

Adverse Events at Research Animal Facilities

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Office of Laboratory Animal Welfare
National Institutes of Health

OLAW Online Seminar
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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



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



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



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.



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.



Identifying Critical Systems and Functions

Identify the essential functions of the facility

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



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?).



Adverse Events Matrix: Extensive Events

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

Adverse Events Matrix: Contained Events

Inadvertent	Possible Secondary Effects
<u>Husbandry-related</u>	
-Inadequate, inaccessible or spoiled food/water	-Health Issues -Morbidity and mortality
-Insufficient enrichment	-Stereotypies
- Overcrowding	-Aggression
<u>Human error</u>	
-Escapes	-Negative publicity
-Improper care during transportation	-Interference with study results
-Inadequate care, Mishandling	-Injury to people, animals
<u>Animal nature</u>	
-Aggression	-Injury to animals and people
-Getting trapped, injured	

Inadvertent	Possible Secondary Effects
<u>Biological</u>	
-Adverse reaction to biologics	-Affect study results
-Veterinary care issues	
-Failed euthanasia	
<u>Mechanical</u>	
-Electrical issues	-Fire and related damage
-Water supply	-Flooding
-HVAC	-Potential for infections
-Lighting	-Affect light/dark cycle
Deliberate	Possible Secondary Effects
-Abuse/ neglect	-Harm to animals
-Theft/ crime	-Protests, negative publicity
-Sabotage	-Damage to building, animals



Extensive Adverse Events: List Available Resources

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



Extensive Adverse Events: Communication Network

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



Extensive Adverse Events: Shelter in Place

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



Extensive Adverse Events: Evacuation Procedures

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



Extensive Adverse Events: Euthanasia

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



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



Testing of Equipment

Regular testing of emergency equipment.

- Live rehearsals
- Other testing
- Regular maintenance



Commonly Reported Adverse Events

- Death during transport
- Failure to provide post procedural analgesia



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



Contained Adverse Events: Communication Network

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



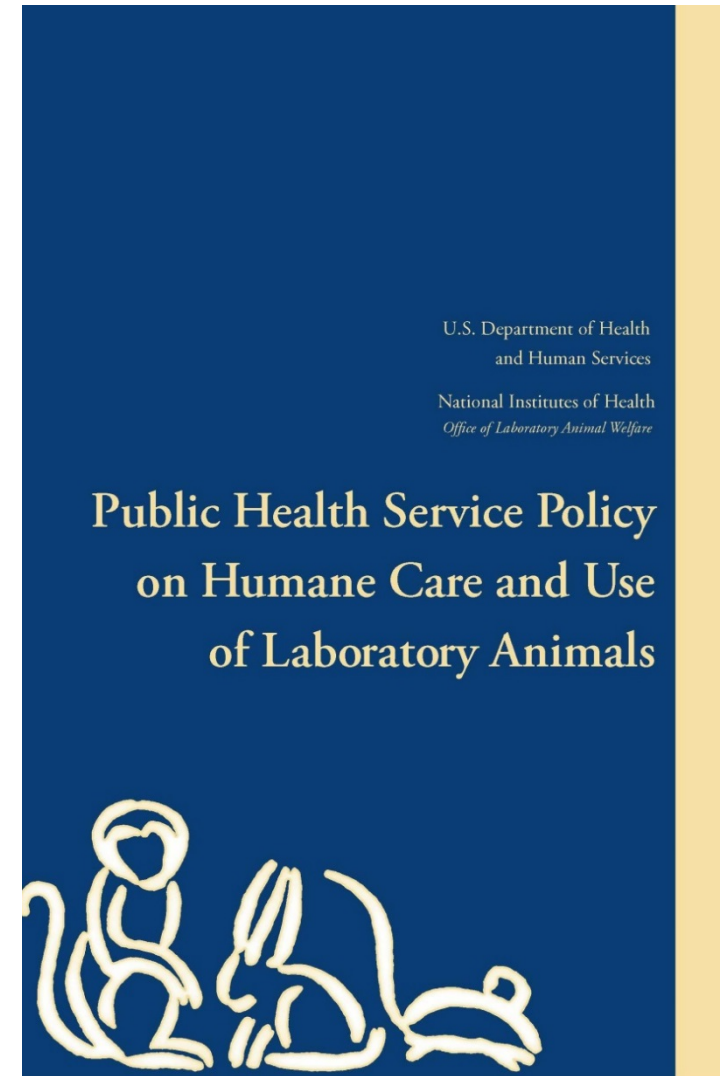
Action Plan for Contained Events

- 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



PHS Policy Philosophy

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



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:

- 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



Routine Reporting Requirements

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



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



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



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



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.



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



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.



