

Testimony in lieu of a presentation to 21st Century Cures Act Listening Session with NIH, USDA, and FDA on January 9, 2018.

This is a request for reconsideration of reporting requirements in NOT-OD-05-034 *Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals* that directly impact and place a burden on Principal Investigators. This is an expansion of recommendations 18 and 19 in *“Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden”* submitted by FASEB, AAMC, and COGR, with assistance from NABR.

PHS Policy IV.F.3 requires “a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
- b) any serious deviation from the provisions of the *Guide*; or
- c) any suspension of an activity by the IACUC.”

Recent publications* by OLAW staff analyzing reports of adverse events submitted by assured institutions in compliance with NOT-OD-05-034 indicate 37% of the reports are on “animal study protocols” or “investigator or research team” issues. These publications do not provide additional information on the nature of said adverse events. In my experience, protocol adverse events cover many activities from doing an additional blood draw to failure to document provision of post-op analgesia to using an AVMA-approved method of euthanasia when the protocol stipulated another AVMA-approved method (the PI was approved to use the second method on another protocol involving the same species) to doing a survival surgical procedure on an animal with no protocol to do so. Similarly, personnel issues are many and varied and range from competent and trained individuals working with animals but not listed on a protocol to unqualified and untrained individuals working with animals.

While some of these incidents have greater animal welfare implications than others, when it comes to reporting such noncompliance to OLAW, regardless of the nature or severity of the situation, they are all treated the same. Because of this reporting requirement, the intensity of internal review and paperwork does not change with severity of the incident: numerous meetings with PI and/or staff, emails back and forth between IACUC and PI, visits to the PI’s lab, committee deliberations, meetings with the IO, etc. Clearly, reviewing incidents, even those with minimal animal welfare implications, puts a burden on the PIs, the IACUC, and IACUC staff. And, regardless of severity of the adverse event, the PI gets the same “punishment” of being reported to OLAW and, possibly, their funding agency. Even though the PI’s name is not required to be reported, the grant number can be used to identify the PI.

Then there is the emotional and/or psychological burden on the PIs, which seems to have been overlooked. Being reported to OLAW and their funding agency is not an insignificant event to PIs who have genuine concern that this will impact their future funding opportunities. They are also burdened by concerns of reprisals from activists when said reports are released to activists’ FOIA requests. Some PIs, their staff, and colleagues have been further burdened as targets of activists using information collected from reports of adverse events.

A related problem is that OLAW’s FAQ G.8 directs institutions to have plans to protect the institution and its investigators from “Acts of vandalism and the threat or use of violence” while requiring institutions to report their PIs in writing for noncompliance regardless of severity. This complication should be resolved to protect animals, investigators, the institutions, and the federal funds the institutions hold.

Assured institutions are **not** required to send reports to OLAW documenting the IACUC has performed the following required activities:

- Addressed all required elements when reviewing protocols and subsequent modifications;
- Assessed all aspects of the institution's animal care program or inspected all animal facilities as part of the semiannual program review; or
- Made recommendations to the IO regarding the program, facilities, or personnel.

Why, then, are assured institutions required to send reports that it has reviewed concerns when such a report does not itself benefit the animals, the investigators, or the institution?

To reduce burden on investigators, IACUCs, and institutions complying with IV.F.3, OLAW should consider:

- Defining serious, perhaps in concert with significant deficiency – “one that, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.”
- Types of incidents that need to be reported promptly:
 - Those that result in harm vs has the potential to cause harm and
 - Egregious, intentional noncompliance.
- Types of incidents that could be included in the assured institution's annual report, or not reported at all, such as:
 - Activities are not compliant but did not cause or have the potential to cause harm to animals;
 - Activities that did not and would not affect animal welfare; and
 - Accidental or unintentional noncompliance with minimal impact on animals.
- Timing or compilation of such reports:
 - Promptly vs annually or
 - In aggregate vs individually.
- Information to be included in such reports:
 - Species – this should not matter even if there is a serious incident that results in harm to animal and certainly should not matter if there are no animal welfare concerns;
 - Grant number – this information allows activists to identify all personnel working on a federally funded grant; and
 - Category of individuals involved, as this information allows activists to identify personnel working on a federally funded grant.
- Whether the same IACUC that is charged by PHS Policy's Section IV.B and C to “oversee the institution's animal program, facilities, and procedures”, to “review concerns involving the care and use of animals at the institution” and to review “activities related to the care and use of animals” can make the determination of the seriousness of any noncompliant or adverse event, correct the problem, and take steps to prevent recurrence without providing a report to OLAW.
- Whether providing detailed reports benefits the animals, the investigators, or the institution.

Sending reports required under NOT-OD-05-034 documents an activity conducted by an institution to benefit the animals, the investigators, or the institution, but does not itself benefit the animals, the investigators, or the institution. But it does put the animals, the investigators, and the institution at risk.

I hope OLAW will consider favorably this change in the way serious or continuing noncompliance with the Policy and serious deviations from the provisions of the *Guide* are managed and reported by assured institutions.

*https://grants.nih.gov/grants/olaw/references/laband46_06_0617.pdf
<https://grants.nih.gov/grants/olaw/references/compliance-data-summary.pdf>