



October 3, 2023

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: Request for Information (RFI) on Flexibilities for Streamlining IACUC Review of Protocols and Significant Changes (NOT-OD-23-152)

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

Dear Dr. Wolff,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Request for Information regarding flexibilities for streamlining protocol review ([NOT-OD-23-152](#)). Processes such as designated member review (DMR), DMR subsequent to full committee review (FCR), veterinary verification and consultation (VVC), and administrative handling of increases in previously approved animal numbers improve the efficiency of institutional animal care programs by decreasing turnaround times while maintaining policy compliance and high-quality animal care. FASEB appreciates the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) for recognizing the importance of reducing the administrative burden associated with protocol review and encouraging stakeholders to correctly implement available flexibilities.

To maximize the benefits and use of these flexibilities, FASEB encourages OLAW to explore additional opportunities that could improve protocol review efficiency and reduce administrative burden for Institutional Animal Care and Use Committees (IACUCs). For example, FASEB recommends aligning IACUC protocol reviews with NIH grant length. The current timing discrepancy between protocol reviews (e.g., three years) and the average length of NIH grants (e.g., four or five years) causes unnecessary research delays and interruptions in animal care. This is because investigators are compelled to keep animals in a holding pattern while experiments are postponed or suspended until protocol reviews are complete.

Although noncompliance with study protocols is the [most common issue](#) reported to OLAW (25 percent of cases), this type of noncompliance has steadily declined since 2020. More importantly, the majority of investigators adhere to the rigorous set of IACUC review processes. Because existing mechanisms such as post-approval monitoring, semiannual inspections, and IACUC amendments are already used to maintain animal welfare and correct potential protocol deviations throughout a grant's duration, the arbitrary three-year protocol review requirement is redundant and an inefficient use of IACUC time. Thus, in the same manner that OLAW offers flexibility for conducting and documenting protocol

reviews—as highlighted in this RFI— FASEB recommends modifying the timing of congruency reviews to maximize research productivity, ensure continuous animal care, and provide IACUCs the flexibility to

implement animal welfare improvement strategies. This adjustment would be comparable to [the 2018 Common Rule revision](#) which eliminated the requirement for grant applications and proposals to undergo Institutional Review Board review and approval for the purpose of certification.

Overall, FASEB applauds the availability of the listed flexibilities as they effectively enable institutions to adapt to local requirements and circumstances. To further encourage IACUCs to use these strategies, we recommend strengthening outreach and communication efforts and highlighting OLAW's support for other ongoing efforts to streamline IACUC processes. This includes the Compliance Unit Standard Procedure (CUSP) project that seeks to develop an online resource where participating institutions can share standard procedures used in animal care protocols. Another strategy that OLAW could consider endorsing is the use of an institutional liaison specifically tasked with assisting investigators throughout the protocol review process. Regularly emphasizing to assured institutions that a "one-size-fits-all" approach is unsustainable and counterintuitive to optimal animal welfare allows institutions of all sizes, particularly small institutions or those that may be more risk-averse, to better allocate staff time and resources that ultimately enhance program efficiency and animal care.

Below, please find FASEB's specific comments on flexibilities for streamlining protocol review processes, organized by category: DMR, DMR subsequent to FCR, VVC, and Administrative Handling of Increase in Previously Approved Animal Numbers.

Topic 1: Proposed Guidance for Streamlining DMR

- 1. The IACUC may determine a reduced, but reasonable, time frame agreed upon by the IACUC to obtain concurrence to call for FCR from all members or concurrence by silent assent once the full time has elapsed (e.g., three instead of seven business days).**

FASEB appreciates the availability of this flexibility as it is an effective strategy for reducing IACUC administrative burden, especially for resource-limited institutions. While we recognize most institutions already use less than seven days to obtain concurrence for potential FCR, OLAW could consider reminding assured entities that the *Guide for the Care and Use of Laboratory Animals* (the Guide) is silent on prescribing the timeframe necessary to obtain concurrence. Many institutions strictly adhere to the *Guide* when implementing their institutional programs to meet Public Health Service (PHS) Policy requirements. This reminder would assure facilities that adopting a timeframe that suits individual IACUCs is both acceptable and policy compliant.

