



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 130,000 Researchers

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October 6, 2020

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health (NIH)
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: Request for Information (RFI) on Clarification of Institutional Responsibilities Regarding Grant to Protocol Congruency [NOT-OD-20-153]

Submitted electronically via portal and via e-mail: olaw@mail.nih.gov

Dear Dr. Brown,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Request for Information (RFI) seeking input on clarification of institutional responsibilities regarding grant to protocol congruency ([NOT-OD-20-153](#)). As a coalition of 29 scientific societies representing over 130,000 researchers and engineers, FASEB commends OLAW's endeavors to address administrative burden associated with animal research and recognize the challenge of maintaining scientific integrity and animal welfare while improving policy coordination.

FASEB acknowledges OLAW's efforts to reduce administrative burden thus far, in accordance with the 21st Century Cures Act Section 2034(d), including harmonization of the annual reporting period with that of the United States Department of Agriculture (USDA) ([NOT-OD-20-109](#)). As deliberations proceed, FASEB encourages the office to heed the mandate defined by the 21st Century Cures Act and minimize duplicative animal research regulations where feasible. Ongoing stakeholder engagement is necessary to maximize the benefits of potential policy modifications, and ensure implementation is transparent and inclusive of multiple perspectives.

Laboratory animal research serves as the primary source of scientific knowledge and remains vital for sustained biomedical progress. However, the exponential increase in administrative work over the past decade has resulted in increased costs and reduced research productivity, jeopardizing long-term national interests in science and medicine. While these requirements are intended to enhance accountability, many of these tasks do not promote animal welfare or improve research quality. Grant to protocol congruency review, as outlined in NIH Grants Policy 4.1.1.2. is a burdensome task with few practical advantages. As OLAW clarifies this requirement, FASEB offers the following comments for consideration.

Full members: The American Physiological Society • American Society for Biochemistry and Molecular Biology • American Society for Pharmacology and Experimental Therapeutics • American Society for Investigative Pathology • American Society for Nutrition • The American Association of Immunologists • American Association for Anatomy Society for Developmental Biology • American Peptide Society • Association of Biomolecular Resource Facilities • The American Society for Bone and Mineral Research American Society for Clinical Investigation • Society for the Study of Reproduction • The Society for Birth Defects Research & Prevention • The Endocrine Society • American College of Sports Medicine • Genetics Society of America • The Histochemical Society • Society for Glycobiology • Association for Molecular Pathology • Society for Redox Biology and Medicine • Society For Experimental Biology and Medicine • American Aging Association • U. S. Human Proteome Organization • Society of Toxicology • Society for Leukocyte Biology • American Federation for Medical Research • Environmental Mutagenesis and Genomics Society **Associate members:** The American Society of Human Genetics

As noted in the 2017 collaborative [report](#), “*Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden*,”¹ grant to protocol congruency review emphasizes the comparison of two documents written at separate times, potentially up to nine months apart.

Consequently, this format prohibits researchers from integrating scientific developments that occurred in the interim period. Therefore, FASEB recommends OLAW eliminate congruency review to reflect the dynamic nature of the scientific and grant application process and provide investigators the flexibility to integrate advancements in research objectives. To account for this disconnect, in 2018, the U.S. Health and Human Services Department [revised](#) the Common Rule for human subjects research noting, “...*experience suggests review and approval of the grant application is not a productive use of IRB time.*” We recommend OLAW implement a comparable modification for congruency review.

FASEB recognizes that performing work not described in an IACUC protocol is the most frequent noncompliance reported to OLAW, comprising 23 percent of cases in 2018². While congruency review may serve to enhance consistency, its timing overlooks the leading cause of noncompliance by excluding consideration of potential IACUC amendments. In several instances, researchers abide by the original protocol but inadvertently fail to submit an amendment when changes occur. Additionally, the statistic above disregards the 77 percent of investigators that fulfill their responsibility to comply with the rigorous IACUC review process. Therefore, just as the *Guide* requires an assurance that proposed activities do not unnecessarily duplicate previous research, federal agencies must ensure taxpayer funds are not spent on redundant processes. This is also consistent with the 21st Century Cures Act. As a compromise, OLAW could incentivize this requirement by waiving congruency review for investigators without noncompliance citations in the last two years. This accommodation will encourage investigators to adhere to best practices, and allows investigators to dedicate more time towards enhancing animal welfare.

Because IACUC protocols must be renewed every three years, another challenge investigators face when completing congruency review is accounting for research conducted after this period, including years four and five of a five-year R01 grant. Recognizing that a one-to-one grant to protocol relationship is not required, FASEB strongly urges OLAW to align IACUC approval with the lengthier grant should investigators secure multiple grants of variable length. Existing mechanisms such as post-approval monitoring and semiannual inspections are in place to ensure animal welfare is maintained, and correct potential protocol deviations throughout a grant’s duration. FASEB appreciates OLAW’s outreach to clarify this issue by [stating](#) that a “brief description” of research conducted in years four and five is sufficient to achieve congruency, provided that protocols are refined at the appropriate time. However, “brief descriptions” on future experiments is inconsistent with the scientific duty to rely on evidence-based data to inform ongoing research and indirectly overlooks institutional Animals Welfare Assurances that commit to IACUC-approved activities from the outset. Furthermore, FASEB recommends OLAW reinstate the “pending” status for IACUC approvals to allow the release of grant funds to institutions. This modification would enable streamlining of administrative tasks—including salary support—and improve preparation of studies before initiating experiments. Together, the time saved from reducing administrative burden associated with IACUC renewals and approval status latency would significantly enhance research productivity and ensure continued funds and resources for essential staff.

¹ FASEB, Association of American Medical Colleges, Council on Governmental Relations, and National Association for Biomedical Research, October 2017.

² OLAW, USDA, and FDA, “Reducing Administrative Burden for Researchers: Animal Care and Use in Research,” August 2019.

Finally, FASEB encourages OLAW to establish a “Congruency Review Best Practices” resource to consolidate guidance and examples. Developing a resource that summarizes successful institutional strategies to fulfill congruency review—including those highlighted during previous OLAW webinars—would clarify expectations and provide demonstrable options for determining a mechanism suitable for institutional needs. Furthermore, we recommend OLAW specify that the objective of congruency review is to identify matching high-level characteristics between grants and IACUC protocols rather than minute details. This distinction will minimize investigator confusion and streamline this time-consuming process.

FASEB appreciates the opportunity to provide feedback on this RFI and looks forward to updated guidance. We thank OLAW’s commitment to animal welfare, and encourage continued engagement with research stakeholders to foster improved coordination of federal animal research regulations.

Sincerely,

A handwritten signature in black ink, reading "Louis B. Justement". The signature is written in a cursive style with a large, sweeping flourish at the end.

Louis B. Justement, PhD
FASEB President