Policy # SI-06-2011

Policy Title: Guidelines for Assigning Animals into USDA Pain and Distress Categories

Policy: 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. The following examples are intended 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.

General guidelines:

- 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.
- If an invasive procedure is performed on an animal (e.g., tail snip or euthanasia), list the animals 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.

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 post-approval monitoring annual review.
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>
<th>Category E</th>
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<tbody>
<tr>
<td>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</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 not relieved with anesthetics, analgesics and/or tranquilizer drugs. Withholding anesthesia/analgesia must be scientifically justified in writing and approved by the IACUC.</td>
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**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 its environment

**Examples**

1. Ear punching of rodents
2. Tail snips in mice ≤ 21 days old
3. Peripheral Injections, blood collection or catheter implantation
4. Feed studies, which do not result in clinical health problems
5. Routine agricultural husbandry procedures approved by the IACUC in a protocol or SOP
6. Live trapping
7. Positive reward training or research
8. Chemical restraint
9. Exposure to alterations in environmental conditions (not
10. Genetically

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 tumors
7. Tattooing
8. Exposure of skin to UV light to induce sunburn
9. Tail snips in mice > 21 days old
10. Genetically

1. Toxicological or microbiological testing, cancer research or infectious disease research that requires continuation after clinical symptoms are evident without medical relief Ocular or skin irritancy testing
2. Food or water restriction deprivation beyond 20% of body weight
3. Application of noxious stimuli such as electrical shock that the animal cannot avoid/escape
4. Any procedures for
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<td>extreme) with appropriate conditioning and microenvironment</td>
<td>engineered phenotype that causes pain or distress that will be alleviated</td>
<td>which needed analgesics, tranquilizers, sedatives, or anesthetics must be withheld for justifiable study purposes</td>
<td>5. Exposure to extreme environmental conditions</td>
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<tr>
<td>6. Paralysis or immobilization of a conscious animal.</td>
<td>7. Genetically engineered phenotype that causes pain or distress that will not be alleviated</td>
<td>5. Exposure to extreme environmental conditions</td>
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