This guidance applies to APLAC approved animal research and details events or circumstances that must be ***promptly*** reported to the APLAC during the conduct of Animal research. "Prompt reporting" is done using the complication form available on the APLAC website.

Events and information which require prompt reporting to the APLAC

1) Complication

A complication is an unexpected outcome of approved animal work that adversely influences animal welfare (and usually involves pain, distress or death of an animal), the possibility of which was not described in the approved APLAC Protocol.

Examples of complications include:

a) Morbidity or mortality resulting from complications not described in the APLAC protocol.

b) Greater number of mortalities, more severe responses, or when animals appear to be in more pain or distress than expected/described in the APLAC protocol:

- Example 1: If 10% of animals die following surgery when a 5% mortality rate was described in the approved protocol.
- Example 2: If a transgenic line is produced and the phenotype is more severe or debilitating than anticipated and/or described in the approved protocol.

c) Post-surgical complications (e.g. respiratory distress, infection, wound dehiscence, mortality).

d) Facility or equipment failure that has a negative impact on animal welfare.

e) Operator error.

2) Noncompliance, Deviations or Deficiencies

An action or activity inconsistent with the approved APLAC protocol, other guidelines or polices of the APLAC, AWA Regulations, PHS policy or other relevant state or federal laws that protect animal subjects used in research, teaching and testing.

Deviations from the *Guide* must be based on scientific, veterinary, medical, or animal welfare issues and must be approved by the APLAC in the protocol or through following approved APLAC guidelines (which must be agreed to in the approved protocol).

Deficiencies are issue that are noted during the IACUC semiannual inspection of animal use areas. Deficiencies are classified as minor or significant.

Examples of reportable noncompliance include:

a) Using more animals for research, teaching or testing than approved in the APLAC protocol.

b) Performing experiments before they have been reviewed and approved by the APLAC:

- Example 1: Administering a test article to an animal prior to receiving APLAC approval.
- Example 2: Performing a surgery that is not described in the APLAC protocol.

c) Individuals that have not been added to the protocol and approved by the APLAC performing work on animals.

d) Deviating from the APLAC approved protocol:

- Example 1: Allowing tumors to grow beyond the limit stated in the approved APLAC protocol or associated APLAC guidelines.
- Example 2: Not administering post-operative analgesics as outlined in the approved APLAC protocol.

Examples of reportable Deviations from the *Guide* include:

a) Singly housing animals without APLAC-reviewed scientific justification, documented veterinary-related concern or reasons outlined in approved APLAC guidelines.

b) Deviations from cage changing schedules without APLAC-reviewed scientific justification documented veterinary-related concern or reasons outlined in approved APLAC guidelines.

Examples of Deficiencies include:

a) **Minor Deficiencies:** A problem for which an immediate solution is not necessary to protect life or prevent distress.
   - Example 1: Peeling or chipped paint in an animal housing room
   - Example 2: Cardboard boxes on the floor in an animal-use room

b) **Significant Deficiencies:** A problem, which is or may be a threat to the health or safety of animals. These deficiencies must be corrected immediately
   - Example 1: Inoperable HVAC systems.
   - Example 2: Situations that cause injury, death, or distress to animals.

3) Other events or information

a) Any event or new information that may be pertinent to the protocol or animal care.

b) Suspension of research.

c) Report from an outside entity.

How to Submit a Report; Timeframes

- **Submit to APLAC** complication form available on the APLAC website.
  - **Timeframe for reports**
    - ***If animal welfare is an ongoing concern***
      The Veterinary Service Center (VSC) must be contacted ***immediately.***
      Please note there is a veterinarian on call and available 24 hours a day, 365 days a year.
    - ***If there is no current animal welfare concern***
      Report to the APLAC using this form ***within 5 working days*** from the Protocol Director (PD) learning of the event.

Definitions

When the event is determined to be:

- Serious Noncompliance:
  - Noncompliance that includes 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
- Continuing Noncompliance:
  - A pattern of noncompliance that continues to occur after a report of noncompliance and a corrective action plan has been reviewed and approved by the APLAC, after an investigator has been warned to correct errors or noncompliance, or a circumstance in which an investigator fails to cooperate with investigating or correcting non-compliance.

Resources: Regulation*s and Guidance*	
OLAW	• PHS Policy, section IV.F.3 • Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals :NOT-OD-05-034 • Guide for the Care and Use of Laboratory Animals (*Guide*)
USDA	• Animal Welfare Act Regulations, 9 CFR AWA §2.31-§2.37
Resources: Other References	
Stanford	• Stanford University DoResearch, https://doresearch.stanford.edu/policies/research-policy-handbook/laboratory-animals-research