Animal Care and Use Program
Policy

Spontaneous or Induced Solid Tumor Burden in Rodents

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BACKGROUND

Solid tumors in mice and rats may be induced by the administration of chemical carcinogens or viruses, inoculation with tumor cell lines, transplant of tumor fragments, or they may also occur spontaneously in certain rodent strains. Solid tumor growth may be debilitating for the animal. Therefore, the health and welfare of test subjects need to be continually assessed and documented in order to maximize data acquisition while minimizing pain and distress. To that end, tumor studies commonly require special consideration of humane endpoints which are the point at which pain or distress in an experimental animal is prevented, terminated, or relieved. The use of humane endpoints contributes to refinement by providing an alternative to experimental endpoints that may result in unrelieved or severe animal pain and distress. The humane endpoint should be relevant and reliable, and should be carefully considered during IACUC protocol review.

POLICY

I. Determination of humane endpoints for tumor studies should involve input from the Principal Investigator, the Veterinarian, and the IACUC. All humane endpoints for tumor studies should be defined in the protocol and approved by the IACUC before study initiation. Information that is critical to the IACUC's assessment of appropriate endpoints during protocol review includes:

II. A precise definition of and rationale for the humane endpoint(s), including assessment criteria;

III. A proposed record for monitoring health of the animal including the frequency of animal observation (written monitoring records must be kept and available for veterinary review so that tumor burden and any associated metastatic disease can be clinically assessed);

IV. The training of personnel responsible for assessment and recognition of associated hallmarks that will necessitate initiation of the humane endpoint(s); and

V. The response required to alleviate animal pain and/or distress upon reaching the humane endpoint(s).

VI. The following are criteria that **may** be used within the protocol in determining endpoints of tumor growth studies. Note that some criteria may not be applicable to tumors on internal organs.

A. Tumor size (diameter not to exceed 2 cm in adult mice and 5 cm in adult rats; for multiple tumors on a single adult animal, the maximum diameter is 1 cm in mice and 2.5 cm in rats)
B. Tumor weight (should be limited to no more than 10% of body weight)
C. Weight loss exceeding 20% of the body weight of a conspecific normal animal (taking into account the tumor mass)
D. Tumor becomes ulcerated, infected or necrotic
E. Tumor impedes ability of animal to ambulate
F. Tumor impedes ability of animal to obtain or consume food or water
G. Animal exhibits signs of pain or distress, or palpation of tumor illicits a pain response
H. Animal is cachexic
I. Animal is dehydrated
J. Animal exhibits respiratory difficulty
K. Animal appears weak, is unresponsive, or is moribund
L. Significant abdominal distension (especially when respiratory ability is compromised)
M. Hunched posture with easily visible vertebral bodies
N. Abnormal (or absent) fecal or urine output
O. Rough hair coat

DEFINITIONS

Experimental endpoint - When the scientific aims and objectives have been reached.

Humane endpoint - The point at which pain or distress in an experimental animal is prevented, terminated, or relieved.

REFERENCES

Guide for the Care and Use of Laboratory Animals, 8th Edition; page 27, *Experimental and Humane Endpoints*