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JOHNSON SPACE CENTER

Animal Care and Use

Handbook

**Johnson Space Center
Animal Care and Use Handbook
2001**

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Preface

Purpose of This Handbook

A core of knowledge about the ethical and humane care and use of animals in instruction and research is essential. Researchers, their staffs (including both permanent and temporary workers), contractors, subcontractors, grantees, and others who work with animals have an obligation to know about laws governing the ethical concerns relevant to the care and use of animals and to be familiar with the guidelines and policies established by Johnson Space Center, scientific societies and other government agencies.

This Handbook is designed to help meet these obligations and to provide you with information about Johnson Space Center's Animal Care Facility, and the services offered.

Johnson Space Center is committed to the ethical and humane care and use of animals and each person must share responsibility in meeting that commitment.

Acknowledgment

We thank our colleagues at other institutions that freely provided some of the material presented here. Persons in Laboratory Animal Science traditionally share information, published or unpublished, because we share the belief that the animals used in instruction and research are totally dependent upon us for their care and well-being.

Much effort has been made to ensure that the information provided herein is accurate. If, however, errors of any kind are identified, please notify the Animal Care Facility Manager (281-483-2846) or the Animal Care Facility Office (281-483-8800).

This Handbook is considered a “living document,” subject to change in the light of new information and changing conditions.

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1 Acronyms and Definitions

<i>AAALAC</i>	Association for the Assessment and Accreditation of Laboratory Animal Care, International
<i>AALAS</i>	American Association for Laboratory Animal Science
<i>ACF</i>	Animal Care Facility at NASA Ames Research Center
<i>ACLAM</i>	American College of Laboratory Animal Medicine
<i>APHIS</i>	Animal and Plant Health Inspection Service
<i>JSC</i>	Ames Research Center
<i>AVMA</i>	American Veterinary Medical Association
<i>AWIC</i>	Animal Welfare Information Center
<i>CDC</i>	Centers for Disease Control
<i>CFR</i>	Code of Federal Regulations
<i>DEA</i>	Drug Enforcement Agency
<i>DOI</i>	Department of the Interior
<i>EPA</i>	Environmental Protection Agency
<i>FDA</i>	Food and Drug Administration
<i>GLP</i>	Good Laboratory Practices
<i>Guide (the)</i>	NRC Guide for the Care and Use of Laboratory Animals
<i>HHS</i>	Department of Health and Human Services
<i>HVAC</i>	Heating, Ventilation and Air Conditioning
<i>IACUC</i>	Institutional Animal Care and Use Committee
<i>ILAR</i>	Institute of Laboratory Animal Resources
<i>IOM</i>	Institute of Medicine
<i>IRAC</i>	Interagency Research Animal Committee
<i>JSC</i>	Johnson Space Center (Houston)
<i>KSC</i>	Kennedy Space Center (Florida)
<i>NAE</i>	National Academy of Engineering
<i>NAL</i>	National Agriculture Library
<i>NAS</i>	National Academy of Sciences
<i>NIH</i>	National Institute of Health
<i>NIH Policy</i>	Public Health Service Policy on the Humane Care and Use of Laboratory Animals
<i>NPD</i>	NASA Policy Directive
<i>NPG</i>	NASA Policy Guide
<i>NRC</i>	National Research Council
<i>NRC Guide</i>	NRC Guide for the Care and Use of Laboratory Animals
<i>NSF</i>	National Science Foundation
<i>OLAW</i>	Office of Laboratory Animal Welfare

<i>OSHA</i>	Occupational Safety and Health Administration
<i>PHS</i>	Public Health Service
<i>PHS Act</i>	Public Health Service Act (Public Law 99-158)
<i>PI</i>	Principal Investigator
<i>POC</i>	Point of Contact Individual
<i>REAC</i>	Regulatory Enforcement and Animal Care
<i>SDHS</i>	State Department of Health Services
<i>SOP</i>	Standard Operating Procedures
<i>USDA</i>	U.S. Department of Agriculture
<i>WI</i>	Work Instruction

2 Ethics and the Care and Use of Animals at Johnson Space Center

Johnson Space Center recognizes this Handbook as a common point of reference in addressing ethical concerns within discussions, evaluations and the implementation of all policies and procedures concerning the care and use of animals at JSC by all JSC investigators, their staffs (including both permanent and temporary), contractors, subcontractors, grantees and others.

