

## **FASEB Webinar Series: Animal Research Regulations**

### **Part 1: Understanding Federal Oversight Mechanisms**

Speakers: **Tanya Times (USDA)**

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#### **Questions from the Audience**

- 1) Is there ever a time when the IACUC approval can be pending (3rd year award) while the bench work is conducted to eventually move to an animal?**

OLAW response: In certain cases, IACUC review of animal activities is conducted later in the life cycle of a grant or contract. IACUC review may be delayed if the animal activities will not occur until a year or later in the award period as part of the research design described in the grant application or contract proposal (e.g., the initial development of a drug or device with subsequent animal testing projected into the future). In these circumstances, the funding component will issue a Notice of Award with a special term and condition indicating that no funds may be drawn from the grant or contract for animal activities until a valid IACUC approval date has been provided to the funding component.

VA response: Before any work on a VA research project may begin, local approval for all areas of research (animal, human, bench) must be in place. Thereafter, the review and approval of the various components are generally independent of each other, and follow the expectations of each committee responsible for reviewing the work (IACUC, IRB, IBC). For VA-funded research with animals, IACUC approval of the protocol for all years of the award is generally required before funding will be released, even if the award is for more than three years, or if the animal studies will not begin until much later in the study (e.g. the 4<sup>th</sup> year). However, there is some flexibility and sometimes the VA Office of Research and Development, which manages the release of the funding, does arrange on a case-by-case basis for the funding of bench research to be released first, while funding for the research with animals is held, pending later review and approval of the protocol by the IACUC and the Chief Veterinarian's office.

- 2) For NIH awards where Just-In-Time (JIT) paperwork is requested how should institutions handle requests from the NIH grants manager for that JIT paperwork in a short time period for example within a week.**

OLAW response: The institution, through the Authorized Organization Representative, should communicate to the NIH grants manager the need for a delay indicating that the IACUC is unable to meet during the short time period requested. If this delay occurs in the last quarter of the fiscal year, the NIH grants manager may issue a restricted award with a special condition which allows funds to be released but restricts the use of funds to research not involving animals.

Instead of waiting until the Just-In-Time notification from NIH, an approach that some institutions have found useful is for the sponsored projects office to contact the PI after receiving

the priority score. If the PI has a fundable score they are asked to determine if a new IACUC protocol or significant changes to an existing protocol are needed based on the new animal research activities to be funded. This will allow the maximum time for IACUC review.

**3) Are there any plans for writing Animal Welfare Regulations (AWR) for birds?**

USDA response: Nothing has started yet. We have no further updates at this time.

**4) When can we expect to see the USDA Policy Manual?**

USDA response: Much of the guidance in the policies was moved to the Inspection Guide or found in the tech notes. These resources are available on the AC website. If/when the policy manual is reissued, it will be posted first on regulations.gov for comment.

**5) Any advice or wisdom you can share as we navigate the COVID-19 pandemic as animal care providers?**

OLAW, USDA and VA are deeply concerned about the impact of the COVID-19 pandemic on the ability of institutions to support the well-being of animals and personnel during this public health emergency.

OLAW response: In Guide Notice [NOT-OD-20-088](#), OLAW provides information on flexibilities in the PHS Policy on Humane Care and Use of Laboratory Animals ([Policy](#)) that are applicable to implementing a pandemic plan for animal care and use programs. In this Notice, you will find measures that institutions may implement for conducting semiannual animal facility inspections and IACUC business, plus how to request a waiver for requirements of the PHS Policy. OLAW's special webinar, Pandemic Contingency Planning and Its Impact on Animal Care, is available online at: <https://olaw.nih.gov/education/educational-resources/webinar-2020-03-19.htm>.

You'll also find Resources and Supporting Materials including:

- NIH Division of Veterinary Resources Continuity of Services Plans
- Johns Hopkins University COVID-19 Phased Contingency Plan
- Michigan State University's Sample Policy for Conducting IACUC Business in the Event of a Pandemic
- NIH 2008 Pandemic Flu Readiness Plan
- Slide Handouts
- Slides, with helpful links

If OLAW determines that additional measures must be implemented to meet the needs of the research community and funding components, additional guidance will be announced.

USDA response: Stay safe. Make sure the animals receive the daily care they need. Contact us anytime with specific concerns. Look at the NIH website for their examples of pandemic planning.

VA response: Remember that both the safety of the personnel and the welfare of the animals must be protected. VA has announced modification of some of the VA-specific requirements for

oversight of VA research with animals, to allow greater flexibility in how that is achieved in these extraordinary times (FAQs available via a link on the home page about VA research with animals, [https://www.research.va.gov/programs/animal\\_research/default.cfm](https://www.research.va.gov/programs/animal_research/default.cfm), in the yellow box below the photo, labeled “COVID-19 and VA Animal Care and Use Programs”). These are being updated as the situation develops, so check back when new questions come up. If you have additional questions, do not hesitate to contact Dr. Michael Fallon (CVMO, [michael.fallon@va.gov](mailto:michael.fallon@va.gov), 404-732-5471) or Dr. Alice Huang (Deputy for IACUC Guidance, Office of the CVMO, [alice.huang@va.gov](mailto:alice.huang@va.gov), 404-217-6553).

For more information on each agency’s overall response to COVID-19, see:

NIH: [NIH Extramural COVID-19 Response webpage](#).

USDA Animal and Plant Health Inspection Service (APHIS) Frequently Asked Questions – <https://www.usda.gov/coronavirus>

COVID-19 and VA Animal Care and Use Programs – Frequently Asked Questions – [https://www.research.va.gov/programs/animal\\_research/animal-care-FAQ-COV-19.docx](https://www.research.va.gov/programs/animal_research/animal-care-FAQ-COV-19.docx)

**6) Do the AWR address issue of MOPs on different protocols**

USDA response: It is addressed in 2.31(d)(1)(x) -part 2 of the AWA R&S (the ‘bluebook’)