Institutional Animal Care and Use Committee (IACUC) Policy for Maximum Tumor Bearing in Laboratory Rodents

These tumor size/number guidelines apply to any solid tumor(s). Any exception(s) to these guidelines need to be justified and approved by the Institutional Animal Care and Use Committee (IACUC). The overriding consideration for humane endpoints of spontaneously forming tumors or oncological experiments must be the overall health of the animal. Any tumor-bearing animal must be humanely euthanized if the tumor becomes ulcerated or necrotic, unless scientifically justified and approved by the IACUC.

<table>
<thead>
<tr>
<th>Species</th>
<th>Tumor Passage and Spontaneous Tumor(s)</th>
<th>Animals with Induced Experimental Tumors and their corresponding controls (IACUC protocol specific)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse ~ 25 g</td>
<td>One tumor no larger than 1.3 cm or Two tumors neither of which measures &gt; 1.0 cm or Body Score ≤ 2 (see chart on following page)</td>
<td>One tumor no larger than 2 cm or Two tumors neither of which measures &gt; 1.3 cm or Body Score ≤ 2 (Note: Tumor necrosis or ulceration - see item # 11 below.)</td>
</tr>
<tr>
<td>Rat ~250 g</td>
<td>One tumor no larger than 2.8 cm or Two tumors neither of which measures &gt; 2.3 cm or Body Score ≤ 2</td>
<td>One tumor no larger than 4 cm or Two tumors neither of which measures &gt; 2.8 cm or Body Score ≤ 2</td>
</tr>
</tbody>
</table>

Animals with subcutaneous tumors or tumor implants should be monitored at least three times weekly once tumors are palpable and daily as tumor(s) approach(es) 85% of the maximum size limit. For subcutaneous solid tumors that can be measured with calipers, the above table gives the greatest maximum dimension in any one direction for mice and rats. As with all animal monitoring described in an approved protocol, investigators must maintain records of tumor monitoring (including date and size) for review by the IACUC or other regulatory body. The following Body Condition Score should be used, especially in rodents with tumors within the body cavity.

Tumors located in areas with limited tissue mass (example – on the calf muscle) must be watched carefully. The tumor should not interfere with or inhibit movement. Animals bearing

Approved July 26, 2002
tumors in such locations are likely to need to be euthanized before the tumors reach the above stated dimensions.

The USDA and PHS policies require proper documentation of animal care and use to assess compliance with research protocols and clinical care procedures. Dates of all observations, treatments, and procedures must be recorded. Dates and times (including AM/PM) of all time-sensitive observations or treatments (post-operative evaluations, pain medication) must be recorded. At minimum, records of the procedure must consist of: Animal ID, date of procedure, type of procedure, anesthetics/analgesics used (dose, route, time), anesthesia chart (vital signs – e.g. pulse rate, heart rate), drugs given (dose, time), general procedures (e.g. intubation, beginning and end of surgery, etc.). Any deviations from the procedure as approved in the protocol due to emergency need must be documented, explained, and reported to the Office of Animal Care and Use. All records must be available for review at any time by IACUC and external regulatory officials.
BC 1
Mouse is emaciated.
- Skeletal structure extremely prominent;
  little or no flesh cover.
- Vertebrae distinctly segmented.

BC 2
Mouse is underconditioned.
- Segmentation of vertebral column evident.
- Dorsal pelvic bones are readily palpable.

BC 3
Mouse is well-conditioned.
- Vertebrae and dorsal pelvis not prominent;
  palpable with slight pressure.

BC 4
Mouse is overconditioned.
- Spine is a continuous column.
- Vertebrae palpable only with firm pressure.

BC 5
Mouse is obese.
- Mouse is smooth and bulky.
- Bone structure disappears under flesh and subcutaneous fat.

A "+" or a "-" can be added to the body condition score
if additional increments are necessary (i.e. ...2+, 2, 2-...)

Laboratory Animal Science 49 (3): 319-323, June, 1999

Approved July 26, 2002
Lymphoid tumors, ascitic tumors, and animal models of tumor metastasis all present special problems with assessment of tumor burden. An animal bearing these kinds of tumors must be monitored very carefully for mobility, eating and drinking habits, and signs of pain, distress, or morbidity. (See the IACUC’s “Guidelines for Humane Euthanasia of Rodents.”)

The following clinical signs are indications of morbidity. Tumor-bearing animals exhibiting these signs should be euthanized.

1. Tumor(s) that interfere with eating, drinking, or elimination.
2. Persistent anorexia or dehydration
3. Unable to maintain an upright posture or to ambulate
4. Muscle atrophy or emaciation
5. Lethargy or failure to respond to gentle stimuli
6. Hypothermia
7. Unconsciousness or coma
8. Bloodstained or mucopurulent discharge from any orifice
9. Labored respiration – particularly if accompanied by nasal discharge or cyanosis
10. Enlarged lymph nodes or spleen due to tumor infiltration
11. Anemia
12. Ulcerated tumors (Note: Tumor necrosis with ulceration of overlying skin is generally considered a humane endpoint. However, an exception may be submitted to the IACUC for consideration on a case by case basis for studies that involve the administration of tumor therapy in which tumor necrosis/ulceration may be a feature of regression. For an exception, the features of tumor regression must be described in an animal use protocol (ACAP) and be approved by the IACUC. Use of purple, Investigator Health Monitoring cards to identify cages receiving tumor therapeutic agents is advised (see DLAM facility supervisor).
13. Significant abdominal distension
14. Incontinence, inappetence or prolonged diarrhea