

TITLE: USDA Pain Categories Use	APPROVED: March 14, 2012
IACUC POLICY: 004 REVISION: 2	REVISED: March 13, 2021
SCOPE: This policy applies to all activities involving the use of animals in research, teaching, or testing.	
PURPOSE: To define the USDA-established pain categories C, D, and E used by the GT IACUC for protocol preparation and review and provide examples for each category	
KEYWORDS: Pain category, USDA, category B, C, D, E	
Policy Owner: Office of Research Integrity Assurance (ORIA) Vice President for Research Development and Operations (VPR-DO)	
Policy Contact: Mary Beran, Director, mberan3@gatech.edu or IACUC@gatech.edu	

1. BACKGROUND:

The Animal Welfare Act Regulations [9 CFR §2.36(b)(5-7)] require research facilities to submit an annual report that accounts for the numbers of animals used in specific categories defined according to whether the animals experienced pain and/or distress and whether relief from pain or distress was provided for such animals. The United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care, Policy 17 provides further guidance on submitting the annual report (APHIS Form 7023) for reporting animal usage numbers according to these pain categories. To facilitate accurate accounting for annual animal usage in the appropriate USDA pain category, the IACUC is adopting these USDA-established pain categories for animals used in protocols at GT.

2. POLICY:

General Notes:

• **Unweaned offspring**

Offspring that are unweaned (nursing) on the last day covered by the report are not counted in any category unless they were used in research, teaching or testing and then they are placed in C, D or E as appropriate.

• **Animals on multi-year studies**

Animals on multi-year studies are counted once per year. The category may change from year to year depending on procedures done during the time period covered by each report.

• **Animals at more than one institution**

If animals move between institutions, only one institution enters them on the report so that each animal is counted only once per year.

• **Animals on more than one protocol or that undergo multiple procedures**

Each animal should be entered only once in the highest pain category.

• **Veterinary procedures do not affect category choice**

Veterinary procedures are here defined as those not described in the IACUC protocol and may include procedures requiring anesthetic, analgesic or distress-relieving drugs. Veterinary procedures include treatment of spontaneous or teaching or research-related disease or injury as well as procedures commonly done to healthy animals such as castration, dental prophylaxis and tuberculosis testing.

USDA Pain Category B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.

“Not yet used” may mean dead

Although the word “yet” appears before “used” in USDA’s documents, animals that are euthanized without undergoing research or teaching procedures go into Category B.

Example: A cat was living in the animal facility during any time covered by the report, but was not used in any research by the last day covered by the report for that year.

Example: A cat was placed in category D on one year’s report because it had a surgery for research purposes during that year. During the subsequent year no research procedures were conducted even though the cat had visible devices on the outside of its body placed there during surgery the year before.

Example: A cat broke its leg jumping from the top of a cage in the housing room. Because the broken leg or treatment for it would not affect the cat’s later research use the veterinarian stabilized the fracture under anesthesia and subsequently prescribed a course of analgesics. The cat was not used in research during the reporting year.

Example: A cat had surgery during the previous year’s report, but during the current year it developed an infection along the wire tract associated with implanted research devices. It was anesthetized for diagnosis and treatment, and then given a course of analgesics. No painful or distressing research or teaching procedures were done during the reporting year.

Example: A researcher ordered and received animals. One animal died spontaneously, another was anesthetized for examination of a spontaneous medical condition and euthanized due to it. Then the researcher suddenly left the institution. The remaining animals were euthanized without research use. All animals go in category B.

Example: From a breeding colony of covered species 212 adults (defined as post-weaning) were alive in the facility during some or all of the covered time period. Five nursing offspring died during the covered period and 6 nursing offspring were used in research. Two adults were euthanized due to naturally occurring illness, one died spontaneously, and 102 were euthanized because they did not have the desired genotype. Enter 212 in category B and enter the 6 nursing offspring used in research under C, D or E as appropriate to what was done with them.

USDA PAIN CATEGORY C: Teaching, research, experiments, or tests conducted involving no pain, distress, or use of pain relieving drugs. Also included are procedures causing only slight or momentary pain or distress.

Chemical restraint

After lengthy discussion and consideration the GT IACUC decided that use of anesthetic, analgesic or tranquilizing drugs for chemical restraint falls in Category C as long as any teaching or research procedure done while under this chemical restraint causes no or maximally slight or momentary pain or distress. Even though it could be argued that chemical restraint prevents the distress of physical restraint that might otherwise be necessary, the spirit of Category C is evoked when procedures done under chemical restraint are no more than minimally painful or distressing.

