

Subject: Painful Procedures Policy #11

References: AWA Sections 13(a)(3), 13(a)(7), 13(e)(2, 3)
9 CFR, Part 2, Sections 2.31(d)(1)(i,ii,iii,iv), 2.31(e)(4), 2.33(b)(4)
9 CFR, Part 3, Section 3.6(b)(5,6,7)

History: —
Replaces letters dated May 8, 1992, November 7, 1991, November 9, 1990,
and March 1, 1990.

Justification: Provides requested guidance. Procedures involving animals will avoid or
minimize discomfort, distress and/or pain.

Policy: A painful procedure is defined as any procedure that would reasonably be
expected to cause more than slight or momentary pain and/or distress in a
human being to which that procedure is applied. The Institutional Animal Care
and Use Committee (IACUC) is responsible for ensuring that investigators
have appropriately considered alternatives to any procedures that may cause
more than slight or momentary pain or distress. A written narrative description
of the methods and sources used to search for alternatives must be provided.
Where specific testing procedures are required by Federal law, the CFR
references or other legal guidelines requiring them should be noted.

Examples of procedures that can be expected to cause more than momentary
or slight pain include, but are not limited to, the following:

- **Terminal Surgery** is considered a painful procedure which is alleviated
by anesthesia.
- **Freund's Complete Adjuvant** used for antibody production may cause
results ranging from momentary or slight pain to severe pain depending
on the product, procedure, and species.
- **Ocular and Skin Irritancy Testing.** The dosing procedure itself is
generally not painful but the reaction caused by the product being tested
may cause pain.

Examples of procedures that may cause more than momentary or slight
distress include, but are not limited to, the following:

- **Food or water deprivation** beyond that necessary for normal presurgical preparation.
- **Noxious electrical shock** that is not immediately escapable.
- **Paralysis or immobility** in a conscious animal.

Many procedures, including any of those in the lists above, may cause both pain and distress. An example of a procedure that can be expected to cause more than momentary or slight pain as well as distress would be a study involving extensive irradiation.

Animals exhibiting signs of pain, discomfort, or distress such as decreased appetite/activity level, adverse reactions to touching inoculated areas, open sores/necrotic skin lesions, abscesses, lameness, conjunctivitis, corneal edema, and photophobia are expected to receive appropriate relief unless written scientific justification is provided in the animal activity proposal and approved by the IACUC.

Research facilities must have a mechanism in place for ensuring that animals are reported in the appropriate pain category on the annual report (APHIS Form 7023). Individual animals that do not experience pain/distress from testing procedures should be reported in column C. Individual animals experiencing pain/distress which is alleviated with anesthetics, analgesics, sedatives and/or tranquilizers should be reported in column D. This category includes terminal surgery under anesthesia. Individual animals in which needed anesthetics, analgesics, sedatives, and/or tranquilizers are withheld should be reported in column E. For all column E animals, a written justification, approved by the IACUC, must be provided, including CFR references or other guidelines if appropriate.