Purpose: To provide guidelines for the monitoring and endpoint criteria of protocols using mice or rats in neoplastic studies. This includes guidelines for solid tumors and liquid or non-palpable tumors that have been implanted, as well as naturally occurring tumors. These guidelines will help ensure the health and well-being of animals used in neoplastic studies.

The Guide for the Care and use of Laboratory Animals 8th edition states the following concerning humane endpoints for research, teaching and testing animals. “While all studies should employ endpoints that are humane, studies that commonly require special consideration include those that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock.

The Guide for the Care and Use of Laboratory Animals 8th edition also gives the following definitions:

Experimental endpoint – the experimental endpoint of a study occurs when the scientific aims and objectives have been reached.

Humane endpoint – the humane endpoint is the point at which pain or distress in an experimental animal is prevented, terminated or relieved.

Humane endpoints should be selected based on their ability to accurately and reproducibly predict or indicate pain and or distress, imminent deterioration, or death.

Animals in tumor studies should be monitored at least weekly, and at least twice a week once palpable tumors are evident. More frequent monitoring may be necessary when rapid tumor growth is expected, when the tumors are nearing endpoint, or when the animal condition begins to deteriorate.

In studies involving neoplasia, endpoints include but are not limited to:

- **Tumor Size:** For an adult mouse, a tumor is allowed to grow to mean diameters of 2.0 cm. For an adult rat, a tumor is allowed to grow to mean diameters of 4.0 cm. Formulas for determining tumor volume are detailed in references at the end of this document.

- **Multiple Tumors:** The total size of all tumors combined should not exceed 3.0 cm, nor should any one tumor exceed 2.0 cm for mice. For rats, the total should not exceed 5.0 cm, or 4.0 cm for any one tumor.

- **Ulceration:** Tumors that ulcerate and become necrotic or infected. Ulceration should be treated with antibiotic ointment 3x/week and the animal should be monitored daily.

Approved by PACUC 11/28/2018
• **Function:** Tumors that interfere with normal functions such as eating, ambulating, eliminating.

• **Body Condition Score:** As the tumor itself could cause the animal to weigh more, and the animal may become cachexic, weight loss should be assessed in the form of a body condition score (BCS), which should be performed at least weekly or more often depending on the study. A BCS of <2/5 must be euthanized. A BCS of 2/5 may need euthanized if the activity level is decreased. A standard BCS chart is provided below.

• **Overall Condition of the Animal:** Animals displaying signs of pain, lethargy, labored breathing, or lack of responsiveness should be euthanized.

For liquid (leukemia) or non-palpable tumors, BCS and overall condition of the animal are typically used to evaluate the state of the animal. In these cases, a scoring system should be developed within the protocol to determine humane endpoints.

**These endpoint criteria are required to be followed for tumor studies. Exemptions must be justified and approved by the PACUC. Implementation will occur immediately for all new protocols and at the triennial review for currently approved protocols.**

**References:**

The Guide the Care of and Use of Laboratory Animals, 8th Ed. 2008. ILAR.

University of Pennsylvania. IACUC Guideline Rodent Tumor Production approved 04/27/10.


The University of North Carolina at Chapel Hill Standard on Tumor Production and Cancer Research in Mice and Rats. May 2018.
Body Condition Scoring in Mice and Rats

**BC 1**
Rat is emaciated
- Segmentation of vertebral column prominent if not visible.
- Little or no flesh cover over dorsal pelvis. Pins prominent if not visible.
- Segmentation of caudal vertebrae prominent.

**BC 2**
Mouse is underconditioned.
- Segmentation of vertebral column evident.
- Dorsal pelvic bones are readily palpable.
- Thin flesh cover over dorsal pelvis, little subcutaneous fat. Pins easily palpable.
- Thin flesh cover over caudal vertebrae, segmentation palpable with slight pressure.

**BC 3**
Mouse is well-conditioned.
- Vertebral and dorsal pelvis not prominent; palpable with slight pressure.
- Moderate subcutaneous fat store over pelvis. Pins easily palpable with slight pressure.
- Moderate fat store around tail base, caudal vertebrae may be palpable but not segmented.

**BC 4**
Mouse is overconditioned.
- Vertebral column palpable only with firm pressure.
- Thick subcutaneous fat store over dorsal pelvis. Pins of pelvis palpable with firm pressure.
- Thick fat store over tail base, caudal vertebrae not palpable.

**BC 5**
Mouse is obese.
- Mouse is smooth and bulky.
- Bone structure disappears under flesh and subcutaneous fat.
- Segmentation of vertebral column palpable with firm pressure; may be a continuous column.
- Thick subcutaneous fat store over dorsal pelvis. Pins of pelvis not palpable with firm pressure.
- Thick fat store over tail base, caudal vertebrae not palpable.

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Hickman D, Swan M, 2010 Use of a Body Condition Score Technique to Assess Health Status in a Rat Model of Polycystic Kidney Disease, JAALAS Vol 49 No 2 pg 155-159.