General Examples

- Behavioral testing

- Brief needle penetrations including but not limited to intramuscular, subcutaneous or intraperitoneal injections of minimally painful or toxic substances, blood withdrawal from veins or small incisions, gavaging or tattooing with or without receiving pain- or distress-relieving drugs.
- Short-term skillful animal restraint
- Food and/or water restriction resulting in a body weight no less than 90% of age-adjusted average body weight for the genotype.
- Mild noxious stimuli from which escape is possible.

Example: A cat was deprived of food for repeated five day periods except during daily 4-6 hour training where it was offered its entire normal daily ration of food. It lost no more than 10% body weight.

Example: A cat was placed in category D on one year's report because it had a research surgery with anesthesia and analgesia during that year. The cat has visible devices on the outside of its body. During the subsequent year the cat was used only in research procedures involving painless measurements, stimulations and food restriction with less than 10% body weight change.

Example: A cat was anesthetized for shaving and/or external measurements of its body for research purposes.

Example: Rabbits were repeatedly anesthetized for photography and then euthanized.

Example: A fractious animal was anesthetized for an injection and then blood was collected by penetration of a vein with a needle.

Example: A 3 mm long and 1 mm deep incision was made in an animal's skin for extracting a small blood sample whether anesthesia was used or not.

Example: Pigs were received, anesthetized then euthanized without recovery from anesthesia with no research procedures done during the period of anesthesia. After euthanasia tissues and organs were collected for research use.

Example: Animals are anesthetized for noninvasive imaging for research purposes.

USDA PAIN CATEGORY D: Experiments, teaching, research, experiments, or tests conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. Category D may be used when animals are euthanized at the onset of pain or distress.

Example: Surgery is done on a cat under anesthesia for research purposes and the cat is used for painless research tests after recovery.

Example: A cat is anesthetized during invasive research procedures, and is then euthanized without recovery.

Example: Rabbits are anesthetized so that suture can be placed in the eye to induce a disease model.

Example: Rabbits are anesthetized so that a needle can be inserted into the back of the eye for injection of test materials. Even though this is only a needle penetration the GT IACUC decided that this particular case would be more than minimally painful without anesthesia and so falls under Category D.

Example: Deadly disease agents are given, but animals are euthanized when their body temperature rises 1.5°F (which is among the earliest clinical signs of disease).

USDA PAIN CATEGORY E: Teaching, experiments, research, surgery, or tests conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

Nonexistent or ineffective treatment

After lengthy discussion and consideration that included evaluating other IACUC's policies, the GT IACUC decided that insufficiency of pain or distress minimization alone does not warrant Category E because this category specifically states that pain or distress-relieving drugs must adversely affect procedures or interpretations.

Examples of significant pain or distress that must be accompanied by justification for withholding drugs:

- Procedures that affect the animals' ability to eat, drink, ambulate or make normal postural adjustments, or severe persistent, irreversible disruption of sensorimotor organization (paralysis) or induction of psychotic-like behavior.
- Decapitation, cervical dislocation, more than brief physical restraint, application of noxious stimuli from which escape is impossible
- Planned experimentally caused death usually referred to as "death as an endpoint." The GT IACUC currently does not approve studies specifying death as an endpoint.
- The administration of toxic compounds or infectious agents that result in significant pain, distress, illness, and/or death (whether expected or not).
- Monoclonal antibody production using the in vivo ascites method in mice.

Example: A segment of the sensory nerve supplying the hindlimb was removed as a research procedure. Inflammation and regrowth of pain neurons in this nerve are believed to cause neurogenic pain similar to phantom limb pain. The animal chews off parts of its hindlimb apparently in response to this pain. No drugs are known to consistently relieve neurogenic pain and the investigator has justified withholding euthanasia because the point of the experiment is to study nerve re-growth.

3. RESPONSIBILITIES:

- A. GT IACUC - review pain category assignments for procedures involving pain or distress in animal protocols to ensure accurate reporting of animal usage for each USDA-established pain category.
- B. GT ORIA - provides resources and guidance to the IACUC, animal research investigators, and care staff on current regulatory and laboratory animal standards for reporting USDA pain category assessment and animal usage.

- C. PIs and research teams - ensure that the appropriate pain category assigned to animals in approved animal studies is based on the provisions described in this policy.

4. REFERENCES:

- A. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care, Research Facility Inspection Guide, Part 14: Records, 14.1: Annual Report, March 2006.
- B. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care Resource Guide, Policy 17: Annual Report for Research Facilities, August 25, 2006.
- C. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Form 7023 “Annual Report of Research Facility”
- D. USDA Policy #11: Painful and Distressful Procedures. Issue Date: March 25, 2011 References: AWA Section 2143, 9 CFR, Part 2, Sections 2.31(d)(1)(i,ii,iv), 2.31(e)(4), 2.33(b)(4), 2.36(b)(5,6,7)

REVISION HISTORY:

Revision Number	Summary of Revisions	Revision Date
1	Update Reference and formatting	March 10, 2015