Humane Endpoints Policy

# Purpose

The purpose of this guideline is to provide criteria for identifying and utilizing the earliest endpoints that are compatible with the scientific objective of research studies while preventing, minimizing, or alleviating any actual or potential pain, distress, or discomfort to study animals.

# Scope

This applies to all animal users working under an AACUC approved protocol. Principal Investigators are responsible for ensuring staff are trained on the humane endpoints listed in the protocol.

# Definitions

**Humane Endpoint:** Humane endpoints refer to one or more predetermined physiological or behavioral signs that define the point at which a research or teaching animal’s pain and/or distress is terminated, minimized, or reduced by taking actions such as euthanizing the animal, terminating a painful procedure or giving treatment to relieve pain and/or distress.

**Experimental Endpoint:** When the scientific aims and objectives are reached.

**Anorexia:** Loss of Appetite

# Guidance

## Animal Welfare Regulations and Policies require: Animals exhibiting signs of pain, discomfort, or distress are to receive appropriate relief unless written scientific justification has been provided in the protocol and approved by the AACUC. Additional points of guidance include:

### Certain animal use protocols include procedures or approaches that require special consideration during the AACUC review process due to their potential for unrelieved pain or distress or other animal welfare concerns.

### The AACUC is obliged to weigh the objectives of the study against potential animal welfare concerns. By considering opportunities for refinement, the use of appropriate non-animal alternatives, and the use of fewer animals, both the institution and the principal investigator (PI) can begin to address their shared obligations for humane animal care and use.

### Use of humane endpoints contributes to refinement by providing an alternative to experimental endpoints that result in unrelieved or severe animal pain or distress, including death.

### The PI should identify, explain, and include in the animal use protocol an experimental endpoint that is both humane and scientifically sound.

### Critical information that should be included in defining experimental endpoints includes precise definition of the humane endpoint (including assessment criteria), the frequency of animal observation, training of personnel responsible for assessment and recognition of the humane endpoint, and the response required upon reaching the humane endpoint.

* 1. Guiding Principles

### The earliest possible experimental endpoints that meet the scientific aims and objectives must be used for studies in which it is anticipated that animals may experience more than mild pain or distress.

### The number of animals that may experience more than momentary pain or distress must be clearly described and scientifically justified. If humane endpoints that allow for greater degrees of pain and/or distress per experimental group are used, the number of animals for each endpoint must be clearly described and justified.

### Animals must be monitored at a frequency acceptable by the AACUC and described in the protocol by personnel trained and experienced in recognizing signs of illness, injury, or abnormal behavior. The frequency of observation of the entire group must be increased when one animal or more animals in a group are observed to be in unrelieved or severe pain or distress, including death.

### Personnel with training to determine humane end points must make an assessment as soon as possible once notified of an adverse health event, including Program Veterinarian and facility manager.

## Examples of conditions where intervention is appropriate include but are not limited to:

### Weight loss exceeding 15% of body weight compared to the pre-study weight or to age-matched controls.

### Body Condition Score (BCS). With some species, disease processes or in growing animals, body weight is a poor indicator, thus body condition scoring (e.g., muscle atrophy or emaciation) may be more useful. No animal should be allowed to fall into poor body condition (less than 2 out of 5 or 3 out of 9), based on the species-specific reference scales defined in the protocol, unless scientifically justified and approved by the AACUC,

### In specific models, animals may be allowed to persist in poor body condition or body weight loss may be allowed to exceed 15%. In these instances, a request for exemption must be written in the AACUC protocol and approved.

### Anorexia. Complete anorexia for up to 5 days, OR partial anorexia (less than 50% of caloric requirement) for up to 7 days. Anorexia may be “normal” for immediate post-surgical patients.

### Inability to obtain food/water. Inability to ambulate to reach food or water; lesions that interfere with eating or drinking or reluctance to stand.

### Infection. Infection involving any organ system (either clinical or as indicated by laboratory testing) which fails to respond to antibiotic therapy and is accompanied by systemic signs of illness.

### Marked change in behavior/depression. Lethargy, abnormal vocalization, aggression, recumbency, rough hair coat/hunched posture.

### Signs of severe organ system dysfunction. Non-responsive to treatment or with a poor prognosis as determined by a consulting veterinarian in consultation with the Program Veterinarian.

## Humane Intervention: If humane endpoints are reached, the consulting veterinarian and Program Veterinarian must be notified. Steps to provide alterations in management and options may include but are not limited to the following:

### Veterinary care, analgesia, and/or supportive care to the animal

### Modification of housing or husbandry practices

### Increasing the frequency of animal observations

### Modification of experimental procedures

### Termination of painful procedures

### Removal of animals from the study

### Humane euthanasia of the animal

# Pilot Studies

### When novel studies are proposed and information on a procedure’s effect on animals is limited or unavailable, or humane endpoints cannot be identified or defined, a pilot study may be recommended or required by the IACUC.

### When such pilot studies are approved by the IACUC, the IACUC must be informed of outcomes (e.g., morbidity/mortality) as described in the approved protocol, and the protocol must be amended to include requirements related to animal monitoring and humane endpoints determined by the pilot study.

### Regular observations of the animals throughout a pilot study are required to identify critical periods during the experiment when the animals’ well-being will be especially at risk.