

William S. Middleton Memorial Veterans Hospital
IACUC Policy #05-13

Pain, Distress, or Death as Experimental Endpoints and Euthanasia

Policy: Some studies may cause pain (severe or chronic) or distress that cannot be relieved by medication or other methods, or death in animals. Examples of conditions capable of causing pain and distress are the use of death as an endpoint, sepsis, excessive tumor burdens (see Tumor Burden policy 27), ulcerative dermatitis that has ulcerated through the skin, and loss of normal functioning (paralysis, e.g.). In such cases, the animals must be euthanized at the end or, if appropriate, during the procedure.

Deviations from this policy may be acceptable if there is a convincing, specific, and detailed, scientific justification for using pain, distress, or death as endpoints in the study. The justification should explain how applying less-severe or extreme endpoints would jeopardize the goals of the research. The methods of euthanasia must be consistent with the AVMA Guidelines for the Euthanasia of Animals (2013 edition).

Responsibilities:

1. Role of the Investigator

The Principal Investigator is responsible for ensuring that the endpoints specified in the approved Animal Component of Research Protocol (ACORP) are used. The protocol must specify objective criteria, such as degree of a physical or behavioral deficit or tumor size, etc., that will enable a prompt decision regarding initiation of euthanasia to be made. It is highly recommended that Body Condition Scoring be used in the endpoint criteria for any protocol in which animal health is expected to deteriorate due to genotype or experimental manipulations. The method of euthanasia must be described in the protocol.

The use of physical methods, such as cervical dislocation or decapitation, on animals that are not sedated or anesthetized requires a scientific justification for withholding sedatives or anesthetics. The Principal Investigator is responsible for monitoring animals assigned to their protocol to ensure that the endpoints specified in the protocol are applied.

2. Role of the Veterinary Medical Consultant (VMC) and Animal Research Facility (ARF) Staff

In addition to the investigator monitoring of animals that might develop severe or chronic pain, distress, or die, the ARF staff also will monitor these animals during performance of their daily animal husbandry duties. Animals in severe pain or distress, sick, injured or requiring immediate attention (conditions not specified in the

protocol endpoints) will be brought to the attention of the investigator and VMC who will reach agreement on treatment. If the VMC judges that the animal needs immediate and urgent attention, and the Principal Investigator or his/her designee cannot be contacted in a reasonable amount of time, the VMC has the authority to implement appropriate intervention, which may include euthanasia.

3. IACUC Oversight

The IACUC has ultimate responsibility for ensuring that pain and distress in research animals is limited to that which is necessary in the course of approved experimentation. This includes review and approval of methods and agents used for euthanasia of animals as well as experimental endpoints. Committee decisions in this regard will be based on regulatory requirements as well as advice from the VMC and the investigators. The IACUC will review issues of pain, distress, or death as an endpoint as part of its three-year review of each protocol, and may do so more frequently.

Questions: Any questions on this policy should be directed to the A.O. (280-7222).

References:

- *U.S. Government Principles for the Care and Use of Animals Used in Testing, Research, and Training*, 1983.
- *Guide for the Care and Use of Laboratory Animals*, NRC, 2011.
- Code of Federal Regulations, Title 9, Chapter 1, Subchapter A - Animal Welfare
- AVMA Guidelines for the Euthanasia of Animals (2013 Edition)
- *Laboratory Animal Science*, Vol. 49, No 3, June 1999.

Effective date: Approved at the ARC meeting on 11/27/01. Subsequent updates and approvals: 7/11/05; 03/10/08, 3/02/2009, 5/10/2010, 1/11/2011, 5/07/2012, 9/11/2013.