

GUIDELINES REGARDING USDA PAIN AND DISTRESS CATEGORIES IN IACUC PROTOCOLS

PURPOSE:

Liberty University adheres to the four reportable pain categories defined by the USDA, (B, C, D, and E). These guidelines serve to help researchers in categorizing animal use for IACUC approved protocols.

GUIDELINES:

Any IACUC protocol submitted for approval must classify the potential for pain or discomfort according to these levels, defined as follows (per the Animal Welfare Act 2.36 (b)(5-8):

CATEGORY B

Animals that are bred, held, or acclimated for teaching, use in research, experiments, or surgery that have not yet been used for such purposes.

CATEGORY C

Animals that have been engaged in teaching, research, experimentation, or testing, but experienced no pain, distress, or pain-relieving drugs. Routine procedures (e.g., blood sampling, injections) shall be classified into this category.

CATEGORY D

Animals that have been engaged in teaching, research, experimentation, testing, or surgery that involved pain or distress to the animal for which appropriate analgesic, anesthetizing, or tranquilizing drugs were used.

CATEGORY E

Animals that have been engaged in teaching, research, experimentation, testing, or surgery for which pain or distress was not alleviated by the use of an appropriate analgesic, anesthetizing agent, or tranquilizing drug per potentially adverse effects on procedures, results, interpretations, teaching, research, testing, or surgery.

APPROACHES FOR CLASSIFYING PAIN AND DISTRESS

1. Comparison with Humans
 - a. Consider equivalent or comparable procedures or states in humans and assess whether it would cause more than minimal or transient pain or distress.
 - b. If pain is an expectation, is it necessary to treat, and if so, how?
 - c. What are the potential consequences of not treating the pain?
2. Objective Signs of Pain and Distress in Animals
 - a. Are there any directly observable signs of pain or distress following the procedure?
 - i. Signs may include:
 1. Changes in activity level, appearance, temperament, feeding behavior, physiology
 2. Vocalizations
 3. Surgical site appearance

TABLE I. USDA PAIN CATEGORIES AND CORRESPONDING EXAMPLES

USDA CATEGORY B	USDA CATEGORY C	USDA CATEGORY D	USDA CATEGORY E
Breeding or holding colony protocols	No more than momentary or slight pain or distress and no use of pain-relieving drugs, or no pain or distress. For example: euthanized for tissues; just observed under normal conditions; positive reward projects; routine injections and/or blood sampling.	Pain or distress appropriately relieved with anesthetics, analgesics, and/or tranquilizer drugs or other methods for relieving pain or distress.	Pain or distress or potential pain that is not relieved with anesthetics, analgesics, and/or tranquilizer drugs or other methods for relieving pain or distress.
	EXAMPLES	EXAMPLES	EXAMPLES
	<ol style="list-style-type: none"> 1. Holding or weighing animals in teaching or research activities 2. Injections, blood collection or catheter implantation via superficial vessels. 3. Tattooing animals. 4. Ear punching of rodents. 5. Routine physical examinations 6. Observation of animal behavior. 7. Feeding studies which do not result in clinical health problems 8. AVMA approved humane euthanasia procedures. 9. Live trapping. 10. Positive reward projects 	<ol style="list-style-type: none"> 1. Diagnostic procedures such as laparoscopy or needle biopsies. 2. Non-survival surgical procedures. 3. Survival surgical procedures. 4. Post-operative pain or distress. 5. Ocular blood collection in mice. 6. Terminal cardiac blood collection. 7. Any post procedural outcome resulting in evident pain, discomfort or distress such as that associated with decreased appetite or activity level, adverse reactions, to touch, open skin lesions, abscesses, lameness, conjunctivitis, corneal edema and photophobia. 8. Exposure of blood vessels for catheter implantation. 9. Exsanguination under anesthesia. 10. Induced infections or antibody production with appropriate anesthesia and post-op/post-procedure analgesia when necessary. 	<ol style="list-style-type: none"> 1. Toxicological or microbiological testing, cancer research or infectious disease research that requires continuation until clinical symptoms are evident or death occurs. 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 if the animal cannot avoid/escape the stimuli and/or it is severe enough to cause injury or more than momentary pain or distress. 5. Infliction of burns or trauma. 6. Prolonged restraint. 7. Any procedures for which needed analgesics, tranquilizers, sedatives, or anesthetics must be withheld for justifiable study purposes. 8. Use of paralyzing or immobilizing drugs for restraint. 9. Exposure to abnormal or extreme environmental conditions. 10. Psychotic-like behavior suggesting a painful or distressful status. 11. Euthanasia by procedures not approved by AVMA. 12. Use of Freund's Complete Adjuvant.

(Note: There is no USDA pain Category A.)

GUIDELINES FOR DETERMINING USDA CLASSIFICATION IN PROTOCOLS INVOLVING TISSUE COLLECTION BEFORE OR AFTER EUTHANASIA AND/OR ANIMAL PERFUSION:

- If an animal will be euthanized by an approved physical or chemical method of euthanasia solely for the collection of tissues (after the animal's death), the procedure shall be classified as USDA Pain Category C.
- If an animal will be anesthetized so that non-vital tissues can be collected (liver biopsy or skin biopsy), and the animal will then be allowed to recover, the procedure shall be classified as USDA Pain Category D (survival surgery).
- If an animal will be anesthetized so that non-vital tissues can be collected (liver biopsy or skin biopsy, etc.); and the animal will be euthanized, the procedure shall be classified as USDA Pain Category D (non-survival surgery). In this scenario, it may be necessary to justify why the animal couldn't be euthanized (USDA Pain Category C) rather than anesthetized.
- If an animal will be anesthetized so that vital tissues can be collected (heart, both kidneys or lungs, whole liver, etc.), the animal will obviously succumb to the procedure. To determine whether this will be euthanasia or non-survival surgery, we must consider the definition of euthanasia. A critical component of this definition is "rapid unconsciousness followed by loss of cardiac, respiratory, and brain function." Based on this definition, procedures that require tissue manipulation or other prolonged techniques prior to the animal's death (more than a few minutes) shall be classified as non-survival surgery (USDA Pain Category D). Similarly, if an animal will be anesthetized so that the tissue can be collected in the "freshest" possible state (i.e., heart) and the tissues will be rapidly excised, the procedure shall be classified as euthanasia (USDA Pain Category C). (Note: In this scenario, it is difficult to justify why the animal couldn't be euthanized rather than anesthetized.)
- If an animal will be anesthetized so that it can be chemically perfused, the same "test of time" applies (i.e., long, technical manipulations shall be classified as USDA Pain Category D while rapid intravascular injection of the perfusate without other manipulations shall be classified as USDA Pain Category C).