Guideline for Assigning Animals into USDA Pain and Distress Categories

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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 next page.
- 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 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 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.