

## Checklist for ACUC Incident Investigation

The ACUC Chair receives notification of issue/incident and documents for the record the time and date of notification, who notified the Chair, and who else was notified.

The Chair initiates appropriate steps to validate the real or potential seriousness of the issue/allegation based on the “Guidance on Prompt Reporting to the Office of Laboratory Animal Welfare (OLAW)” <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>.

The OLAW guidance states that events should be reported if they involve:

- Any serious or continuing noncompliance with the PHS Policy
- Any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*
- Any suspension of an activity by the ACUC

And OLAW provides the following examples of potential reportable issues:

- Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- Conduct of animal-related activities without appropriate ACUC review and approval;
- Failure to adhere to ACUC-approved protocols;
- Implementation of any significant change to ACUC-approved protocols without prior ACUC approval;
- Conduct of animal-related activities beyond the expiration date established by the ACUC;
- Chronic failure to provide space for animals in accordance with recommendations of the Guide; g) participation in animal-related activities by individuals who have not been appropriately trained; h) failure to monitor animals post-procedurally as necessary to ensure well-being;
- Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- Failure to ensure death of animals after euthanasia procedures;
- Failure of animal care and use personnel to carry out veterinary orders (e.g., treatments);
- Conduct of official ACUC business requiring a quorum in the absence of a quorum;
- conduct of official ACUC 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;
- ACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the NIH IRP Animal Welfare Assurance.

If the issue/incident was initiated by the NIH ARAC Ombudsman, the guidance provided in the ARAC Guideline should be followed: [http://oacu.od.nih.gov/ARAC/documents/Complaint\\_Response.pdf](http://oacu.od.nih.gov/ARAC/documents/Complaint_Response.pdf).

The Director, Office of Animal Care and Use (OACU) should be notified as soon as the Chair has determined a potential reportable incident has occurred. The OACU Director may render an opinion upon receiving the Chair’s initial report whether the issue/allegation appears to be an incident that should be reported to the OLAW.

If appropriate, the Chair appoints an investigative agent or subcommittee from the ACUC membership to investigate the issue/allegation.

If the issue/incident occurred in a shared or central facility, the guidance provided in the following ARAC Guideline should be followed:

[http://oacu.od.nih.gov/ARAC/documents/Core\\_Special\\_Labs.pdf](http://oacu.od.nih.gov/ARAC/documents/Core_Special_Labs.pdf).

The investigative agent or subcommittee conducts investigation, formulates recommendations, and reports back to the ACUC.

At a convened meeting with a quorum present, the ACUC then deliberates the investigative report & associated recommendations, formulates any additional conditions and/or corrective actions, and either:

- Awaits further information from the subject of the investigation
- Awaits further information from the investigative body or
- Closes out the investigation and renders a final report

The final report for OLAW reported events should be:

- In memo format and a draft version shared with the Director, OACU prior to submission
- Free of building numbers and names; rather should use nouns such as animal caretaker, technician, investigator, animal facility
- Signed by the ACUC Chair;
- Addressed to Michael M. Gottesman, M.D., Deputy Director for Intramural Research; and **NOT** be through: OACU in the heading
- Delivered to OACU for final routing and disposition

Attachments may be appended to the final report if their inclusion is integral to informing OLAW of key aspects of the background surrounding the incident and demonstrate the ACUC's conviction that the corrective actions taken preclude a reoccurrence of the incident. Attachments to be appended to the final report may include:

- Relevant background/supporting documentation
- Interim reports
- subcommittee reports

Upon receipt of the ACUCs final report, OACU will prepare a cover letter for Dr. Gottesman's signature and correspondence transmitting the IC ACUC report to OLAW.

Close-out reports of incidents not destined for reporting to OLAW should be kept internally.

*Revised 06/01/2005, 06/14/2006, 05/10/2011, 01/02/2013*