A) RESPONSIBILITIES

It is the responsibility of all investigators using animals in research or teaching at UTSA and the animal care staff to abide by and enforce this policy.

B) APPLICATION

This policy sets a Default Endpoint that will be enacted in cases where protocol-specific endpoints are not written into the applicable protocol and approved by the IACUC.

C) DEFINITIONS:

N/A

D) PROCEDURES:

This policy provides Default Endpoints for principal investigators (PIs) and laboratory staff to deal with anticipated or unanticipated severe or chronic pain or distress, which may occur in some animal research studies. If the PI does not identify and properly justify alternative endpoints in the protocol application that is approved by the IACUC, the Default Endpoints stated in Section 1 below will be applied, followed by euthanasia of animals and/or termination of study experimental procedures. If an animal research study involves death as an endpoint, the PI shall include the information required by Section 2 below in his/her protocol application.

1) Default Endpoints

a) Loss of 20% of body weight from baseline weight when assigned to the protocol. A growth normogram must be used to adjust the basal weight for growing animals.

b) Major organ failure or medical conditions unresponsive to treatment such as respiratory distress, icterus, uremia, intractable diarrhea, self-mutilation or persistent vomiting.

c) Surgical complications unresponsive to immediate intervention; i.e., bleeding, vascular graft/circulation failure, infection, and wound dehiscence.
d) Rodents that have complete anorexia for 2 days and non-rodents for 4 days.
e) Clinical or behavioral signs in rodents unresponsive to appropriate intervention. In the case of rodents, abnormalities persisting for 24 hours and for non-rodents, abnormalities persisting for 48 hours. Abnormalities would include:

1. inactivity
2. labored breathing
3. sunken eyes
4. hunched posture
5. piloerection/matted fur
6. one or more unresolved skin ulcers
7. abnormal vocalization when handled
8. tumors that affect normal function or that become ulcerated
9. anorexia
10. persistent coughing
11. excessive scratching or inability to rest due to dermal changes

The above endpoints are minimal and are not necessarily consistent with pain and distress-free research. In his/her protocol applications, the PI is encouraged to identify earlier, more refined endpoints that avoid or minimize discomfort, distress and pain to the animals and that are compatible with experimental objectives. If the LARC or laboratory staff identifies an animal as having any of the endpoints identified above, the LARC or laboratory staff shall immediately report their observations to the PI and the LARC Veterinary staff. If an animal needs to be euthanized and the PI is unavailable to euthanize the animal the UV or designee will euthanize the animal.

If the PI or laboratory staff identifies an animal as having any of the endpoints identified above, he/she shall immediately follow this policy and euthanize the animal. If an animal has any of the endpoints identified above and the PI feels that the animal should not be euthanized, for any reason, the UV should be immediately consulted. In this circumstance the UV will make the final clinical decision regarding the need to euthanize the animal.

2) Death Endpoints

If the protocol involves death as an endpoint, the following shall be included in the protocol:
a) Written justification when appropriate including:
   (1) discussion of alternative endpoints
   (2) literature citation
   (3) copies of pertinent publications where appropriate
b) Justification of the numbers of animals to be included
c) Justification for non-use of analgesics if this is so
d) At least twice-daily monitoring (not more than 14 hours apart) once animals exhibit
   abnormal signs
e) Maintenance of written records of monitoring