

Maintaining Compliance in Unprecedented Times: Flexibilities for Compliance with the PHS Policy During the COVID-19 Pandemic

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The Office of Laboratory Animal Welfare (OLAW) provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training. Through memoranda of understanding, OLAW also provides oversight for research conducted or supported by the Biomedical Advanced Research and Development Authority (BARDA), Department of Veterans Affairs (VA), National Aeronautics and Space Administration (NASA), and the National Science Foundation (NSF).

During the coronavirus disease 2019 (COVID-19) pandemic, institutions have been seeking guidance from OLAW about implementing alternative mechanisms to maintain compliance with the PHS Policy while simultaneously protecting human and animal health. In response, OLAW has developed a dedicated COVID-19 webpage, olaw.nih.gov/covid-19.htm, to address concerns and highlight flexibilities for Institutional Animal Care and Use Committees (IACUCs) to continue functioning during the pandemic. Here you will find FAQs, Guide Notices, webinars, example disaster plans, and even strategies to optimize personal protective equipment (PPE) supplies. Throughout this pandemic, OLAW's primary concern continues to be the health and well-being of humans and animals.

Coping with COVID-19 is an unprecedented challenge for us all. While we all endeavor to preserve human lives throughout this pandemic by non-pharmaceutical interventions like physical distancing, mission-critical research with laboratory animals has never been more crucial. Extreme circumstances like this pandemic are an opportunity to streamline processes, be creative, and reevaluate how we conduct business. To this end, OLAW is encouraging institutions to take advantage of existing flexibilities to facilitate physical distancing during this public health crisis while maintaining compliance with applicable federal regulations and continuing to ensure that animal care and use programs function optimally. Many of these flexibilities also have the potential to reduce administrative burden, allowing personnel to prioritize and preserve research integrity while ensuring personnel safety and animal welfare.

IACUC Functions

COVID-19 mitigation measures have given institutions the opportunity to implement innovative strategies and mechanisms to fulfill institutional and IACUC responsibilities. Most PHS Policy-mandated IACUC functions⁵ including semiannual program review, semiannual report preparation and submission, review of new and ongoing animal activities, recordkeeping, and reporting to OLAW can be accomplished remotely in accordance with OLAW guidance. Further easing logistical constraints, there are only two circumstances when a convened meeting of a quorum of the IACUC is required: 1) to suspend an activity involving animals,⁷ or 2) to conduct full committee review of protocols and significant changes.⁶ However, these functions may also be conducted virtually in accordance with OLAW telecommunications guidance.⁴ While implementing these flexibilities may reduce the number of IACUC meetings for some institutions, the *Guide* states that "The committee must meet as often as necessary to fulfill its responsibilities..."². OLAW strongly recommends that IACUCs meet at least once every six months in order to effectively carry out their functions to comply with the PHS Policy.

At any time, IACUCs may expand their use of designated member review (DMR) in lieu of full committee review (FCR) as described in the PHS Policy. Protocol review via DMR is equally as valid as FCR,³ and DMR may reduce administrative burden on the IACUC. DMR may be utilized only after all members have been provided the opportunity to call for FCR. If no member calls for FCR, the IACUC Chair appoints at least one qualified member to conduct the review. If there is a call for FCR, the review must defer to that method.

There are also flexibilities that promote physical distancing while allowing the continued performance of IACUC functions under pandemic situations, including conducting semi-annual inspections. The PHS Policy allows the IACUC to determine the best means of conducting semiannual inspections. This includes using a minimum of one qualified individual as an *ad hoc* consultant to inspect areas housing non-USDA regulated species. Consultants need not be IACUC members and may include facility managers and other similarly qualified individuals with existing access to facilities. Animal facilities, including satellite and remote facilities where in-person inspections are unsafe or impractical, may be inspected using videos or other appropriate remote methods. In addition, the timing of semiannual facility inspections may extend 30 days beyond the six-month interval from the last inspection if there is no forward drift from year to year. If inspections cannot be conducted in this time frame, institutions may request a waiver from OLAW as described below.

Deviations from the PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and Assurance

PHS-Assured institutions must have an approved Animal Welfare Assurance using the PHS Policy and *Guide for the Care and Use of Laboratory Animals* (*Guide*) as the basis for developing and implementing an institutional animal care and use program. Institutions that are unable to comply with a PHS Policy provision may submit a waiver request with justification to OLAW, the only entity authorized to approve waivers to the PHS Policy.⁵ Currently, OLAW is evaluating and approving waivers for the conduct of semiannual facility inspections if inspections cannot be safely conducted as a result of the pandemic. An authorized institutional representative, such as the Institutional Official, IACUC Chair, IACUC Coordinator, or Attending Veterinarian, may submit a waiver request with justification to olawdpe@mail.nih.gov. The IACUC should determine the best means of informing all members of any temporary or permanent changes to the institution's animal care and use program (including waivers) by teleconferences, virtual meetings or email, for example.

If an institution cannot conduct business as described in their Assurance, the business may be conducted in an alternative manner both temporarily during the pandemic, and permanently, if the solution is more effective for the institution. In both cases, flexibilities must be compliant with the PHS Policy and the *Guide*, and not compromise personnel safety or animal welfare. A waiver from OLAW is not required for the implementation of such temporary changes. However, the changes should be documented in the institution's disaster or emergency preparedness plan. Institutions must also ensure that all IACUC members are kept apprised of the proposed changes before implementation. Lastly, only permanent program changes should be included in the 2020 Annual Report to OLAW, and the Assurance should be updated at the time of renewal.

The *Guide* endorses a performance-based approach which provides flexibility in achieving a desired outcome using

professional input, sound judgment, and a team approach.¹ *Guide*-specific exceptions and well-established performance standards are not considered departures and are acceptable to implement without IACUC approval. However, for changes that are departures from the *Guide*, the IACUC must review and approve them before implementation, and they must be based on scientific, veterinary, or animal welfare justifications. For more information on departures, visit olaw.nih.gov/guidance/departures-from-the-guide.htm.

Conclusions

Although many of the flexibilities discussed here are not pandemic specific and can be implemented as standard IACUC business practices, they are extremely valuable during pandemic situations. OLAW's COVID-19 webpage provides resources specific for the COVID-19 pandemic. A Disaster Planning and Response Resources page, olaw.nih.gov/resources/disaster-planning.htm, can assist institutions with planning and responding to a variety of public health crises.

Coping with the coronavirus pandemic is challenging, but it is also an opportunity to learn and to develop more resilient animal care and use programs. As COVID-19 continues to spread, institutional displays of solidarity abound, and the initiatives and efforts taken in the face of adversity have been remarkable. However, there are still many unanswered questions. How did your institution cope? Where was your disaster plan strong, and where was it weak? What worked, what could be improved? How could your institution update IACUC policies and procedures to reduce administrative burden? How can institutions safely return their personnel to work? If you have any questions, you can always contact OLAW at olaw@mail.nih.gov, and we will be happy to assist you. As always, we are only a call or email away to provide the much-needed virtual advice to ensure the continued health and well-being of personnel and animals during these challenging times.

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