

## Adverse Events at Research Animal Facilities

Dr. Swapna Mohan, DVM, MS, PhD    Dr. Neera Gopee, DVM, PhD, DACLAM, DABT  
Division of Policy & Education    Division of Compliance Oversight

Office of Laboratory Animal Welfare  
National Institutes of Health

OLAW Online Seminar  
December 7, 2017



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### Contents

**Adverse Events at Research Facilities**, *Lab Animal* 2017; 46(6):244-249

- What are adverse events at research facilities?
- Categorizing adverse events
- Steps for prevention and mitigation
- Reporting requirements
- Support and resources



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### What are Adverse Events?

Unexpected incidents that lead to harm, or endanger the well-being of animals and humans at a research facility.

Broad term covering many unforeseen events

- Weather related events
- Accidents
- Animal husbandry issues



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### Examples of Adverse Events

Natural disasters

Over 15 weather related incidents in 2017 causing loss of >\$1B

Accidents

Human error, accident, neglect

Mechanical failures

HVAC, power, ventilation, and light issues

Biological events

Veterinary care issues, reaction to drugs

Animal husbandry-related events

Food and water availability, sanitation failure, enrichment issues



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### Preparedness and Risk Mitigation

- Each institution is unique in terms of its location, size, research specialization, animal numbers, and construction.
- Review of prior adverse events and their sequelae will help prepare for the most likely effects.
- Accurate assessment will help to identify flaws, and to test out action plans.



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### Categorizing Adverse Events Into a Matrix

- Many adverse events have unforeseen sequelae.
- Risk management requires assessment of probability, function/system that may be disrupted, and impact.
- Identifying possible events and categorizing them can help with:
  - planning effective preventive measures,
  - prioritizing action plans, and
  - coordinating efforts to mitigate impact.



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### Identifying Critical Systems and Functions

Identify the essential functions of the facility

- Ventilation
- Potable water
- Food
- Power
- Prevention of animal injury
- Biosafety



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### Building the Matrix: Unanticipated Effects

Compare adverse events and their sequelae to the critical functions.

Prepare for hypothetical scenarios by linking the two (How would X affect Y?).



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### Adverse Events Matrix: Extensive Events

Natural	Possible Secondary Effects	Technical	Possible Secondary Effects
<b>Weather</b>			
-Drought	-Power outage	<b>Hazardous materials</b>	
-Hurricane	-Equipment failure	-Water supply contamination	-Spread of hazardous materials
-Tornado	-Temperature fluctuations	-Chemical spills	-Health hazard
	-Inaccessibility of supplies, personnel	-Radiation leak	-Long term effects
-Winter storm		<b>Large scale failures</b>	
<b>Seismic</b>	-Power outage	-Mechanical	-Temperature fluctuations
-Earthquake	-Equipment failure	-Electrical	-Disruption of the light/dark cycle
-Tsunami/ flooding	-Temperature fluctuations		
	-Inaccessibility of supplies, personnel	<b>Civil</b>	<b>Possible Secondary Effects</b>
-Landslides		<b>Attack</b>	
<b>Emergencies</b>		-Terrorism	-Access to facility limited
-Fire	-Damage to building, structures		-Damage to building, people, animals
-Flood	-Equipment malfunction	-Assaults	-Transportation systems affected
<b>Biological</b>		-Bomb threats	-Negative publicity
-Disease outbreak	-Rapid spread	-Demonstrations	-Equipment malfunction
-Infestations (mold, insects)	-Mass culling required	<b>Computer security breach</b>	

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### Adverse Events Matrix: Contained Events

