



Standard Adverse Effects and Early Removal Criteria Policy

Purpose:

This policy provides standard ERC which apply to all research and teaching protocols at OSU unless exceptions have been scientifically justified and approved by the IACUC.

Background:

Animal research must utilize the most humane methods and endpoints while accomplishing the research goals. Ideally, experimental endpoints occur with minimal or no adverse effects, pain, or distress to the animal. In some cases however, studies will result in pain/distress in order to accomplish the scientific objectives. In all cases, early removal criteria (ERC) are utilized as a basis for euthanasia in the event pain and/or distress or imminent deterioration occurs prior to the planned study endpoint. Furthermore, the IACUC recognizes that experimentally induced or spontaneous clinical signs in animals may be unexpected or otherwise not specifically identified in the IACUC protocol. Consultation with the veterinary staff is expected when unanticipated adverse effects are observed.

Requirements:

Investigators must ensure humane care of their research animals by checking all animals at least weekly to utilize ERC as listed in their protocol. Some animals will require more frequent oversight due to model/study endpoints and such oversight by the research team must be clearly outlined in the animal use protocol. Once an animal meets the ERC, the principal investigator is responsible for promptly (< 24 hrs.) removing the animal from the study or initiating treatment as outlined in the protocol. Alternatively, consultation with a veterinarian would be required to discuss treatment options. The following items are standard ERC:

1. Weight loss:

- a. Loss of 20% baseline body weight or compared to an age-matched control (for young growing animals)

2. Body Condition Score:

- a. Rodents
 - Poor body condition scores ≤ 2 or ≥ 4
 - See [Body Condition Score chart](#) (*Lab Anim Sci.* 1999;49(3):319-323).
- b. Non-rodents
 - Poor body condition based on the species-specific reference scale as defined in the protocol

3. Weakness/inability to obtain feed or water:

- a. Inability or extreme reluctance to stand/ambulate for 24 hours

4. Tumor production:

- a. Tumor size must not exceed 1.6 cm in any dimension in a mouse, or 3.6 cm dimension in a rat. When multiple tumors are present, tumor size must be based on cumulative longest dimensions. The IACUC will consider alternative endpoint criteria if justified and clearly described in your protocol.
- b. Depending on the anatomic location, animals with tumors that interfere with normal function of vital organs (breathing, etc.) or impede the expression of normal activities (must be able to place all four feet on the ground and walk normally) must be removed.
- c. Ulceration greater than 2mm

Experiments that necessitate unrelieved pain and/or distress as approved by the IACUC must be clearly identified to care staff at the cage level. This includes but is not limited to protocols using moribund as sole criteria for removal and death as an endpoint.

Applicable Regulations

1. Health Research Extension Act of 1985 and Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals.

Additional Information/Guidance

1. Guidelines for Endpoints in Animals Study Proposals, ARAC Guideline approved 03/04/16 https://oacu.oir.nih.gov/sites/default/files/uploads/arac-guidelines/asp_endpoints.pdf.
2. [Guideline for Rodent Tumor and Cancer Models, UPenn IACUC approved 06/28/16](#)

Body Condition Scoring references for large animals:

- <https://www.extension.purdue.edu/extmedia/as/as-550-w.pdf>
1. Horses
 - http://www.vetmed.ucdavis.edu/ceh/local_resources/pdfs/CAStandards-Feb2014.pdf
 - <http://extension.umaine.edu/publications/1010e/>
 2. Beef Cattle
 - <http://beef.unl.edu/learning/condition1b.shtml>
 - <https://pubs.ext.vt.edu/400/400-795/400-795.html>
 3. Dairy Cattle
 - <https://www.uaex.edu/publications/pdf/FSA-4008.pdf>
 - <https://www.elanco.us/pdfs/ai10752-body-condition-score-insert.pdf>
 4. Swine
 - https://www.aphis.usda.gov/animal_health/vet_accreditation/nvap_modules/FIT/FIT/Assets/NVAP_Mod21_BodyConditionScores_Swine_July2011.pdf

5. Sheep

- [http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/agdex9622/\\$FIL E/bcs-sheep.pdf](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex9622/$FIL E/bcs-sheep.pdf)
- <https://www.agric.wa.gov.au/management-reproduction/condition-scoring-sheep>

History of Revisions

36-1 New policy approved 11/01/2009

36-2 This policy was retitled and formerly known as the Early Removal Criteria and Non- CO2 Euthanasia. In addition, the policy was revised and includes criteria from the tumor production policy. IACUC approved this policy on 06/20/2014.

36-3 This revision reflects the early removal criteria for weight loss, body condition scores, and clarifies tumor production models by defining the size of ulcerations. Approved 02/19/2016

36-4 This revision reflects the requirement that investigators must ensure humane care of their research animals by checking animals at least weekly to utilize ERC as listed in their protocol. Revised multiple tumor production to emphasize endpoint criteria being described in the protocol. Approved 06/16/2017

036-05 This revision reflects a requirement being added for experiments that necessitate unrelieved pain and/or distress as approved by the IACUC must be clearly identified at the cage level. This includes but is not limited to protocols using moribund as sole criteria for removal and death as an endpoint. Approved 01/19/2018

036-06 – Policy was revised to remove the requirement for immobile and remove the weight limit related with the tumor size for rodent tumor production models; Approved 11/20/2020

036-07 – Policy revised requirement 4a for tumor production to clarify that alternative endpoint criteria will be considered by the IACUC if justified and clearly described in the protocol.