



Cornell University Institutional Animal Care and Use Committee

Guidelines for Assigning Animals into USDA Pain and Distress Categories

The intent of this policy is to assist Principal Investigators in protocol preparation by describing the guidelines for assigning research or teaching animals into USDA pain and distress categories on protocols. This policy is intended for use by all personnel involved in writing or reviewing research or teaching protocols.

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1. **Introduction:** All vertebrate animals used for research or teaching must be assigned to a USDA pain and distress category on the protocol under which they are used. Procedures that could cause pain or distress in humans should be assumed to cause pain or distress in other animals. This document provides definitions and examples of the USDA pain and distress levels to ensure that animals are listed on their protocol under the correct USDA pain and distress category.

2. Procedures:

- Assign each animal listed on a protocol to one of the following USDA pain and distress categories: B, C, D or E. For definition and examples of USDA pain and distress categories, see Appendix 1.
- List each animal under the highest pain and distress category that will apply to the animal at any time while the animal is listed on the protocol, even if it is for a short duration of time.
- Do not include non-research related veterinary care in determining USDA pain and distress category.
- See Appendix 2 for examples of clinical signs of pain or distress.
- If a procedure is done on an animal (e.g. tail snip or euthanasia), list the animals are category C or greater. This includes animals used for breeding if they are later

euthanized. Thus, breeding mice should be placed in category C rather than category B. List breeding animals as category B only if no procedure are done, including euthanasia.

- Genetically engineered animals
 - Place animals in category C if the phenotype produced by the genetic alteration is unknown. Amend the category once the investigator or veterinary staff recognizes phenotype-related pain or distress.
 - Place animals in category D if the phenotype is expected to cause, pain or distress that will be alleviated by IACUC approved methods.
 - Place animals in category E if the phenotype is expected to cause, pain or distress that will not be alleviated.
 - Describe any new information regarding the phenotype, including adverse events, and adjust the pain and distress category as necessary during the annual review.

3. References:

- Bloom, F., Brown, M. (Eds). (2003). *Guidelines for the care and use of mammals in neuroscience and behavioral research*. Washington DC: The National Academies Press.
- http://www.aphis.usda.gov/animal_welfare/downloads/policy/policy11.pdf
- http://www.aphis.usda.gov/animal_welfare/downloads/awr/9cfr2.36.txt
- http://www.mtu.edu/research/administration/integrity-compliance/pdf/Pain_and_Distress_Categories.pdf
- <http://compliance.vpr.okstate.edu/acuc/USDA%20Pain%20Levels.doc>

4. Appendix 1: Definition and Examples of USDA Pain and Distress Categories

Category B	Category C	Category D	Category E
Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. Non-invasive observation only of animals in the wild.	Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain-relieving drugs.	Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs.	Animals subjected to potentially painful or stressful procedures that are not relieved with anesthetics, analgesics and/or tranquilizer drugs. Withholding anesthesia/analgesia must be scientifically justified in writing and approved by the IACUC.
Example	Examples	Examples	Examples
1. Animals being bred or housed, without any research manipulation, prior to euthanasia or transfer to another protocol 2. Observation of animal behavior in the wild without manipulating the animal or it's environment	1. Holding or weighing animals in teaching, outreach or research activities 2. Observation of animal behavior in the lab 3. Ear punching of rodents 4. Tail snips in mice ≤ 21 days old 5. Peripheral Injections, blood collection or catheter implantation 6. Feed studies, which do not result in clinical health problems 7. Routine agricultural husbandry procedures approved by the IACUC in a protocol or SOP 8. Live trapping 9. Positive reward training or research	1. Survival surgery 2. Non-survival surgical procedures 3. Laparoscopy or needle biopsies 4. Retro-orbital blood collection 5. Exposure of blood vessels for catheter implantation 6. Induced infections or antibody production 7. Tattooing 8. Exposure of skin to UV light to induce sunburn 9. Tail snips in mice > 21 days old 10. Research procedures that could potentially increase pain or distress (ex: anesthesia/analgesia studies) on client owned	1. Toxicological or microbiological testing, cancer research or infectious disease research that requires continuation after clinical symptoms are evident without medical relief or require death as an endpoint 2. Ocular or skin irritancy testing 3. Food or water deprivation beyond that necessary for ordinary pre-surgical preparation 4. Application of noxious stimuli such as electrical shock that the animal cannot avoid/escape 5. Any procedures for which needed analgesics, tranquilizers, sedatives, or anesthetics must be withheld for justifiable study purposes

Category B	Category C	Category D	Category E
	10. Chemical restraint 11. Research procedures that involve no potential increase in pain or distress on client owned animals that are undergoing Clinical procedures (ex: drawing extra blood, choice of antibiotics). 12. Exposure to alterations in environmental conditions (not extreme) with appropriate conditioning and microenvironment 13. Food restriction that reduces the animals weight by no more than 20% of normal age matched controls 14. AVMA approved euthanasia procedures 15. Euthanasia of breeding animals or unused offspring 16. Exsanguination with anesthesia 17. Perfusion with anesthesia 18. Unknown genetically engineered phenotype	animals that are undergoing Clinical procedures. 11. Genetically engineered phenotype that causes pain or distress that will be alleviated	6. Exposure to extreme environmental conditions 7. Euthanasia by procedures not approved by the AVMA 8. Paralysis or immobilization of a conscious animal 9. Genetically engineered phenotype that causes pain or distress that will not be alleviated

Appendix 2: Clinical Signs of Pain or Distress

Species	Clinical Signs of Pain
Rodents, rabbit	1. Avoidance, vocalization and aggressiveness (mainly if the animal cannot escape) 2. Spontaneous activities are reduced. The animal is isolated from the social group 3. Altered gait 4. Hunched posture 5. Pilo-erection 6. Reduced grooming; dark-red stain around the eyes and at nostrils 7. Reduced appetite and subsequent weight loss 8. Increased respiration rate 9. Failure to explore cage when disturbed
Cat, dog	1. Avoidance, vocalization, eyebrow movements, escape and aggressiveness 2. Spontaneous activities are reduced. The animal is isolated from the social group 3. Apathy, anxiety, plaintive 4. Altered gait 5. Nibbling, licking, scratching, rubbing 6. Eyes are semi-closed 7. Head shaking (ear pain) 8. Reduced appetite and subsequent weight loss
Swine	1. Tolerate manipulations 2. Lying down more frequently, immobile 3. Aggressive vocalization and behavior 4. Altered gait 5. Increased muscle tension around the eye 6. Pilo-erection 7. Reduced appetite (sometimes) 8. Reluctance to move

Ruminants	1. Vocalization
	2. The animal is isolated from the social group
	3. Lying down more frequently, immobile
	4. Apathy, depression
	5. Altered gait, lameness
	6. Increased respiratory rate (abdominal pain) or shallow respiration
	7. Cessation of rumination; teeth grinding, dorsal lip-curling (goats)
	8. Loss of appetite (partially or totally)
	9. Tucked abdomen
Birds	1. Inappetence
	2. Wasting
	3. Ruffled feathers
	4. Altered gait or posture
	5. Rapid open mouth breathing (panting)
	6. Dull eyes
Horses	1. Reluctance to handling (acute pain)
	2. Restlessness
	3. Anxious appearance with dilated pupils
	4. Ears drawn back, flat to head
	5. Rigid stance
	6. Profuse sweating
	7. Kicking at abdomen (abdominal pain)
	8. Flehman-like lip posturing