JSC recognizes the legitimacy, importance and sensitivity of the public debate concerning the ethics of animal care and use. We further recognize that within this debate there are a number of legitimate and responsible perspectives and many unresolved issues. We recognize that legitimate concerns and views are expressed in various ways -- including the concept of animal rights and the consideration of animal use versus the significant enhancement of human and animal life. We, therefore, commit ourselves to be a respectful and responsible party within this on-going public debate.

Our role in the care and use of animals carries the responsibility to effectively meet the needs of the animals in our charge while actively seeking and employing methods that embody respect for the life of animals.

.1 NASA Principles for the Ethical Care and Use of Animals (The Sundowner Report) October, 1996.

.2 Introduction

Only the strongest possible allegiance to principles of bioethics can offer a sound basis for any discussion of responsible research. As reflected in the earliest considerations of the National Commission for the Protection of Human Subjects, "scientific research has produced substantial social benefits ...[and] some troubling ethical questions" (The Belmont Report, 1979). The Belmont Report identified fundamental principles underlying the ethical evaluation of research involving human subjects. Similarly, the principles governing the ethical evaluation of the use of animals in research must be made equally explicit.

Vertebrate animals deserve moral concern. The following principles are offered to guide careful and considered discussion of the ethical challenges that arise in the course of animal research, a process that must balance risks, burdens and benefits. NASA will abide by these principles as well as all applicable laws and policies that govern the ethical use of animals (see list at end). It is recognized that awareness of these principles will not prevent conflicts. These principles are also not meant to prescribe definite procedures for resolving such conflicts but rather to provide a framework within which challenges can be addressed in a rational manner.

2.3 Basic Principles

The use of animals in research involves responsibility for the stewardship of the animals, and responsibility to the scientific community and society. Stewardship is a universal responsibility that extends beyond the immediate use of the animals for research to include their acquisition, care and disposition while responsibility to the scientific community and society requires an appropriate understanding of, and sensitivity to scientific needs and community attitudes toward the use of animals.

Among the basic principles generally accepted in our culture, three are particularly relevant to the ethics of research using animals: respect for life, societal benefit and nonmaleficence.

.2.1 Respect for Life

Living creatures deserve respect. This principle requires that animals used in research should be of an appropriate species and health status and should involve the minimum number required to obtain valid scientific results. It also recognizes that the use of different species may raise different ethical concerns. Selection of appropriate species should consider cognitive capacity and other morally relevant factors. Additionally, methods such as mathematical modes, computer simulation, and in vitro systems should be considered and used whenever possible.

.2.2 Societal Benefit

The advancement of biological knowledge and improvements in the protection of the health and well being of both humans and other animals provide strong justification for biomedical and behavioral research. This principle entails that where animals are used, the assessment of the overall ethical value of such use should include consideration of the full range of potential societal goods, the populations affected, and the burdens that are expected to be borne by the subjects of the research.

.2.3 Nonmaleficence

Vertebrate animals are sentient. This principle entails that the minimization of distress, pain and suffering is a moral imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in humans may cause pain or distress in other sentient animals.

.2.4 Cited Documents

Belmont Report, 1979

Animal Welfare Act (Public Law 89-544 as amended)

Government Principles for the Utilization and Care of Vertebrate Animals Used In Testing, Research, and Training, Developed by IRAC and endorsed by the Public Health Service Policy on the Humane Care and Use of Laboratory Animals, 1985

International Guiding Principles for Biomedical Research
Involving Animals, Developed by the Council for International
Organizations of Medical Sciences, Switzerland, 1985
Public Health Service Act (Public Law 99-158, 1985)
Guide for the Care and Use of Laboratory Animals, 1996

3 Responsibilities

3.1 Center Director

The Center Director is charged with the overall administrative responsibility for implementing and maintaining an institutional animal care and use program to assure that all humane, ethical, and legal requirements are met.

