

UC Denver IACUC

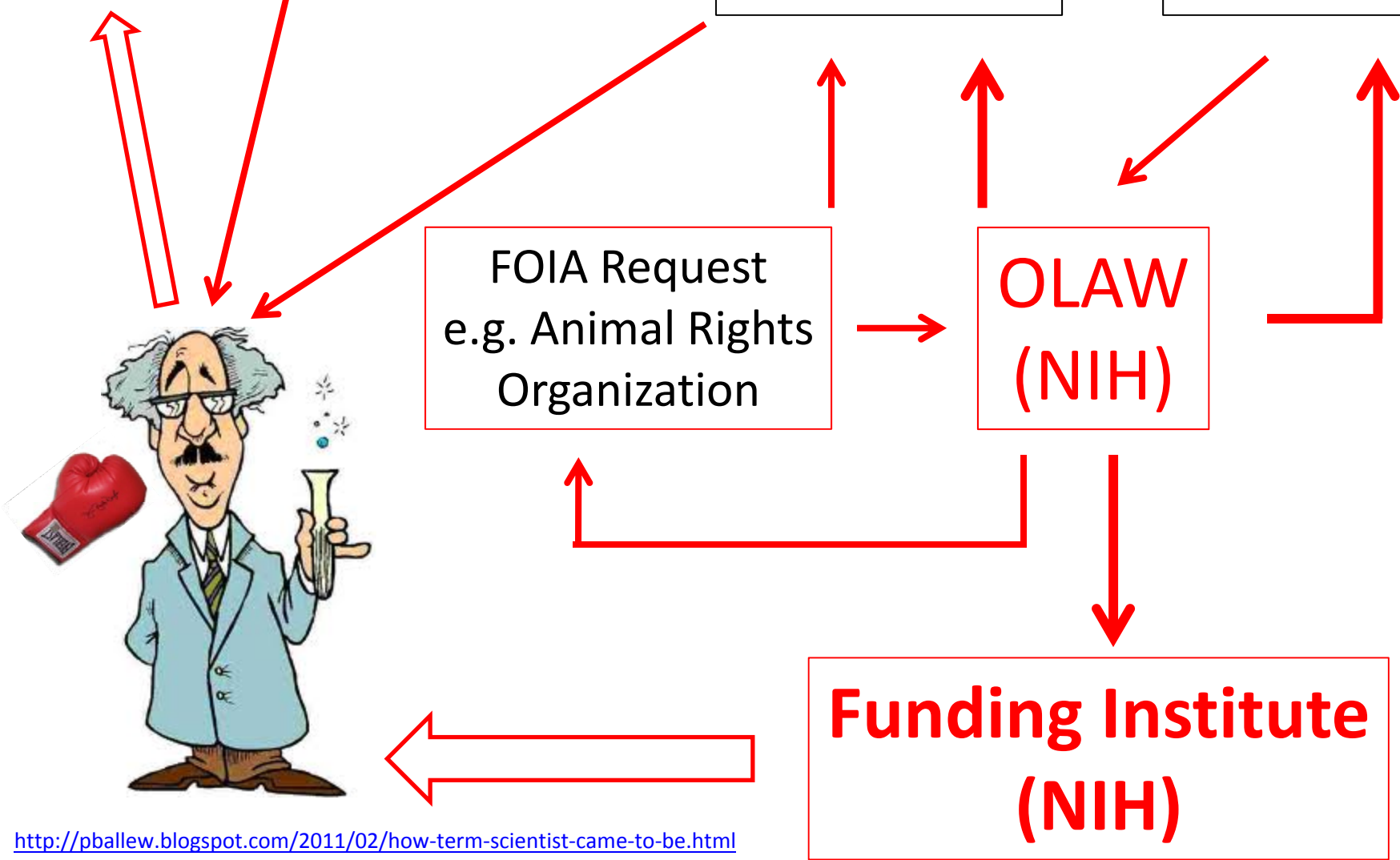
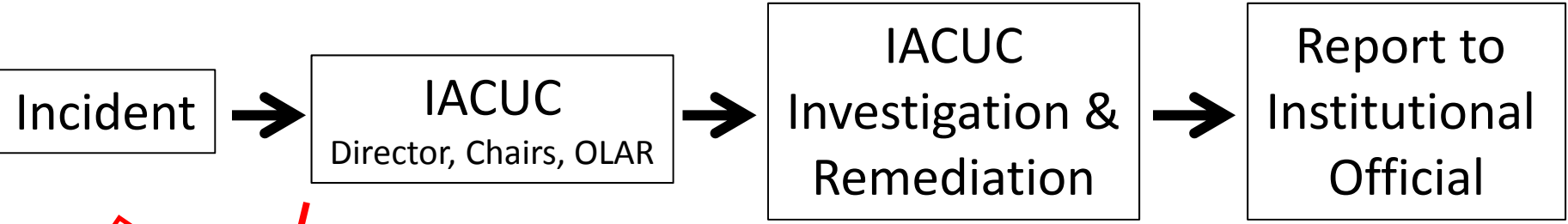
(Institutional Animal Care and Use Committee)