- 2. Submissions may be routed for DMR to allow the DMR process to be initiated while the IACUC is provided time to call for FCR. However, the outcome of the review *cannot* be finalized until all IACUC members have been provided a reasonable time to call for FCR ([OPRR Reports 90-01](#)). If all voting members respond before the end of the predetermined time frame, and there are no requests for FCR, DMR may be finalized.**

FASEB considers this to be a valuable flexibility that allows IACUCs to expedite submission review processes. We encourage OLAW to clarify that concurrence by silent assent by the end of a predetermined time frame is an acceptable strategy for achieving complete IACUC consideration. This clarification aligns with the first flexibility and could encourage more assured institutions to take full advantage of DMR benefits.

3. **The IACUC may establish criteria for which some types of research or significant changes may be flagged for DMR. All members must be provided with a reasonable time to call for FCR, but the DMR process may be initiated during that time. Only when there are no requests for FCR at the end of the predetermined time frame, may DMR be finalized.**
 - a. **Examples of criteria based on types of research:**
 - i. **Involve minimal or no pain or distress to the animal(s)**
 - ii. **Utilize species not regulated by the USDA**
 - iii. **Are minimally invasive (e.g., euthanasia for tissue harvest, breeding or holding protocols, injections, routine blood collection, minor surgery, non-survival surgery)**
 - b. **Examples of criteria based on significant changes:**
 - i. **Change in PI**
 - ii. **Change or addition of species without a change in study objectives**
 - iii. **Housing in a location that has not been previously approved by the IACUC**
 - iv. **Addition of a procedure that does not result in greater pain, distress, or degree of invasiveness**
 - v. **Addition of anesthesia, sedation, or analgesia that will improve animal well-being**

We appreciate OLAW's recognition that local IACUCs may establish predetermined research criteria that qualify for DMR and providing a list of common criteria examples. One additional criterion that we encourage adding to the list of "examples of criteria based on significant changes" is *change or addition of an Association of Veterinary Medical Association (AVMA)-approved euthanasia method that minimizes animal pain or distress*. Changes to euthanasia are a common occurrence ideally suited for DMR. This addition coincides with the final bullet point listing anesthesia, sedation, or analgesia changes and encourages IACUCs to prioritize the 3Rs (Reduce, Replace, Refine) through widely respected standards such as AVMA guidelines.

4. **The IACUC chairperson may designate only one qualified member to conduct the review, which may reduce the burden associated with designating multiple reviewers because it eliminates the requirements that:**
 - a. **Reviewers must be unanimous in any decision.**
 - b. **Reviewers must review identical versions of the protocol.**
 - c. **If modifications are requested by any reviewer, then the other reviewers must agree to the modifications.**

As a frequently used and understood part of the DMR process, FASEB appreciates this guidance and has no additional comments or suggestions.

5. **The IACUC has the flexibility to determine the best way for the chairperson to assign the designated reviewer, including creating a policy. The policy should accommodate future assignment changes for conflicts of interest or unavailable reviewers, while ensuring that the designated member is qualified to conduct the review. Using a rotational list of reviewers based on their expertise, and appointing a vice chairperson to assign reviewers in the chairperson's absence are other mechanisms to increase efficiency.**

As previously noted, we thank OLAW for providing local IACUCs the flexibility to set policies and processes that work best for their needs and circumstances. Assigning a chairperson for DMR via a rotational list and appointing a vice chairperson to assign reviewers in the IACUC chair's absence are

regularly used strategies that maximize the IACUC's time and expertise. Perhaps one way to promote greater use of this flexibility is modifying [OLAW FAQ D.3](#) to emphasize that the chairperson may determine the best means for assigning a designated reviewer. Sharing example mechanisms, such as those listed above, could stimulate more IACUCs to adopt strategies that enhance review efficiency.

6. Designated reviewers may refer to scientific-based publications in peer-reviewed journals or guidelines prepared by professional organizations (see [OLAW FAQ D.17.](#)) as an alternative to ad hoc consultants.

