

Revising the Requirements for Prompt Reporting under PHS Policy IV. F. 3ⁱ

– Slightly over 12 years ago, OLAW issued its revised Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals (NOT-OD-05-034). Since the release of that guidance, the management of Animal Care and Use Programs (ACUP) has evolved due to a significant commitment on the part of the research community to assure institutional compliance with the interrelated system of regulations, policies and guidelines that make up the dynamic oversight process for the care and use of laboratory animals. Given the dynamic nature of the process and the experience gained over the past 12 years, it would seem that revisiting the previous guidance would be in order and to make changes that could reduce the administrative burden on those involved in the administration of ACUPs and the OLAW without impacting the humane care and use of laboratory animals.

Background

Sec. 495 of the Health Research Extension Act of 1985 (HREA) - Public Law 99-158 directs the Secretary of Health and Human Services acting through the director of NIH to establish guidelines for the proper care and treatment of animals used in biomedical and behavioral research. The Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) contains the guidelines developed under the authority of PL 99-158. The PHS Policy is administered by the Office of Laboratory Animal Welfare (OLAW). Within that Policy is a requirement for promptly providing OLAW with a full explanation of the circumstances and actions taken with respect to any serious or continuing noncompliance with the Policy, any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals (Guide) or any suspension of an activity by the Institutional Animal Care and Use Committee (IACUC).

In 2005, NIH released guidance and outlined when non-compliance should be reported.¹ This guidance was intended to replace previous guidance issued January 12, 1994 and updated in 2004, which contained criteria for what constitutes a serious or continuing noncompliance with the PHS Policy and a serious deviation from the Guide. The 2005 guidance did not specifically include these criteria but rather included a list of examples starting with one of the criteria “conditions that jeopardize the health or well-being of animals, including natural disasters, accidents and mechanical failures, resulting in actual harm to the animals”. Many of the remaining examples may or may not have any impact on animal health and well-being that would appear to warrant prompt reporting. In the 2005 guidance a dual purpose is identified as requiring prompt reporting. The first to ensure that issues affecting animal welfare are addressed and corrected which is consistent with the language cited above. The second involves monitoring the institution’s animal care and use program oversight under the policy, evaluating allegations of noncompliance and assessing effectiveness of the PHS policies and procedures. Since the issuance of this guidance, institutions have been routinely submitting non-compliance reports where there was no apparent negative impact on animal welfare rather than focusing on those that directly impact it. The examples described in the second purpose for prompt reporting could be effectively addressed by changing the guidance to require prompt reporting of issues that directly affect animal health and well-being, while all others are included in a summary report included with the annual report.

¹ <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>

In addition to what actually needs to be reported promptly to enable OLAW to monitor an institution's animal care and use program oversight under the policy, evaluate allegations of noncompliance and assess effectiveness of the PHS policies and procedures is the issue of what constitutes a full explanation of the circumstances and actions taken. The current recommendations for the final report ² require a level of detail that could be reduced and still provide OLAW with the necessary information to carry out the duties listed above. Since the Policy only requires a full explanation of the circumstance and actions taken, it should not be necessary to include any information on any preliminary reports especially with the specificity included in the guidance document. It would also appear that the explanation of the incident does not need to contain more than general details of the events, such as failure to follow an approved protocol, failure to provide appropriate training to staff, failure to follow internal policies related to the care and use of animals, etc. It is also unclear as to why the inclusion of the species is required, since all vertebrate animals are covered and thus subject to the same level of care. The first sentence of the bullet on corrective actions would appear to be sufficient to meet the requirements of the Policy. It is unclear why the bullet on the "Impact on PHS-Supported Activities:" is even necessary since the explanation of the incident should provide that information.

Recommendation: The current guidance for reporting a serious or continuing noncompliance with the Policy or a serious deviation from the provisions of the Guide should be revised. Currently the guidance does not distinguish between the two types of reportable incidents in terms of the requirements for reporting or the examples of what should be promptly reported. Since the Policy specifically addresses the functions of the Institutional Animal Care and Use Committee including the review of proposed research activities and the institutional requirements for maintaining required records, any failure to comply with any of the requirements delineated in these sections of the Policy should be promptly reported. When it comes to deviations from the provisions of the Guide, the requirement for prompt reporting should be based upon whether the incidence had a negative impact on animal health and well-being, while any incidents that did not directly impact animal health and well-being could be summarized in annual report. In addition the level of detail required in the report should be changed such that the report addresses the general nature of the incidents and how the incident was addressed.

¹ **PHS Policy IV. F. 3**

3. The IACUC, through the Institutional Official, shall promptly provide OLAW with 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.

² https://grants.nih.gov/grants/olaw/reporting_noncompliance.htm