

Guidelines for Classifying Category 3 Procedures on Animals

Any animal that experiences unrelieved pain or generalized discomfort without the provision of anesthetics, analgesics, or tranquilizers is placed in Category 3 under Section G of the Frederick National Lab Animal Study Proposal form. For classification purposes, a procedure causing unrelieved pain or generalized discomfort is defined as any procedure that would be expected to cause more than momentary pain or generalized discomfort in a human and for which a human would receive pain-reducing medications including aspirin, ibuprofen, acetaminophen, lidocaine, or prescription medications. To assist with the appropriate classification of animals into Category 3 (Unrelieved Pain or Generalized Discomfort) the ACUC has provided the following examples:

- *Studies that propose death as an endpoint (e.g., lethal dose studies, infectious agent models, neoplasia survival studies). Death as an endpoint is not sanctioned by the ACUC. Extenuating circumstances for which death is an expected endpoint require scientific justification;*
- *Pain studies that would not be possible if pain-relieving agents were administered;*
- *Psychological conditioning experiments that involve painful stimuli such as a noxious electrical shock that cannot immediately be avoided by an animal;*
- *Procedures that are known to induce a painful inflammatory response (e.g., peritonitis);*
- *Neurological studies that result in the loss of normal body function (e.g., paralysis, difficulty with ambulation, difficulty with urination/defecation, inability to obtain food or water);*
- *Studies where it is not possible to relieve progressive or persistent clinical signs of pain or distress.*

Please note that this is not a comprehensive list of procedures that could warrant a Category 3 designation. The ACUC reviews each study on a case-by-case basis to determine if animals are undergoing procedures that require Category 3 classification. If a procedure is classified as Category 3, the investigator is required to provide the following information to the ACUC for consideration:

- *A scientific justification as to why the appropriate use of anesthetics, analgesics, sedatives, tranquilizers, or timely euthanasia are contraindicated in the study;*
- *A description of his/her consideration of alternatives and the determination as to why alternatives are not available; and*
- *A literature search statement to include the database(s) searched, the date of the search, the period covered, and the keywords that were used.*

Additional information regarding alternatives to painful procedures and database reference searches can be found at <http://web.ncifcrf.gov/rtp/lasp/intra/acuc/fred/alternatives.asp>

Reference:

Working with the IACUC: Writing an Animal Protocol. American Association for Laboratory Animal Science. April 2002.