FASEB considers this to be a beneficial flexibility that is regularly employed by various institutions. We appreciate its reference in the OLAW FAQs and the recognition that the use of scientific-based publications is consistent with the *Guide's* recommendations. We have no additional comments or suggestions.

7. The IACUC may determine the best means of documenting the DMR process from review to approval (e.g., emails or forms).

FASEB appreciates this flexibility, as it allows institutions to adopt strategies that best fit their unique needs. Because IACUC documentation is a major source of administrative burden, we encourage OLAW to consider creating a new "Fast Facts" segment on DMR within the [guidance section](#) of its website. In addition to clarifying that IACUCs are free to determine the most effective means of documenting the DMR process, a "Fast Facts" segment could serve as an effective platform to outline additional strategies for IACUCs to streamline DMR protocol review processes. Raising awareness through website resources is crucial for reducing confusion and maximizing the use of flexibilities to improve policy compliance.

8. Designated member approval does not require subsequent reapproval by the IACUC at a convened meeting.

As a frequently used and understood part of the DMR process, FASEB appreciates this guidance and has no additional comments or suggestions.

9. The IACUC may expedite the three-year complete review of an ongoing protocol that is due to expire. This may only occur during extenuating circumstances, such as disasters impacting research or extended unplanned PI unavailability. The intent of this flexibility is to permit the continuation of research in accordance with [PHS Policy IV.C.5.](#)

a. The expedited review process must include the following parameters:

- i. Members may agree to a shortened response time to call for FCR. If no member calls for FCR, the protocol may be reviewed by DMR ([PHS Policy IV.C.2.](#)).**
- ii. The IACUC must have a policy describing a shortened approval period for ongoing activities (i.e., previously approved protocols due to expire) to extend only for the duration of the unplanned circumstances.**
- iii. No significant changes are allowed using the expedited process. Any significant changes must be submitted and reviewed after the circumstances have resolved.**

This flexibility allows IACUCs to streamline three-year complete reviews during unexpected circumstances, permitting research to continue unimpeded. However, as written, the second bullet

point on having an IACUC “policy describing a shortened approval period for ongoing activities” lacks clarity and context. To mitigate the risk of noncompliance with expired protocols, FASEB recommends clarifying what must be included in such policies and whether IACUCs may dictate the timeframe for “shortened approval periods.” Providing additional context and/or example policies where appropriate could facilitate understanding and promote greater use of this flexibility.

Topic 2 – Proposed Guidance for Streamlining DMR Subsequent to FCR

- 1. Neither a convened meeting nor a vote is necessary to propose a DMR subsequent to FCR policy. Emails and forms are acceptable, though each member must be given the opportunity to provide their input in person or electronically prior to its approval. The policy may be implemented as soon as all members agree to it. New members must be informed of the policy and agree to its use.**

FASEB appreciates this flexibility and understands that it is regularly used by institutions of various sizes and research capacities. Allowing for in-person, written, or electronic communication enables IACUCs to quickly onboard new members.

- 2. Members are not required to sign the policy (either physically or electronically) and there is no requirement for a written statement at every meeting.**

We appreciate OLAW for making this distinction. Despite its mention in [OLAW FAQ D.19](#), several IACUCs maintain requirements for signing internal policies related to DMR subsequent to FCR. To increase awareness about this flexibility and further alleviate IACUC administrative burden, we encourage adding this distinction to the proposed “Fast Facts” segment of the website and alerting assured institutions of its availability through public webinars, e-mail communications, etc. FASEB welcomes the opportunity to collaborate with OLAW to facilitate outreach efforts.

- 3. If an IACUC uses a primary reviewer during FCR, the IACUC chairperson may designate this reviewer for DMR subsequent to FCR and for any future proposed significant changes, provided no member calls for FCR.**

As a frequently used and understood part of the protocol review process, FASEB appreciates this guidance and has no additional comments or suggestions.