3.2 Institutional Official

The Director, Space and Life Sciences Office, has been delegated by the Center Director to serve as the Institutional Official and is responsible for the management of the Animal Care Facility except for signing and submitting the Animal Welfare Assurance to the Office of Laboratory Animal Welfare (OLAW). This responsibility has been retained by the JSC Center Director.

3.3 Director, Space and Life Sciences Office

The Director, Space and Life Sciences Office, is responsible for the oversight of the management of JSC Animal Care Facilities and all issues pertaining to the care and use of animals except as noted above.

3.4 Attending Veterinarian

The Attending Veterinarian will have delegated responsibility for the health of all animals involved in teaching, exhibition and research.

3.5 NASA Chief Veterinary Officer

The Chief Veterinary Officer is responsible for coordinating veterinary and animal care and use activities for all NASA facilities, including the Space Shuttle and Space Station.

3.6 JSC Institutional Animal Care and Use Committee

The Institutional Animal Care and Use Committee (IACUC) is charged with developing, recommending and monitoring NASA-JSC policies and standards relating to animal acquisition, care and use.

3.7 Animal Care Facility Operations

The Animal Care Facility staff is responsible for implementing professionally acceptable standards for the proper care and use of all animals within all animal facilities, and assuring that those standards are met and maintained.

.8 Investigator and Staff

The individual investigators, their staffs, contractors, subcontractors, grantees and others who are involved with the care and use of animals in instruction and research (including field studies of live vertebrates) are expected to study and review this Handbook and to acknowledge their acceptance of the responsibilities therein.

Individuals are accountable by law to comply with the rules and regulations of the applicable statutes. Individuals are also accountable to NASA-JSC to conform to the policies and guidelines adopted by this Institution. These regulations and policies cover:

- the acquisition, care and use of animals;
- efforts to minimize animal pain and distress;
- the training of personnel using animals; and
- consideration of alternatives to animal use.

As a matter of educational policy, even personnel who do not themselves use animals should be aware of these regulations and policies since their co-workers, staffs or others may use animals at a later time. Likewise, instruction of students in proper animal use is an essential component of education in the sciences.

4 Policies, Principles, Standards and Guidelines

4.1 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (<http://www.nih.gov/grants/olaw/tutorial/relevant.htm#2b>)

The principles were developed by the U.S. Government's Interagency Research Animal Committee. Both Public Health Service (PHS) policy and NASA-JSC policy require that all research and instructional uses of animals conform to these Principles.

.2 Public Health Service Policy on the Humane Care and Use of Laboratory

Animals (NIH Policy) <http://grants.nih.gov/grants/olaw/references/phspol.htm>)

The Public Health Service Policy on the Humane Care and Use of Laboratory Animals (1986) incorporates the changes in the Public Health Service Act (PHS Act) mandated by the Health Research Extension Act of 1985 (Public Law 99-158). The PHS Act (herein referred to as the NIH Policy), frequently requires that each institution receiving PHS funds for research involving animals submit detailed information regarding the institution's program for the care and use of animals to the Office of Laboratory Animal Welfare (OLAW). This information is in the form of an Animal Welfare Assurance Statement, and it must be resubmitted at least every five (5) years. Significant changes in existing assurance status or problems encountered in implementing this policy must be reported immediately to the OLAW. In addition, an annual report is submitted utilizing the form provided by OLAW.

An institution's failure to comply with these policies may lead to various actions, including ***the termination of PHS/NASA support for all projects involving animals.***

- 4.3 The NRC Guide for the Care and Use of Laboratory Animals (<http://www.nap.edu/readingroom/books/labrats/>)

The purpose of the NRC guide is to assist scientific institutions in using and caring for laboratory animals in ways judged to be professionally appropriate.

This guide is ***required reading*** for all managers, investigators and staff involved in the animal care and use program at NASA-JSC.