Townhall Meeting

5-15-2012

Regulatory Requirements for
Reporting Animal Incidents
&
Rodent Anesthetic/Analgesic
Records

How We Handle Animal Incidents



PHS Policy, section IV.F.3

August 1, 2002

Require us to report:

- Any serious or continuing non-compliance with the Policy
- Any serious deviation from the provisions of the guide
- Any suspension of an activity by the IACUC

Reporting Guidelines (NOT-OD-05-034)

February, 24, 2005

Examples of reportable situations:

- 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 IACUC review and approval;
- ***failure to adhere to IACUC-approved protocols;***
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
- conduct of official IACUC 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;
- chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;
- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
- IACUC 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 institution's Animal Welfare Assurance.

ALL issues of non-compliance, ALL deviations from the guide, and accidents or mistakes that harm animals even when we were compliant or had no deviations from the guide.

Reporting Guidelines (NOT-OD-05-034)

February, 24, 2005

Examples of situations *not* normally required to be reported:

- death of animals that have reached the end of their natural life spans;
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;
- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;
- animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or
- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, *must* be reported promptly along with corrective plans and schedules).

Death from natural causes, common animal behavior, illness from expected disease, infrequent drowning from cage flooding-

essentially most issues when compliant and no deviations occur.

Consequences of Getting Reported?

- **Actions required**
 - e.g. Additional training
- **Monitored for continuing problems**
 - PI and/or grant # followed, action taken
- **Maybe financial**
 - Grants funds may be in jeopardy

Grant Expenditures (NOT-OD-07-044)

January 26, 2007

Policy The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) **do not permit charges to grant awards** for the conduct of animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld.

Specific situations under which charges are not allowable are:

- The conduct of animal activities in the absence of a valid Assurance on file with OLAW.
- *The conduct of animal activities in the absence of valid IACUC approval of the activity.* Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval. Suspension is described in the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) at section IV.C.6. (<http://grants.nih.gov/grants/olaw/references/phspol.htm>)

Grant Expenditures (NOT-OD-10-081)

April 15, 2010

- ... In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges.

What Can You Do?

- **Know your protocol**

- PI's and lab personnel should be aware of what is approved and not approved; check each other.
- Follow your approved procedures, time of monitoring, following specific signs, dosing, and treatments.
- Pro-actively amend your protocol when these details need to be changed.
- Be prepared for your Post-Approval Monitoring meetings

- **Broaden your protocol's umbrella**

- Move toward fewer, larger protocols; if 3 or 4 projects can fit under a broad set of project goals, use 1 protocol.
- Back-up or alternative procedures, anesthetics, drugs, timelines, or euthanasia; account for weekends in your health monitoring plan.
- Broaden the umbrella, but don't get vague.