Topic 3 – Proposed Guidance for Streamlining VVC

- 1. IACUCs may authorize more than one veterinarian, who need not be an employee, to conduct VVC. If the veterinarian determines the requested change is consistent with the VVC policy and appropriate for the animals in question, it may go into effect immediately.**

IACUCs extensively use this flexibility and is especially valuable for small institutions that hire contractors. Considering protocol review can be particularly burdensome for resource-limited institutions, OLAW may wish to consider compiling strategies that could specifically benefit these institutions into a dedicated tab on the agency website. Creating a comprehensive resource for small institutions could facilitate efforts to streamline protocol review, including VVC, while enhancing

policy compliance and animal welfare.

- 2. IACUCs may use *established* references (e.g., formularies, guidance documents, institutional policies, standard operating procedures) to set allowable parameters for each VVC-eligible significant change included in the VVC policy. This reduces the burden of developing references when established references that meet the needs of the IACUC are already available.**

FASEB appreciates highlighting the ability to use established references to meet IACUC needs. When drug shortages occur, veterinarians can reference formularies to avoid waiting for IACUC amendments.

- 3. The IACUC has flexibility to determine the processing and documentation of VVC (e.g., emails or forms handled by any individual in the IACUC office, IACUC chairperson, or veterinarians).**

Similar to our comments on DMR documentation, we appreciate that this flexibility is both available and consistent with OLAW's expectations for DMR and DMR subsequent to FCR.

- 4. Changes handled by VVC do not require subsequent reapproval by, or notification to, the IACUC.**

We encourage OLAW to strengthen outreach and communication efforts about this specific flexibility because numerous institutions remain reluctant to use VVC or misunderstand how to optimize it to improve IACUC efficiency. This increases administrative burden unnecessarily.

One way to increase awareness is to formally recognize VVC in OLAW's guidance on "Significant Changes to Animal Activities," ([NOT-OD-14-126](#)) which describes the VVC process in bullet #2 but does not explicitly identify it as such. To further mitigate confusion, we encourage emphasizing in the guidance that VVC changes do not require reapproval by the IACUC, as stated in the above flexibility.

Topic 4 – Proposed Guidance for Streamlining Administrative Handling of Increases in Previously Approved Animal Numbers

- 1. The increase may be expressed as a percentage, an exact number, or a number relative to the original number approved, and may be taxa-specific (e.g., a 10% increase in rodents).**

FASEB appreciates that this flexibility is written sufficiently broad to allow IACUCs the necessary freedom to review and approve animal numbers according to each protocol's needs. Additionally, we thank OLAW for clarifying that changes may be taxa-specific, as changes in the number of rodents versus primates hold separate study considerations.

- 2. The IACUC has flexibility to determine the most appropriate individuals and means of handling and documenting this process. (e.g., emails or forms handled by any individual in the IACUC office, IACUC chairperson, or veterinarians).**

Similar to our comments on DMR and VVC documentation, we appreciate that this flexibility is both

available and consistent with OLAW's expectations for DMR, DMR subsequent to FCR, and VVC.

3. Changes handled administratively do not require subsequent reapproval by, or notification to, the IACUC.

As noted previously, this is an important distinction that many IACUCs may overlook or be unaware of. We encourage OLAW to regularly communicate to assured institutions through website pages, public webinars, and social media about instances where subsequent reapproval by the IACUCs is *not* necessary. These forms of outreach and communication can be particularly meaningful for new investigators and IACUC members.

Conclusion

Thank you for the opportunity to offer comments on ways to increase the use of flexibilities for streamlining IACUC review of protocols and significant changes. However, because most IACUCs already employ these flexibilities, we encourage OLAW to publish separate RFIs specifically aimed at collecting feedback on *new* strategies designed to reduce burdensome IACUC processes such as protocol review. Organizing supplemental engagement opportunities such as listening sessions is another effective way to incorporate stakeholder feedback and make meaningful steps towards implementing the 21st Century Cures Act.

FASEB welcomes the opportunity to collaborate on future outreach and engagement efforts to effectively bridge communication gaps, improve policy compliance, and decrease administrative burden. A coordinated effort is essential to advance our shared goal of enhancing animal care and welfare.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary-Ann Bjornsti". The signature is written in a cursive, somewhat stylized font.

Mary-Ann Bjornsti, PhD
FASEB President