- 4.4 NASA Policy Directive (http://nodis.hq.nasa.gov/Library/Directives/NASA-WIDE/Policies/Program_Management/N_PD_8910_1.html)

The NASA Policy Directive details the policy of the National Aeronautics and Space Administration regarding all animal-related activities. This NPD is based on provisions of the latest issues of the *NRC Guide*, on the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and on the Animal Welfare Act 89-544, 1966, as amended (PL 91-579, 94-279, and 99-198) et. seq., 42 U.S.C. 2473(c)(1) of the National Aeronautics and Space Act of 1958, as amended, and the Code of Federal Regulations (CFR) (9 CFR Subchapter A, Parts 1-4).

4.5 NASA Policy Guideline (NPG)

<http://nodis.hq.nasa.gov/displayDir.cfm?t=NPR&c=8910&s=1A>

<http://nodis.hq.nasa.gov/displayDir.cfm?t=NPD&c=8910&s=1B>

The NASA Policy Guideline delineates the implementing guidelines for the Agency's use of animals in research, testing, teaching and hardware development activities, including such activities conducted in non-U.S. facilities and flight vehicles. This NPG applies to NASA Headquarters and NASA Centers, including Component Facilities, and will be followed by all individuals responsible for any activity involving animals funded by or sponsored by NASA; conducted in or on any NASA facilities, aircraft or spacecraft; or that involve NASA to any degree. Such activities include those conducted under a cooperative agreement, or other arrangement or agreement, entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity.

4.6 Independent Professional Organizations

4.6.1 The American Association for Laboratory Animal Science (AALAS) (<http://www.aalas.org>)

The American Association for Laboratory Animal Science (AALAS) is an organization composed of individuals and institutions professionally concerned with the husbandry, care, and use of laboratory animals. It provides a means for the collection and exchange of information on all phases of laboratory animal care and management. The Association's Animal Technician Certification Board provides a means of developing uniform standards for technician training by defining the qualifications, preparing and approving examinations for training programs, and certifying successful candidates.

.2 The Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC), International is the organization for voluntary peer-review accreditation of laboratory animal care facilities and programs. AAALAC judges animal care by the standards set forth in the *NRC Guide for the Care and Use of Laboratory Animals*. Inspections are made every 3 years by representatives of this organization to ensure that the institution continues to meet these standards. The NIH, in its current policies, accepts AAALAC accreditation as the best means of demonstrating conformance with NIH requirements for animal care and use.

.3 The American College of Laboratory Animal Medicine (ACLAM) (<http://www.aclam.org>)

The American College of Laboratory Animal Medicine (ACLAM) is a specialty board recognized by the American Veterinary Medical Association (AVMA). Founded in 1957, its purposes are to:

- encourage education, training, and research;
- establish standards of training and experience for qualification; and
- to certify, by examination, qualified laboratory specialists as diplomats.

To achieve these goals, the College seeks to interest veterinarians in furthering both training and qualifications in laboratory animal medicine.

.4 The Institute of Laboratory Animal Resources (ILAR)(<http://www2.nas.edu/ilarhome>)

The Institute for Laboratory Animal Resources develops guidelines and disseminates information on the scientific, technological and ethical use of animals and related biological resources in research, testing and education. ILAR promotes high-quality, humane care of animals and the appropriate use of animals and alternatives. ILAR functions within the National Academy of Sciences as an advisor to the Federal Government, the biomedical research community, and the public.

.5 Miscellaneous Professional Societies

In addition to the above, a number of scientific societies have developed guidelines of their own (usually in more detail). The American Psychological Association has published *Guidelines for Ethical Conduct in the Care and Use of Animals*. The American Toxicological Association, the Society for Neurosciences and the American Physiological Society have published guidelines pertaining to the use of animals.

Guidelines have also been developed for the study of animals in their natural environment. For example, the American Society of Mammalogists developed *Acceptable Field Methods in Mammalogy*; the American Ornithologists' Union developed *Guidelines for the Use of Wild Birds in Research*; the American Society of Ichthyologists and Herpetologists have developed *Guidelines for the Use of Fishes in Field Research* and *Guidelines for the Use of Reptiles and Amphibians in Field Research*, and the National Science Foundation has sponsored *Field Research Guidelines: Impact on Animal Care and Use Committees*. Refereed journals are increasingly requiring compliance with pertinent guidelines before accepting papers for publication. All of the above mentioned guidelines can be requested through the ACF Office.