Inadvertent	Possible Secondary Effects	Inadvertent	Possible Secondary Effects
<b>Husbandry-related</b>			
-Inadequate, inaccessible or spoiled food/water	-Health issues	<b>Biological</b>	
-Insufficient enrichment	-Morbidity and mortality	-Adverse reaction to biologics	-Affect study results
-Overcrowding	-Stereotypies	-Veterinary care issues	
	-Aggression	-Failed euthanasia	
<b>Human error</b>		<b>Mechanical</b>	
-Escapes	-Negative publicity	-Electrical issues	-Fire and related damage
-Improper care during transportation	-Interference with study results	-Water supply	-Flooding
-Inadequate care, Mishandling	-Injury to people, animals	-HVAC	-Potential for infections
<b>Animal nature</b>		-Lighting	-Affect light/dark cycle
-Aggression	-Injury to animals and people	<b>Deliberate</b>	<b>Possible Secondary Effects</b>
-Getting trapped, injured		-Abuse/ neglect	-Harm to animals
		-Theft/ crime	-Protests, negative publicity
		-Sabotage	-Damage to building, animals

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### Extensive Adverse Events: List Available Resources

- Emergency contacts
- Emergency equipment and use
- Equipment capacities, spare parts
- Floor layouts

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### Extensive Adverse Events: Communication Network

- Facility administrators
- Animal care staff
- Local emergency responders
- Service technicians for equipment
- Vendors for supplies
- Research personnel



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### Extensive Adverse Events: Shelter in Place

- Shelter-in-place procedures
- Steps to mitigate animal distress
  - HVAC, power, food and water
  - Storage of provisions



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### Extensive Adverse Events: Evacuation Procedures

- Evacuation procedure
  - Triage and prioritization
  - Escapes
- Temporary housing locations
- Transportation
- MOU and agreements with local/ partner institutions



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### Extensive Adverse Events: Euthanasia

- Humane and timely euthanasia
  - Prioritization
  - Supplies
  - Personnel
- Disposal of carcasses
  - Temporary storage



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### Extensive Adverse Events: Personnel Training

- Identify essential personnel
- Table top exercises to walk through response steps
- Rehearsals of scenarios
- Update contacts regularly
- Copy of action plan to local emergency personnel



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### Testing of Equipment

Regular testing of emergency equipment.

- Live rehearsals
- Other testing
- Regular maintenance



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### Commonly Reported Adverse Events

- Death during transport
- Failure to provide post procedural analgesia



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### Contained Adverse Events: Available Resources

- Emergency contacts
- Emergency equipment and use
- Equipment capacities, spare parts
- Floor layouts

Additional items for contained events:

- Alternate housing
- Service person contact information



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### Contained Adverse Events: Communication Network

- Attending veterinarian
- Animal care staff
- Facility director
- Facility administrators
- Research personnel
- Local emergency services



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### Action Plan for Contained Events

- Should be described for possible adverse events during routine facility operations
- Can be part of protocols or other documents
- Personnel should be familiar with these plans




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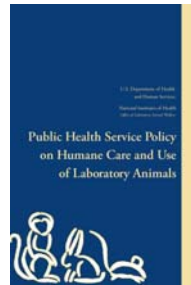
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### PHS Policy Philosophy

The underlying foundation of the PHS Policy is one of institutional self-evaluation, self-monitoring and self-reporting.




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### Routine Reporting Requirements

PHS Policy, IV.F.3, requires that the IACUC... **promptly** provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- any serious or continuing noncompliance with this Policy
- any serious deviation from the provisions of the *Guide* or
- any suspension of an activity by the IACUC




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### Routine Reporting Requirements

- Prompt preliminary report as phone call, email or fax
- Follow-up thorough report signed by the Institutional Official



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### What to Report to OLAW?

- 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.
- Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals, **NOT-OD-05-034 Feb 24, 2005**



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### Disaster Reporting Requirements

**What to Report :**

- Any serious noncompliance with the PHS Policy
- Any serious deviation from the provisions of the *Guide*
- Any suspension of an activity by the IACUC
- Includes departures from the *Guide*, program or facility deficiencies and any event which cause injury, death, or severe distress to animals



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### Disaster Reporting Requirements: Acute Crisis Phase

#### Acute Crisis Response:

- Highest priority must be to save human and animal lives
- OLAW may issue temporary waiver of prompt reporting requirement to FEMA (Federal Emergency Management Agency) declared disaster areas



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### NIH Extramural Natural Disaster and Emergency Response

NIH will coordinate with other Federal agencies (such as HHS, FEMA and OMB), as well as with state, local, and institutional representatives, to develop any additional response.



