be included in the semiannual report to the Institutional Official. This would be consistent with OMB's Agency Good Guidance Practices Bulletin and would significantly reduce administrative burden without compromising animal welfare.			
6	OLAW should cease using the word "deviation" in their guidance documents when referring to IACUC-approved alternative strategies to "should" statements in the *Guide*. As with USDA regulations, the meaning of words used in OLAW guidance documents not defined in legislation or the PHS Policy should be that of a standard dictionary.		• Investigator • IACUC	13–14
7	The *Guide* should be a "living" document that continuously incorporates changes in the scientific literature. Consideration should be given to an online version of the *Guide* with periodic updates provided in partnership with an independent group such as the American Association for Laboratory Animal Science.		• Investigator • IACUC	13–14
11	Amend the third bullet in section 8.1.2.5 of NIH Grants Policy to read "Change from the approved use of live vertebrate animals *that would result in an increased risk*."	Amend third bullet in section 8.1.2.5 of the NIH Grants Policy	• Investigator • IACUC	17
13	Eliminate the requirement for verification of protocol and grant congruency in NIH Grants Policy 4.1.1.2 to allow for reasonable advances, discoveries, and other developments of the overall research objectives.	"Delete section 4.1.1.2 "'Verification of IACUC Approval'" from the NIH Grants Policy	• Investigator • IACUC • Institution	19–20
18	Revise the NIH guidance in NOT-OD-05-034 regarding prompt reporting to include only those incidents that jeopardized the health or well-being of animals.	Delete all other examples of reportable situations except "conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals" in NOT-OD-05-034	• Investigator • IACUC • Institution	22–23
19	OLAW specifies that the grant number be included in noncompliance reports, but this is not required in PHS Policy (IV.F.3). Grant numbers should not be required on noncompliance reports in order to protect investigators and study teams from harassment by parties seeking to disrupt animal research.	Delete second bullet under "Information to Be Reported" in NOT-OD-05-034	• Investigator • Institution	22–23
20	Streamline the assurance for animal research. In addition, for Category 1 institutions, allow proof of accreditation in lieu of the detailed program description.	Using the Federalwide Assurance for Human Subjects Research as a guide, streamline the Animal Welfare Assurance	• IACUC • Institution	23

United States Department of Agriculture				
Corresponding Recommendation		Statutory or Regulatory Action Required	Reduction of Burden for	Report Page
8	Revise §2.31(d)(5) of the AWA Regulations (AWR) as follows: "The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, including a review as required in §2.31(d)(1-4) at least once every three years" (emphasis added). This would make review frequency consistent with the PHS Policy.	Amend §2.31(d)(5) of the AWR	• Investigator • IACUC • Institution	15
10	Revise USDA Animal Care Policy #14 to reflect the language in the AWA §2143 and AWR §2.31(d)(1)(x)(A-C), allowing approval of multiple survival operative procedures at the discretion of the IACUC and as justified for scientific and animal welfare reasons. This will enhance the community's efforts to reduce the number of animals involved in research.	Amend USDA Animal Care Policy #14	• Investigator • IACUC	16–17
12	Amend the language in USDA Animal Care Policy #12 with respect to literature searches to be consistent with AWR §2.31 (d)(1)(ii), which charges the IACUC to determine "that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources…"	Amend USDA Animal Care Policy #12	• Investigator	18–19
15	Revise §2.31(c)(3) of AWR to state: "*The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities that includes all members wishing to participate in the process. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report*."	Amend §2.31(c)(3) of the AWR	• Investigator • IACUC • Institution	21
17	With respect to inspection frequency based upon historical compliance, USDA should consider including AAALAC International accreditation as a factor.	Include AAALAC International accreditation as a criteria on the APHIS website: https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa/ct_awa_risk_based_inspection_system	• Investigator • IACUC • Institution	21–22

Minor recommendations are not color-highlighted

Science

United States should dramatically retool animal research rules, groups say

By Warren CornwallOct. 24, 2017 , 5:45 PM

http://www.sciencemag.org/news/2017/10/united-states-should-dramatically-retool-animal-research-rules-groups-say