5 Laws, Rules and Regulations

.1 Federal

.1.1 The Animal Welfare Act (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>)

The Animal Welfare Act of 1966 and its amendments regulate the transportation, purchase, sale, housing, care, handling and treatment of animals used in research, for exhibitions, and sold as pets. The Act specifically includes dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, wild animal species, and any other warm-blooded animals that the Secretary of Agriculture determines are being used or are intended for use in research, testing, experimentation, exhibition purposes, or as pets.

Recent amendments address such issues as exercise for dogs; care of nonhuman primates to ensure their psychological well-being; the composition and duties of the institutional animal care and use committee; adequate veterinary care and responsibilities of the attending veterinarian; training of all personnel using laboratory animals in humane methods of animal maintenance and experimentation; and record keeping.

The IACUC is responsible for reviewing all protocols involving animals to make certain that they meet criteria listed in the amendments. In addition, it must conduct semiannual reviews of the total program as well as inspections of all animal study areas and animal facilities to ensure that there are no significant deviations in the use of animals from approved protocols. The importance of this requirement is underscored by the fact that the Chief Executive Officer of an institution (the Center Director) must certify that the attending veterinarian and the IACUC have the authority to enter any animal area at any reasonable time.

The Animal Welfare Act is administered by the United States Department of Agriculture (USDA), specifically, the Regulatory Enforcement and Animal Care (REAC) component of the Animal and Plant Health Inspection Service (APHIS). Research facilities are subject to unannounced inspections by USDA veterinarians, and are required to furnish annual reports that include, in addition to other information and assurances, the common names and numbers of animals used in procedures involving:

- no pain, distress or use of pain-relieving drugs (USDA Categories B and C);
- pain or distress for which appropriate anesthetic, analgesic or tranquilizing drugs were used (USDA Category D); and

- pain or distress for which the use of appropriate drugs adversely affect the procedures, results, or interpretation of the research (USDA Category E).

Routine procedures such as injections are exempt from the reporting requirements. The report must certify that anesthetic, analgesic, and tranquilizing drugs were used appropriately during research and testing, and that the principal investigator has considered alternatives to painful procedures.

Although Federal Research Facilities are not generally subject to inspection by USDA, NASA JSC has requested that the Animal Care Facility be voluntarily inspected following the same procedures utilized for inspection of private institutions (i.e. unannounced).

Noncompliance with USDA rules and regulations for the humane handling, treatment, and transportation of animals may lead to substantial fines and/or suspension of animal research activities.

An amendment to the Act resulted in establishing the Animal Welfare Information Center (AWIC) in the National Agriculture Library (NAL), in cooperation with the National Library of Medicine, to provide reference material and services covering many aspects of animal welfare. In addition, AWIC information be found at the AWIC website (<http://www.nal.usda.gov/awic/>).

.1.2 The Health Research Extension Act of 1985.

(<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>)

The Health Research Extension Act of 1985 (Public Law 99-158) directed the Secretary of Health and Human Services, acting through the Director of NIH, to establish guidelines for:

- the proper care of animals used in research;
- the proper treatment of animals while being used research;
- the establishment of animal care and use committees;
- the establishment of requirements for the composition and function of these committees; and
- the reporting of animal research activities to the government.

This law amended the Public Health Service Act to address the problems of "animals in research" in a more comprehensive fashion than ever before.

The implementation of this law resulted in an amended Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals.

.1.3 The Controlled Substances Act of 1970

Potentially addictive or habituating drugs for human or animal use are classified under this law (Public Law 91-513). Examples of controlled substances include barbiturates and narcotics. The Department of Justice, Drug Enforcement Agency (DEA), enforces this law and requires appropriate security and record management of these substances.