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### Disaster Reporting Requirements: Post Acute Crisis Phase

#### Post Acute Crisis Response: When to Report?

- **ONLY** after attending to the critical needs of ensuring the health and safety of personnel and animals
- As soon as possible and when feasible following the acute crisis



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### Disaster Reporting Requirements: Post Acute Crisis Phase

#### Post Acute Crisis Response: How to Report?

- Submit preliminary report to OLAW using available resources
- Reporting is not necessary if no damage was sustained.



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### Disaster Reporting Requirements: Recovery Phase

#### Rebuilding and Recovery Response:

- Report **reasonable and specific plan and schedule** for correcting deficiencies to OLAW



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### Disaster Reporting Requirements: Long-Term Recovery Phase

- A good model for disaster recovery phase should have:
  - Established target dates for correction
  - Monitoring of progress on ongoing basis
  - Establishment of interim plans to make best use of resources



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### Why Contact OLAW?

- Reassure the public and other interested parties (Congress, media, animal interest groups) of adequate welfare of animals.
- Provide assistance to institutions to correct serious deficiencies related to the adverse event.
- Provide access to various resources and contacts.
- Ensure compliance with the PHS Policy.

Email [olaw@mail.nih.gov](mailto:olaw@mail.nih.gov) or Phone 301-496-7163




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### Resources

- OLAW Disaster Planning and Response Resources: [https://grants.nih.gov/grants/olaw/disaster\\_planning.htm](https://grants.nih.gov/grants/olaw/disaster_planning.htm)
- NIH Extramural Response to Natural Disasters: [https://grants.nih.gov/grants/natural\\_disasters.htm](https://grants.nih.gov/grants/natural_disasters.htm)
- U.S. Government website <https://www.disasterassistance.gov/>
- FEMA website <https://www.fema.gov/>
- Public Health Service emergency website: <https://www.phe.gov/emergency/>




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### Additional Resources

- Disaster Planning
  - The NIH Office of Animal Care and Use Disaster Management plan
  - Disaster planning information from USDA
- Government
  - Resources from the NLM, CDC, USDA APHIS
- Organizations
  - Disaster Preparedness for Veterinarians, AVMA
- Publications and Reports
- Resources
  - DANR Guide




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### Additional Resources Cont.

- Potential NIH Responses to Natural Disasters
  - Limited expenditure of award funds
  - Waiving certain approval requirements
- NIH Emergency Contact Information
- NIH Responses to Recent Events
- FAQs on the NIH Extramural Response to Natural Disasters and Other Emergencies




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### Questions?



[olawdpe@mail.nih.gov](mailto:olawdpe@mail.nih.gov)

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### Question 1

How many adverse events are reported to OLAW each year?




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### Question 2

During a recent adverse event, our animals suffered some distress because of higher temperatures in the animal facility. This was soon detected and corrected. No animal deaths occurred due to this incident. Should this be reported to OLAW?



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### Question 3

Is the IACUC expected to meet and vote during a long lasting emergency event?



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### Question 4

Our facility sustained flooding following a hurricane and animals died. These animals were not on a PHS study. Is this reportable to OLAW?



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### Question 5

A power outage affected our vivarium and the back-up generator came on and kept temperature, lights, power to racks within the *Guide* parameters. Is this reportable?



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### Question 6

How soon should a report be made after a disaster?



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### Question 7

Can OLAW provide help with drafting a disaster plan at our institution?



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### Question 8

How have institutions fared in the recent hurricanes in Texas, and other places? Have you heard from them?



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### Questions?



[olawdpe@mail.nih.gov](mailto:olawdpe@mail.nih.gov)

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