

Chapter 4. Animal Care and Use

**Specifications for the Conduct of Chemistry Activities for Toxicology
Research Performed by the
Division of Translational Toxicology at the
National Institute of Environmental Health Sciences**

4. Animal Care and Use Requirements

Bradley J. Collins¹, Suramya Waidyanatha¹ (Editors)

¹Division of Translational Toxicology, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, USA

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4.1. General Requirements

The contractor must conform to the requirements included in the documents listed below and all federal, state, or local regulations.

- DTT Toxicology Specifications (Specifications for the Conduct of Toxicity Studies by the Division of Translational Toxicology) (NIH 2023)
- National Research Council Guide for the Care and Use of Laboratory Animals (NRC 2011)
- Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (NIH 2015)
- The Animal Welfare Act (USDA 1966)

The contractor must be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International.

Contractors must have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW) at the time of contract award. *(Note: an offeror that does not have a PHS Assurance may be selected but the contracting officer (CO) will have to initiate the process of obtaining an assurance from OLAW, and contract funds may not be expended for animal work until the assurance has been approved).*

Contractors must provide the contracting officer's representative (COR) with Animal Care and Use Committee (ACUC)-approved protocols for the proposed work prior to commencement of work.

If animal species regulated by the U.S. Department of Agriculture are involved in a contract, the contractor shall be registered with the Secretary of Agriculture of the United States in accordance with 7 U.S.C 2136 and 9 Code of Federal Regulations.

The contractor shall use a laboratory animal veterinarian to supervise the care and health of the animals.

A brief description of animal care and use is given in the following sections. Refer to the Specifications for the Conduct of Toxicity Studies by the Division of Translational Toxicology for requirements on animal care and use (NIH 2023).

4.1.1. Humane Care of Animals

Animals shall be anesthetized to alleviate pain in procedures that may cause more than momentary or slight pain.

Animals with the following conditions shall be euthanized immediately to avoid further pain and distress:

- Conditions interfering with their normal postural movements, eating, or drinking
- Debilitating conditions or other conditions indicating pain or distress, as judged by an experienced laboratory animal specialist, or major injuries or ulcers

Moribund animals and animals scheduled for interim and final necropsies shall be euthanized, preferably by asphyxiation via CO₂, by appropriately trained personnel using methods and techniques established by the American Veterinary Medical Association panel of euthanasia and approved by the contractor's Institutional Animal Care and Use Committee and the COR. For euthanasia of moribund animals during the course of a study, the above criteria should be supplemented with professional judgment. The final decision for euthanasia of moribund animals shall be made by the responsible scientist or the Principal Investigator and shall not be left to the discretion of the technicians. Other conditions for euthanasia of rodents can be found in Rao and Huff (1990).

Recommended methods of euthanasia include the following: prolonged exposure to CO₂ gas in cylinders for rodents >10 days old; anesthetic overdose or injection of euthanasia solution; or decapitation with or without anesthesia by trained personnel.

4.1.2. Strains and Sources

Unless otherwise specified by the COR or in the study protocol, Sprague Dawley (Hsd:Sprague Dawley[®] SD[®]) rats and B6C3F1 mice shall be the study rodent models. Other animals (e.g., New Zealand white rabbit) or rodent strains (e.g., CD-1 mouse) may be used in studies if directed by the COR. Animals shall be obtained by the contractor from commercial sources as directed by the COR.

4.2. Animal Receipt and Quarantine Requirements

Shipping cartons/crates must be examined to identify any damage that may have occurred during transit. Animals in damaged cartons/crates shall not be used in the study.

The laboratory animal veterinarian must examine the animals within 24 hours of arrival to assess their health status.

Animals shall be quarantined for a minimum of 14 days under conditions simulating study conditions prior to dosing; COR approval must be obtained for a shorter duration.

At the end of the quarantine/acclimation period, the animals shall be examined and released from quarantine for study (if healthy) by a laboratory animal veterinarian.

4.2.1. Animal Identification and Assignment to Study

During the last few days of the quarantine period, animals must be assigned to the study following formal randomization procedures.

The method of identification must be approved by the National Institute of Environmental Health Sciences. Animals must be uniquely and consecutively numbered.

4.3. References

National Institutes of Health (NIH), Office of Laboratory Animal Welfare (OLAW). 2015. Public health service policy on humane care and use of laboratory animals. Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health. NIH Publication No. 15-8013.

<https://grants.nih.gov/grants/olaw/references/phspolicylabanimals.pdf>

National Research Council (NRC). 2011. Guide for the care and use of laboratory animals. 8th ed. Washington, DC: The National Academies Press. <https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>

Rao GN, Huff J. 1990. Refinement of long-term toxicity and carcinogenesis studies. Fundam Appl Toxicol. 15(1):33-43. [https://doi.org/10.1016/0272-0590\(90\)90160-L](https://doi.org/10.1016/0272-0590(90)90160-L)

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U.S. Department of Agriculture (USDA). 1966. Animal Welfare Act. An act to authorize the secretary of agriculture to regulate the transportation, sale, and handling of dogs, cats, and certain other animals intended to be used for purposes of research and experimentation, and for other purposes. Public Law 89-544, 89th Congress, H.R. 13881, August 24, 1966. <https://www.nal.usda.gov/animal-health-and-welfare/animal-welfare-act>