.1.4 The Endangered Species Act of 1973 (<http://endangered.fws.gov/esa.html>)

This law (Public Law 93-205, as amended) seeks "to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide a program for the conservation of such endangered species and threatened species, and to achieve the purposes of the treaties and the conservation of wild flora and fauna worldwide".

Regulatory authority under this Act is vested in the Secretary of the Interior and is implemented by the Federal Fish and Wildlife Service. Implementing rules and regulations are published in the Code of Federal Regulations (CFR), Title 50 (Wildlife and Fisheries).

.1.5 Other Federal Agencies and Regulations

Other federal agencies having jurisdiction over animal research include:

The Bureau of Customs for monitoring importation and quarantine;
Centers for Disease Control (CDC) on the use of infectious agents (<http://www.cdc.gov/>);

Food and Drug Administration (FDA) for radiation protection and approval of medical devices (<http://www.fda.gov/>);

Environmental Protection Agency (EPA) for Good Laboratory Practices (GLPs) (<http://www.epa.gov/>), Pesticides and Toxic Substances;

Department of the Interior (DOI) (<http://www.doi.gov/>),

Marine Mammal Conservation and Protection (<http://www.fws.gov/laws/digest/reslaws/marmam.html>),

and the Lacey Act on interstate transportation (<http://www.fws.gov/laws/digest/reslaws/lacey.html>);

U.S. Nuclear Regulatory Commission on medical, academic, and commercial use of radioisotopes (<http://www.nrc.gov/>);

and the Occupational Safety and Health Administration (OSHA), under the Department of Labor, on hazardous substances (<http://www.osha.gov/index.html>)

and the new Hazard Communication Standards (<http://www.osha-slc.gov/SLTC/hazardcommunications/index.html>).

.2 State of Texas

There are no Texas state laws relating to the use of research animals. However, there is a state law regarding the penalty for vandalism and break-ins of research facilities.

6 Animal Care and Use at Johnson Space Center

This section of the Handbook provides basic information necessary for all persons involved with the care and use of animals at Johnson Space Center.

6.1 Institutional Animal Care and Use Committee

The JSC IACUC was established by the Center Director in 1990 to ensure that experimental animals would be treated according to the regulations then in place and that animal husbandry at JSC would meet required standards. By semi-annual inspection and review, the IACUC ensures that animal care and use at JSC conforms to all pertinent regulations and meets all required standards related to the health and safety of both animals and humans, animal procurement and transportation, quarantine, animal identification, periodic census, and termination and disposal of animals.

The Committee reports to the Director, Space and Life Sciences Office. The required composition of the Committee and its functions are stated on pages 5-7 of the PHS Policy. Specific functions relative to NASA's requirements are given in the NASA Policy Directive and NASA Policy Guidelines.

The IACUC also reviews all animal-related designs of experimental devices originating at JSC in order to determine their appropriateness and humaneness for animals.

6.1.1 General Considerations When Using Animals

The use of animals in instruction and research generally occurs in two contexts:

- the animals serve as model systems for the investigation of phenomena and processes which cannot be studied in any other way; or
- the animals are being studied to investigate a problem specific to the particular species.

Most basic research involving animal use falls into the former category. Examples of the latter include field studies of behavioral and ecological adaptations of animal species, studies of taxonomic relationships among species, or studies of physiological or behavioral processes that form an important part of the adaptations of one or more selected species.

It is the responsibility of each Investigator using animals to ensure that they and their staff (co-Investigators, postdoctoral fellows, technicians, assistants, students, etc.) are informed about the current complex environment in which animals are used.

They should be knowledgeable about the animal model and the techniques used. The Chief Veterinary Officer, Attending Veterinarian, IACUC Administrator or ACF Facility Manager should be consulted if questions arise. In addition, information regarding the basic needs of each species is readily available in the ACF Reference Library.

It should be kept in mind at all times that animal experimentation is a privilege accorded to scientists which can be protected only by humane and appropriate care and treatment of animals as well as by their thoughtful and judicious use. The rules and regulations for humane treatment have evolved to assure certain minimal standards of humane care. At the same time these standards provide baselines from which significant interpretation of data may result. It is, therefore, in the best interests of those engaged in animal-related activities that their own standards of humane care and treatment conform with, or even exceed, those stipulated by law.

