Incorporation of the OLAW Guidance on Significant Changes to Animal Activities

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ABSTRACT

On August 26, 2014 the Office of Laboratory Animal Welfare (OLAW) released Guidance on Significant Changes to Animal Activities (NOT-OD-14-126). The guidance clarified that a veterinarian could serve as a subject matter expert and could approve the following types of changes:

a. Anesthesia, analgesia, sedation, or experimental substances;
b. Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and
c. Duration, frequency, type, or number of procedures performed on an animal.

The guidance states the veterinarian review must be documented and allow the Institutional Animal Care and Use Committee (IACUC) to determine the best documentation process for the Committee and the institution.

The Jackson Laboratory’s (JAX) Animal Welfare & Compliance Office sought to develop a new process that clearly (1) documented changes, (2) reduced regulatory burden, (3) provided clear instructions to the end user, (4) kept the IACUC informed, and (5) provided a thorough review.

THE PROCESS

1. The Principal Investigator submits the change request to the AWC office.
2. The AWC office processes the request and then submits the request for review. The change is assigned to a veterinarian and the IACUC is copied on the correspondence.
3. The veterinarian reviews the change and notifies the AWC office of his/her approval or the need to reclassify the review type.
4. If approved; the AWC office records the approval, issues the approved change request to the Principal Investigator and project managers, and maintains a record of the correspondence.
5. All staff working under the animal use protocol receive a copy of the approved change request.

THE BENEFITS

JAX found that implementing the new process yielded the following benefits:

1. Reduction in the number of IACUC members required to review significant changes from 3 to 1;
2. Reduction in the number of significant changes the Environmental Health and Safety Services (EHSS) representative was required to review. Previously, the EHSS representative was required to review all changes even if there were no safety related concerns;
3. Allows for significant changes to be approved immediately after the veterinarian has provided approval. Previously, Minor and Major change amendments required a twenty-four (24) hour approval hold period from the time they were distributed to the IACUC even if all Designated Member Reviewers approved. This time was designated to allow other IACUC members time to comment on the requested change;
4. Allows the Principal Investigator to gather timely feedback from the IACUC and accommodate last minute changes;
5. Strengthens the relationship between the IACUC and Principal Investigators;
6. On average, the amendment approval period dropped from two (2) business days down to 0.25 business days;
7. Reduces the regulatory burden on PIs and administrative personnel.

CONCLUSIONS

The Jackson Laboratory’s Animal Welfare & Compliance office implemented the veterinarian review process with the assistance of the IACUC, veterinary staff, and the Principal Investigators. The joint effort allowed for all parties to contribute their feedback and expertise which yielded a robust review process which reduces regulatory burden, clearly documents and tracks changes to animal use summaries, allows the changes to be implemented in a timely fashion, and does not negatively impact animal welfare.

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