

## New guidance on prompt reporting to OLAW under PHS Policy

On 24 February, the Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, published new guidance on the prompt reporting requirements of the PHS *Policy on Humane Care and Use of Laboratory Animals*<sup>1</sup> (*Policy*) to help Institutional Animal Care and Use Committees (IACUCs) and Institutional Officials (IOs) determine “what, when, and how situations should be reported under IV.F.3 of the *Policy*, and to promote greater uniformity in reporting<sup>2</sup>.”

PHS *Policy* at IV.F.3, requires that the IO promptly report to OLAW any situation involving (1) serious or ongoing noncompliance with PHS *Policy*; (2) serious departure from the requirements outlined in the

*Guide for the Care and Use of Laboratory Animals (Guide)*; or (3) suspension of any activity by the IACUC.

In its new guidance, OLAW lists examples of situations that institutions should report to OLAW, as well as situations that do not have to be reported. In addition to those identified by the US Department of Agriculture (USDA), the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), or by outside individuals, reportable situations include the following examples:

- “Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical fail-

ures, resulting in actual harm or death to animals;

- “Conduct of animal-related activities without appropriate IACUC review and approval;
- “Failure to adhere to IACUC-approved protocols;
- “Implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
- “Conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- “Conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
- “Conduct of official IACUC business during a period of time that the Committee is improperly constituted;
- “Failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- “Chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
- “Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;
- “Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- “Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);

## REGULATION UPDATE

### NIH updates regulations on conflict of interest

On 3 February, in response to Congressional inquiries and public hearings in the House and Senate about consulting activities of several NIH employees, the National Institutes of Health (NIH) published an interim rule with request for comments relating to outside activities, financial holdings, and awards for all NIH employees<sup>1</sup>.

According to a recent press release from the agency, “All NIH employees are prohibited from engaging in certain outside employment with:

“1) Substantially affected organizations, including pharmaceutical and biotechnology companies;

“2) Supported research institutions, including NIH grantees;

“3) Health care providers and insurers; and

“4) Related trade, professional or similar associations<sup>2</sup>.”

NIH employees may not invest in organizations substantially affected by the NIH (e.g., biotechnology and pharmaceutical industries), and are required to file public and confidential financial disclosure reports. However, according to the NIH, they may continue “teaching courses at universities, writing general textbooks, performing scientific journal reviews, participating in scientific meetings and providing general lectures to physicians and scientists at continuing professional education and similar events, as well as practicing medicine as appropriate, provided that the activities are otherwise in accordance with existing law and adhere strictly to the conditions specified in the new rules<sup>2</sup>.”

1. DHHS. Interim final rule with request for comments. Supplemental standards of ethical conduct and financial disclosure requirements for employees of the Department of Health and Human Services. *Federal Register* **70(22)**, 5543–5565 (3 February 2005).

2. NIH. NIH announces sweeping ethics reform. (1 February 2005). <http://www.nih.gov/news/pr/feb2005/od-01.htm>.