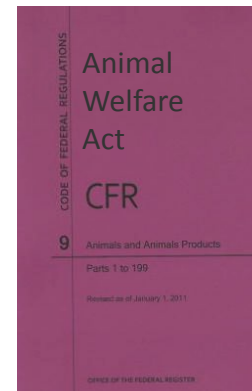
- **Be Careful What You Report on Annual Reviews**

- Reporting unexpected deaths without specific details; offhandedly exaggerating the number of animals affected; expressing frustration with research.
- We have to investigate these to assess whether they are reportable.

Regulatory Requirements for Rodent Anesthetic/Analgesic Records

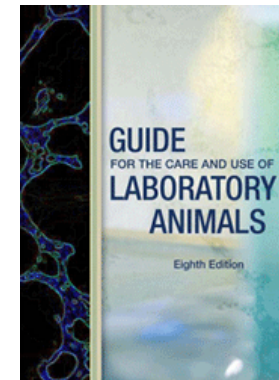
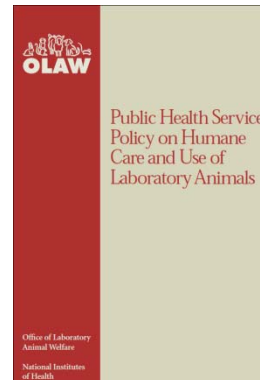
USDA Species

- The mandate for medical records is quite clearly outlined for USDA covered species.
 - USDA Animal Care Policies #3



Rodent Species

- **Guide for the Care and Use of Laboratory Animals (8th); pg 115**
 - [Recordkeeping] “Medical records are a key element of the veterinary care program and are considered critical for documenting animal well-being as well as tracking animal care and use at a facility.”
 - The Guide reference Field et al 2007 for further details.
- **Guide for the Care and Use of Laboratory Animals (8th); pg 120**
 - [Postoperative Care] “Appropriate medical records should also be maintained.”



Medical Records for Animals Used in Research, Teaching, and Testing: Public Statement from the American College of Laboratory Animal Medicine

ACLAM Medical Records Committee: Karl Field (Chair), Michele Bailey, Larry L. Foresman, Robert L. Harris, Sherri L. Motzel, Richard A. Rockar, Gaye Ruble, and Mark A. Suckow

ILAR Journal; 48(1): 37-41, 2007

- **Pg 40; Section: Records of Sedation or Anesthesia and Peri-Surgical/Peri-Procedural Care for Survival and Terminal Procedures**
 - Records of sedation and anesthesia (with or without surgery), and peri-surgical / peri-procedural care, document adequate veterinary care and the alleviation of pain and distress during the conduct of these procedures..., whether survival or terminal.
 - Procedures of this nature should be documented in a medical record and/or research record, or can be linked and available to the record, as deemed appropriate by the institution
 - ...followed by 8 bullet points that are to be included in anesthesia record

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- Information requested on the rodent anesthesia record have been taken from this list specifically.

1. Animal or group identification and the date of the procedure,
2. All drugs administered, including dose, route, time, and the ability to identify the person administering the drugs,
3. A description of the surgical procedure and identification of the surgeon(s),
4. Ongoing findings during monitoring,
5. Notation of any variations from the normal and expected events during the anesthetic and recovery periods, including the actions taken and the time performed, the animal's response to these actions, and the ability to identify the person performing these actions,
6. Assessment for pain and distress,
7. Actions taken to alleviate pain and distress, including non-pharmacologic interventions, and the response to these actions,
8. A notation defining the end of the monitoring period (euthanasia or functional recovery from the sedation or anesthesia), including the time, date, and the ability to identify the person performing this observation.

Rodent Anesthesia Record

- Please see the Animal Program website Forms page for an editable WORD sample document:
- <http://www.ucdenver.edu/academics/research/AboutUs/animal/Pages/Forms.aspx>