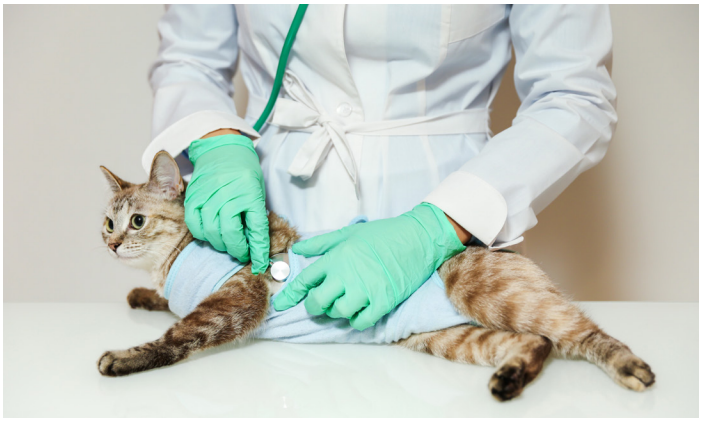
Animal Care Tech Note

Categorizing Animal Pain or Distress in Research Facility Annual Reports

The Animal Welfare Act (AWA) requires research facilities to submit an annual report that states the common names and numbers of animals used in research, testing, or experimentation. The report must also categorize these animals based on procedures involving pain, distress, and/or the use of pain-relieving drugs. Research facilities may use this tech note as a reference when assigning animals to pain and distress categories.

Animal Welfare regulations define a painful procedure as "any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure is applied, that is, pain in excess of that caused by injections or other minor procedures" (9 CFR § 1.1).



Categorizing Procedures Involving Pain and/or Distress

You should evaluate only study-related procedures when categorizing animals for reporting purposes. Veterinary care or colony management procedures performed for the health of an individual animal or the colony should not be considered. For example, treating wounds acquired in fights with other animals is not study-related and should not be considered for annual reporting.

If multiple categories may apply, you should report each animal only once in the category consistent with the greatest amount of pain or distress they experienced during that period. For this reason, animals on long-term studies that span multiple reporting periods may be reported in different categories for each period.

The table on page 2 shows the pain categories listed on the annual report and examples of procedures that apply to each category. These examples are not intended to be exhaustive. You should consider the specific animal-use activity when categorizing animals.

When anesthetics, analgesics, or sedatives are used only for restraint during procedures that do not involve more than slight or momentary pain, these animals should be placed in Category C. For example, animals that are anesthetized or sedated for collecting blood samples or for imaging procedures should be assigned to Category C.

Animals exhibiting signs of pain, or distress such as weight loss, abnormal activity level, adverse reactions to touching inoculated areas, open sores/necrotic skin lesions, abscesses, lameness, ocular pain and/or inflammation, corneal edema, and photophobia must receive appropriate and effective relief consistent with the current standard of care. Appropriate and effective relief may not necessarily require analgesics. It may also include supportive care such as ice packs, heat, soft bedding, diet alterations, and/or anti-nausea medications in addition to analgesic therapy when necessary. Animals that receive appropriate relief are listed in Category D.

You should place in Category D any animals that experience breakthrough pain after receiving appropriate anesthetic or analgesics or experience pain or distress before you detect the need for analgesics, as long as:

- The animals are appropriately monitored;
- The type, dose, and frequency of analgesics being administered are appropriate for the procedure and species; and,
- The intent is to alleviate the pain and distress as needed.

A Category D procedure may become a Category E procedure if appropriate anesthetics, analgesics, or sedatives are withheld because these agents would adversely affect the procedure, results, or interpretation of the test or research. When appropriate relief of pain or distress cannot be administered to maintain the validity of the test or research, or the nature of the activity does not allow appropriate relief, the activity must be scientifically justified in the animal activity proposal and approved by the Institutional Animal Care and Use Committee. You must report animals in this situation in Category E.

You must attach a description of the procedures producing pain and distress in Category E animals and the reasons pain-relieving drugs were not used to the annual report.

Prospective or Retrospective Reporting

You can categorize pain and distress prospectively or retrospectively. Retrospective reporting involves collecting data on individual study animals to determine the most appropriate category based on clinical signs of pain and distress the animal experienced during the reporting period. While labor intensive, this method generally produces more accurate reporting. Prospective reporting means that all animals used for a particular activity are categorized in the highest applicable pain category based on anticipated pain and distress associated with that activity. This method is less labor intensive but may result in animals being placed in a higher category than necessary.

If animals experience pain or distress during the study due to research procedures that are in a higher pain category than originally designated, you must report the animal(s) in the higher pain category. In other words, your reporting will be retrospective to indicate the pain or distress level the animal actually experienced.

For More Information

The AWA and its regulations establish the legal requirement and standards research facilities must follow. For details, see USC Title 7, Chapter 54, Sections 2131-2159 and CFR, Title 9, Chapter 1, Subchapter A, Parts 1-4.

If you have questions, contact the U.S. Department of Agriculture (USDA) Animal Care staff at (970) 494-7478 or animalcare@usda.gov.

Pain Categories

Category	Explanation	Example
B	Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	• Animals on breeding protocols with no research or experimental component • Animals acquired by the facility but held in quarantine or acclimation period prior to use • Euthanizing animals on a holding protocol following current professional standards • Observing animal behavior in their home enclosures without manipulation
C	Animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	• Observing animal behavior in the lab • Positive reward training or research • Food restriction that reduces the animal's weight by no more than 15 percent of normal age-matched controls • Manipulative procedures such as weighing, injections, palpations, skin scrapings, and radiography • Administering an anesthetic, analgesic or tranquilizing drug to an animal for restraint purposes to perform a procedure that involves no pain or distress such as imaging procedures • Exposure to mild alteration in environmental conditions with appropriate acclimation
D	Animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	• Surgical manipulations (survival or terminal) in which the animals received appropriate pre-, intra-, and post-operative anesthetics and analgesics • Using Freund's complete adjuvant if alleviation of pain/distress occurs • Tumor induction or implantation if alleviation of pain/distress occurs • Induced infections or antibody production in which animals experience pain alleviated by analgesics • Exsanguination under anesthesia
E	Animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests	• Paralysis or immobilization of a conscious animal • Any Category D procedure for which needed analgesics, tranquilizers, sedatives, or anesthetics are withheld for justifiable study purposes • Toxicological, microbiological, or infectious disease research that requires continuation after clinical signs are evident without medical care or that requires death as an endpoint • Food or water restriction which reduces the animal's weight by more than 15 percent of normal age-matched controls • Certain types of forced exercise protocols that could reasonably be expected to cause distress or exhaustion • Applying noxious stimuli that the animal cannot avoid/escape • Exposure to extreme environmental conditions • Long-term restraint (days to weeks)

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