Adverse Events at Research Animal Facilities

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Contents
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• 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

<table>
<thead>
<tr>
<th>Natural Possible Secondary Effects</th>
<th>Technical Possible Secondary Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weather</strong></td>
<td></td>
</tr>
<tr>
<td>风</td>
<td>- Power outage</td>
</tr>
<tr>
<td>雨</td>
<td>- Temperature fluctuations</td>
</tr>
<tr>
<td>灾</td>
<td>- Equipment failure</td>
</tr>
<tr>
<td>寒</td>
<td>- Inaccessibility of supplies, personnel</td>
</tr>
<tr>
<td>震</td>
<td>- Power outage</td>
</tr>
<tr>
<td>海啸、洪水</td>
<td>- Temperature fluctuations</td>
</tr>
<tr>
<td>- Inaccessibility of supplies, personnel</td>
<td>- Disruption of the light/dark cycle</td>
</tr>
<tr>
<td><strong>Earthquakes</strong></td>
<td></td>
</tr>
<tr>
<td>- Damage to building, structures</td>
<td>- Damage to building, people, animals</td>
</tr>
<tr>
<td>- Equipment malfunction</td>
<td>- Assaults</td>
</tr>
<tr>
<td><strong>Biological</strong></td>
<td></td>
</tr>
<tr>
<td>- Rapid spread</td>
<td>- Birth threats</td>
</tr>
<tr>
<td>- Spoiled food/water</td>
<td>- Transportation systems affected</td>
</tr>
<tr>
<td>- Inadequate, inaccessible or insufficient enrichment</td>
<td>- Demonstrations</td>
</tr>
<tr>
<td>- Aggression</td>
<td>- Negative publicity</td>
</tr>
<tr>
<td><strong>Human Error</strong></td>
<td></td>
</tr>
<tr>
<td>- Escapes</td>
<td>- Fire and related damage</td>
</tr>
<tr>
<td>- Inadequate care, mishandling</td>
<td>- Water supply</td>
</tr>
<tr>
<td>transportation</td>
<td>- Flooding</td>
</tr>
<tr>
<td>- Injurious care and handling</td>
<td>- HVAC</td>
</tr>
<tr>
<td>- Interference with study results</td>
<td>- Potential for infections</td>
</tr>
<tr>
<td>- Injury to people, animals</td>
<td>- Lighting</td>
</tr>
<tr>
<td><strong>Deliberate</strong></td>
<td></td>
</tr>
<tr>
<td>- Abuse/ neglect</td>
<td>- Harm to animals</td>
</tr>
<tr>
<td>- Sabotage</td>
<td>- Damage to building, animals</td>
</tr>
<tr>
<td>- Getting trapped, injured</td>
<td>- Protections, negative publicity</td>
</tr>
<tr>
<td>- Injury to animals and people</td>
<td>- Equipment malfunction</td>
</tr>
</tbody>
</table>

Adverse Events Matrix: Contained Events

<table>
<thead>
<tr>
<th>Inadvertent Possible Secondary Effects</th>
<th>Inadvertent Possible Secondary Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Husbandry related</strong></td>
<td><strong>Biological</strong></td>
</tr>
<tr>
<td>- Health issues</td>
<td>- Adverse reaction to biologics</td>
</tr>
<tr>
<td>- Stereotypies</td>
<td>- Affect study results</td>
</tr>
<tr>
<td>- Aggression</td>
<td>- Veterinary care issues</td>
</tr>
<tr>
<td><strong>Environmental</strong></td>
<td><strong>Mechanical</strong></td>
</tr>
<tr>
<td>- Negative publicity</td>
<td>- Electrical issues</td>
</tr>
<tr>
<td>- Interference with study results</td>
<td>- Fire and related damage</td>
</tr>
<tr>
<td>- Injury to people, animals</td>
<td>- Water supply</td>
</tr>
<tr>
<td>- Sabotage</td>
<td>- Flooding</td>
</tr>
<tr>
<td>- Equipment malfunction</td>
<td>- HVAC</td>
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<td>- Harm to animals</td>
<td>- Protections, negative publicity</td>
</tr>
</tbody>
</table>

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
  • DAMR 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

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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