Disaster Reporting Requirements: Recovery Phase

Rebuilding and Recovery Response:

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



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



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 or Phone 301-496-7163



Resources

- OLAW Disaster Planning and Response Resources:

https://grants.nih.gov/grants/olaw/disaster_planning.htm

- NIH Extramural Response to Natural Disasters:

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/>



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



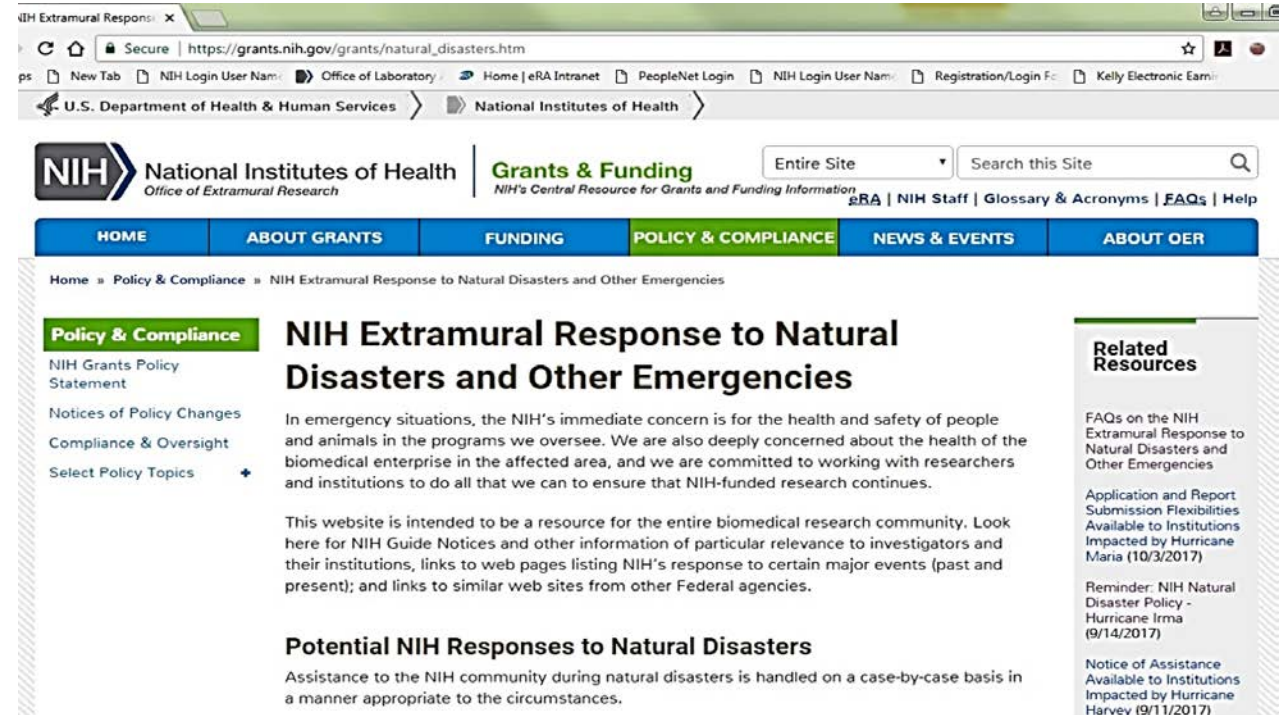
The screenshot shows a web browser window displaying the NIH Grants & Funding website. The URL is https://grants.nih.gov/grants/olaw/disaster_planning.htm. The page title is "Office of Laboratory Animal Welfare - Disaster Planning and Response Resources". The main content area lists several resources for disaster planning, including:

- Adverse Events at Research Facilities (PDF), *Lab Animal* 2017; 46(6):244-249: Describes types of adverse events for facilities to consider when assessing risk and developing a disaster plan.
- Disaster Planning (PDF), *Animal Lab News* 2007; 6(3):21-24: Points to consider when developing a disaster plan for your animal facility.
- Disaster Planning, U.S. Department of Agriculture (USDA): Provides animal emergency and disaster planning information.
- NIH-OACU: Disaster Response, NIH Office of Animal Care and Use (OACU) animal program disaster response resources. Although specific to NIH facilities, these resources provide multiple references and templates that may be useful to other research animal facilities when developing contingency plans for natural and other disasters.
- OLAW Webinar: Disaster Planning, March 7, 2013: Stephen Durkee provides best practice insights into developing a disaster plan compliant with the *Guide*.



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



The screenshot shows a web browser window displaying the NIH Extramural Response to Natural Disasters and Other Emergencies page. The browser address bar shows the URL: https://grants.nih.gov/grants/natural_disasters.htm. The page header includes the NIH logo, the text "National Institutes of Health Office of Extramural Research", and a search bar. The main navigation menu is highlighted, with "POLICY & COMPLIANCE" selected. The page content includes a "Policy & Compliance" sidebar with links to "NIH Grants Policy Statement", "Notices of Policy Changes", "Compliance & Oversight", and "Select Policy Topics". The main content area features the title "NIH Extramural Response to Natural Disasters and Other Emergencies" and a paragraph stating: "In emergency situations, the NIH's immediate concern is for the health and safety of people and animals in the programs we oversee. We are also deeply concerned about the health of the biomedical enterprise in the affected area, and we are committed to working with researchers and institutions to do all that we can to ensure that NIH-funded research continues." Below this is a section titled "Potential NIH Responses to Natural Disasters" with the text: "Assistance to the NIH community during natural disasters is handled on a case-by-case basis in a manner appropriate to the circumstances." A "Related Resources" sidebar on the right lists: "FAQs on the NIH Extramural Response to Natural Disasters and Other Emergencies", "Application and Report Submission Flexibilities Available to Institutions Impacted by Hurricane Maria (10/3/2017)", "Reminder: NIH Natural Disaster Policy - Hurricane Irma (9/14/2017)", and "Notice of Assistance Available to Institutions Impacted by Hurricane Harvey (9/11/2017)".



Questions?



olawdpe@mail.nih.gov

Question 1

How many adverse events are reported to OLAW each year?



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?



Question 3

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



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?



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?



Question 6

How soon should a report be made after a disaster?



Question 7

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



Question 8

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



Questions?



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