



October 30, 2020

Via Email Submission to Office of Laboratory Animal Welfare

**National Institutes of Health
Office of the Director**

RE: Comments Submitted in Response to Notice Number [NOT-OD-20-153](#), Request for Information

To Whom It May Concern:

The Council on Governmental Relations (COGR) is an association of 190 public and private U.S. 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. One area of significant interest and expertise among COGR member institutions is ensuring the integrity of basic and applied animal research. This research enables fundamental knowledge that leads to new treatments and insights to improve human health.

COGR appreciates the opportunity afforded by the National Institutes of Health (NIH) to provide information in response to the July 29, 2020 [Request for Information \(RFI\) on Clarification of Institutional Responsibilities Regarding Grant to Protocol Congruency, NOT-OD-20-153](#) ("RFI").

The 21st Century Cures Act's requires the National Institutes of Health (NIH), in collaboration with the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) to review regulations and policies concerning the care and use of laboratory animals and make revisions, as necessary, to reduce administrative burden, as appropriate. COGR members support this initiative and are keenly aware of the need to ensure appropriate protections for research animals, while eliminating requirements that do little to promote such protections and place unnecessary burden on researchers and research oversight units.

The letter provides general comments regarding the grant to protocol congruency review requirement ("Congruency Requirement"), followed by specific comments concerning the clarifications regarding the Congruency Requirement included in the RFI.

General Comments

COGR believes that the Congruency Requirement is ripe for elimination under the 21st Century Cures Act directive because it consumes a great deal of IACUC time and resources, without meaningfully contributing to the health, safety, or welfare of research animals. IACUC review of research protocols, and any changes to these protocols, is key to ensuring animal health, safety, and welfare. Yet, this review can be completed without the need for Congruency Review, and the use of time and resources to complete the Congruency Review, takes away time and resources from other activities that have a direct impact on animal welfare. This is particularly true considering that the Congruency Review takes place *before* the proposal is funded. In fact, NIH acknowledges in the RFI that the protocol may (and in fact, is likely to) change between the time of Congruency Review and the initiation of the research, and such changes do not require NIH approval unless there a change in scope of the research project:

The [NIH GPS section 8.1.2.5](#) allows the investigator to make changes in the methodology and approach of the project without prior approval by NIH grants management. However, the recipient must obtain prior approval from the NIH awarding Institutes and Centers (ICs) for a change in scope, which could include significant changes to IACUC protocols. Once the initial congruency review is completed and submitted to NIH, there is no requirement to amend and resubmit to the NIH either the grant application, the Vertebrate Animals Section, or other documentation unless requested by the NIH awarding IC.

Further, all significant changes to animal research protocols require IACUC review ([Public Health Service Policy on the Human Care and Use of Laboratory Animals](#) (“PHS Policy”) [Section IV.C.1](#)). Accordingly, the Congruency Review does nothing more than provide a point-in-time comparison of the grant to a protocol that is likely to change. As the protocol, and any significant changes, must always receive IACUC review, this comparison does nothing to further the IACUC’s mission of protecting research animals.

The Office of Human Research Protections (OHRP) concluded that its grant to protocol congruency review process was not a value-added exercise when it issued its 2018 interpretation that such reviews were no longer required. This interpretation was recently formalized when OHRP issued its final [Guidance on Elimination of Institutional Review Board \(IRB\) review of Research Applications and Proposals: 2018 Requirements](#) on July 25, 2018. ([83 FR 35278](#)). The comments that OHRP included in this *Guidance* regarding the requirement apply equally to the Congruency Review for animal research:

Experience suggests that review and approval of the application or proposal is not a productive use of IRB time. Elimination of that requirement is not expected to reduce protections for human subjects because the research study (e.g. a research protocol) would remain subject to the requirement for IRB review and approval, assuming that an HHS component funds the research.

COGR urges the Office of Laboratory Welfare (OLAW) to follow OHRP's lead and offer meaningful reduction of administrative burden by eliminating the Congruency Review. Further, there are no significant hurdles to eliminating this requirement because it is not statutory or regulatory in nature.

Specific Comments Regarding Clarifications in RFI

Clarification 1 -- Institutional Responsibility to Ensure Congruency Review

The RFI states that the Congruency Review may be performed by an office or position within the institution other than the IACUC. This clarification simply shifts, rather than eliminates, administrative burden, and as previously discussed, the Congruency Review does little to add value from either an administrative or animal welfare perspective. Further, from a practical perspective, although the task could be assigned to another unit, the IACUC is the institutional unit that has experience in handling protocols, reviewing descriptions of planned work for regulatory compliance, and that typically controls the software platform on which the protocols are housed making transfer of the task impractical.

Clarification 2 -- Congruency Review Need Only be Conducted Prior the Initial Grant or Contract Award & Clarification 4 – Investigator May Make Changes in Methodology and Approach without NIH Grants Management Approval

Many of the points discussed in Clarification 2 and Clarification 4 are addressed in the General Comments section of this letter. As noted, the fact that the Congruency Review takes place long before the actual research is conducted, coupled with the requirement that significant changes to the protocol always require IACUC review illustrate that the Congruency Review does little to add administrative or animal protection improvements.

Clarification 3: No Explicit Requirement for Side-by-Side Comparison

COGR appreciates all flexibilities available to institutions in how the Congruency Review is conducted.

Clarification 4: Investigator May Make Changes in Methodology and Approach without NIH Grants Management Approval

In addition to the comments regarding this clarification listed under Clarification 2, COGR requests that NIH consider clarifying the following statement in this clarification: "Once the initial congruency review completed and submitted to NIH, . . ." The NIH GPS states "[i]t is an institutional responsibility to ensure that the research is described in the application is congruent with any corresponding protocols approved by the IACUC," but it does not require that the ***congruency review be submitted to NIH***. Further, OLAW training materials regarding Congruency Review state only that "[i]nstitutions should maintain congruence review records for their own purposes and have them available for possible review by NIH." [Brown, P. & Varghese, S. *OLAW – Online Webinar: The 2016 Vertebrate Animals Section, Grants Policy, and Congruence*, Slide 31, (March 10, 2016)]. COGR requests

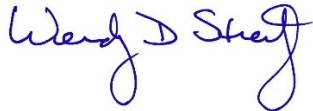
that NIH amend this statement to clarify that verification of IACUC approval must be provided to NIH, but there is no requirement to provide documentation of Congruency Review.

Conclusion

COGR appreciates the opportunity to provide comments in response to this RFI and to work in partnership with NIH to lessen regulatory burdens that do not impact animal welfare. Overall, the Congruency Review presents an additional layer of administrative burden without additional benefit because the protections afforded by the IACUC process lie in the protocol review process, not Congruency Review. Accordingly, we hope that NIH will take this opportunity to follow OHRP's path and retire this requirement.

If you have any questions regarding these comments, please contact Kris West, Director of Research Ethics and Compliance, at kwest@cogr.edu.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Wendy D. Streit
President