The **USDA AWA regulations** stipulate that the number of animals used in research and teaching by an institution must be reported annually to the USDA. The animals must be placed by species into one of four USDA pain/distress categories. To help collect accurate information, IACUCs ask an investigator to categorize the animals requested using the same system.

To do this properly, you must understand how animals are assigned to the four USDA pain/distress categories. The category labels (B through E) come from the column labels used on the USDA annual report form. The categories will be discussed in order from no pain/distress (B) to most pain/distress (E).

A simple yet useful **definition of a painful or distressful procedure on an animal** is this:

"A procedure that would cause pain or distress in a human."

It is important to understand that if multiple procedures will be performed on an animal, the animal is placed in the category appropriate for the most painful/distressful procedure. One animal cannot be placed in multiple categories.

**Category B animals** are those that are being "bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes." These animals have not been used for any research procedure, however minor. Category B is the place to put breeders and other animals that are not undergoing any experimental procedures.

**Category C animals** are not subjected to procedures that involve pain or distress or would require the use of pain-relieving drugs. Routine procedures such as injections and blood sampling from veins that produce only mild, transient pain or discomfort are reported in this category. Another example of category C procedures is an observational study of animal behavior. Animals that are euthanized **before** tissue collection or other manipulations are also commonly placed in this category, if no other procedures are to be performed that put them in a higher pain/distress category.
**Category D animals** are those subjected to potentially painful procedures for which anesthetics, analgesics, or tranquilizers will be used. The important concept is that animals are given appropriate anesthesia and/or pain relief to limit their pain and distress as much as possible.

Examples of category D procedures are

- Surgery conducted with appropriate anesthesia and postoperative analgesia.
- Rodent retroorbital eye bleeding performed under anesthesia.
- Primate tattooing performed for identification under anesthesia.
- Removal of a small tumor under local or general anesthesia.
- Use of analgesia after an animal's skin is exposed to ultraviolet light to cause a "sunburn".
- Terminal exsanguination (euthanasia by removal of blood) under anesthesia.

**Category E animals** are those that are subjected to painful or stressful procedures without the use of anesthetics, analgesics, or tranquilizers. Withholding of anesthetics, analgesics, or tranquilizers can only be allowed if it is scientifically justified in writing and approved by the IACUC. Examples of category E procedures are lethal dose studies (e.g., LD50 studies) that allow animals to die without intervention, pain studies that would not be possible if pain-relieving agents were administered, and psychological conditioning experiments that involve painful stimuli such as a noxious electrical shock that cannot immediately be avoided by an animal.

Category E studies are given increased scrutiny by IACUCs because they must be satisfied that less painful or stressful alternatives are not available, or that less painful/stressful endpoints cannot reasonably be used. By law, the institution must **annually report all category E procedures** to the USDA and include a scientific justification supporting the IACUC's decision to approve them. Often, the justification given by the researcher on the animal forms submitted to the IACUC is used for the annual report.

It is important for information on category E procedures to be complete and accurate. Once submitted to the USDA, this information will likely be available to the public through a Freedom of Information Act request.