IACUC Policy # 320: Guidelines for Assigning Animals into Pain and Distress Categories

The intent of this policy is to assist Primary 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 under the correct USDA pain and distress categories. The IACUC will make the final decision about the correct pain category assignment for each protocol.

2) Procedures:
   A Assign each animal listed on a protocol to one of the following USDA pain and distress categories: B, C, D or E. For definitions and examples of USDA pain and distress categories, see Appendix 1.
   B 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.
   C Do not include routine veterinary care procedures under USDA pain and distress categories.
   D See ACUP 102 (in References) for examples of clinical signs of pain or distress.
   E If a procedure is performed on an animal (e.g. tail snip or euthanasia), list the animal as 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 procedures are done, including euthanasia.
   F Genetically-engineered animals
      1 Place animals in category C if the phenotype produced by the genetic alteration is unknown. File a subsequent amendment to change the category if the investigator or a veterinarian recognizes a phenotype-related pain or distress.
      2 Place animals in category D if the phenotype is expected to cause, pain or distress that will be alleviated by IACUC-approved methods.
3) Place animals in category E if the phenotype is expected to cause, pain or distress that will not be alleviated.
4) Describe any new information regarding the phenotype, including adverse events, during the annual review.

3) References:
B. Animal Welfare Act
C. Animal Welfare act Regulations
D. ACUP 102 Analgesia
### Appendix 1: Definition and Examples of USDA Pain and Distress Categories

<table>
<thead>
<tr>
<th>Category B</th>
<th>Category C</th>
<th>Category D</th>
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<tbody>
<tr>
<td>Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery, <strong>but not yet used</strong> for such purposes. Non-invasive observation of animals in the wild.</td>
<td>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.</td>
<td>Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs.</td>
<td>Animals subjected to potentially painful or stressful procedures that are <strong>not</strong> alleviated with anesthetics, analgesics and/or tranquilizer drugs. Withholding anesthesia/analgesia must be scientifically justified in the protocol and be approved by the IACUC.</td>
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#### Example

1. Animals that are bred or housed without any research manipulation, including euthanasia.
2. Observation of animal behavior in the wild without manipulating the animal or its environment

#### Examples

1. Holding or weighing animals in teaching, outreach or research activities
2. Ear punching of rodents
3. Animal behavior studies
4. Imaging procedures (e.g., MRI, ultrasound, x-ray)
5. Peripheral injections, blood collection or percutaneous 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
10. Tattooing
11. Anesthesia used for restraint for a painless, or momentarily painful, procedure
12. Euthanasia

1. Survival surgery
2. Non-survival surgical procedures
3. Laparoscopy or needle biopsies
4. Retro-orbital blood collection from animals without a retro-orbital sinus
5. Exposure of blood vessels for catheter implantation
6. Induced infections, tumors or antibody production (ascites method), provided that animals are carefully monitored and euthanized in a timely manner.

#### Examples

1. Toxicological or microbiological testing, cancer research or infectious disease research that requires continuation after clinical signs are evident (i.e., without medical relief) or requires death as an endpoint
2. Severe food or water deprivation beyond that necessary for ordinary pre-surgical preparation
3. Application of noxious stimuli (e.g., electrical shock) such that the animal cannot avoid/escape the stimuli and/or it is severe enough to cause more than momentary pain or distress.
4. Any procedures for which needed analgesics, tranquilizers, sedatives, or anesthetics must be withheld for justifiable study purposes

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