6.2 Initiation of Project: Protocol for Animal Use

6.2.1 Who Must Submit a Protocol to the JSC ACUC

All instructional and research use of live vertebrates at Johnson Space Center (including Ellington Field) by Investigators or staff requires the submission of a *Protocol For Animal Use* to the Institutional Animal Care and Use Committee (IACUC) for review. JSC Civil Service and Contractor PI's conducting animal research at other institutes must submit a protocol to the JSC ACUC. JSC Co-Investigators must submit a copy of the protocol and approval letter from the IACUC of the Institute where the work is being done.

The protocol must be fully approved before an animal user may order, acquire, house, or use animals in any studies.

Copies of the protocol form may be obtained from the ACF Laboratory Associate (x38800).

6.2.2 Information Required for the Protocol

The protocol form *requires* a non-technical (lay) description of the research, including a description of the benefits to society, a justification for the use of animals, including results of a search for alternatives, a detailed description of all procedures to be performed on animals, and precautions to be taken to guarantee humane care and treatment. Investigators with questions regarding protocol preparation are encouraged to contact the IACUC Chair, the ACF Laboratory Associate, the Chief Veterinary Officer, the Attending Veterinarian, or the ACF Facility Manager. Thorough preparation of protocols facilitates the review process and reduces the chance of delay in initiating projects and in review of applications by extramural funding agencies. Once approved by the IACUC, the protocol becomes a public document and is obtainable by the general public through the Freedom of Information Act.

Accordingly, Investigators should anticipate that the protocol will be reviewed by the general public interested in animal welfare and should make an effort to prepare protocols that are appropriately non-technical and clearly worded (i.e., no jargon).

6.2.3 Timetable for Protocol Submission

6.2.3.1 NIH and NSF Applications – At this time, this does not apply to JSC ACF.

6.2.3.2 All protocols must be submitted for review according to the IACUC calendar that is available from the ACF Laboratory Associate. Any actions resulting from review of the protocol by another IACUC must be documented at the time of submission.

6.2.4 Protocol Review Process

A copy of the signed protocol should be submitted to the ACF Laboratory Associate who will schedule an IACUC meeting for protocol review as soon as possible. Please allow 3-4 weeks between the time a protocol is submitted and the Committee meeting to discuss it. As soon as the meeting is scheduled, the ACF Laboratory Associate will notify the investigator of the date and time of meeting. If possible, the principal investigator, or designated representative, should be available during the time the protocol is reviewed in case there are questions from the Committee. The IACUC can fully approve the protocol, give provisional approval subject to minor modifications, defer a vote until more information is provided, or disapprove the protocol. The Investigator will be notified of the Committee's decision in writing as soon as possible.

6.3 The JSC Animal Facility

The personnel of the JSC Animal Care Facility (hereinafter referred to as the ACF) consist of contractor staff. The ACF Laboratory Associate is responsible for managing and administering a centralized program of animal care in compliance with the Federal Animal Welfare Act, the *NRC Guide for the Care and Use of Laboratory Animals*, the Public Health Service Policy on *Humane Care and Use of Laboratory Animals*, and the U.S. Government *Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*. The ACF is a service organization that reports to the Director, Space and Life Sciences Office. The functions of the ACF include, but are not limited to, daily animal husbandry and care, veterinary care, provision of information and technical assistance, monitoring the animals' environment, purchase of live vertebrates, training of research and technical personnel who use live animals for instruction or research, processing animal use protocols for the IACUC, and consultation and service in all phases of animal care and use at Johnson Space Center.

6.3.1 The ACF Physical Plant and Functions

The Animal Care Facility (ACF) provides an integral service to JSC Investigators by procuring, housing, and maintaining experimental animals and by providing general assistance in connection with animal-related problems in research. The ACF houses animals (rodents) in support of flight projects and ground-based studies conducted by NASA and by NASA-supported outside Investigators. In addition, support and space is provided to commercial partners under the auspices of the Space Act Agreement.

The ACF is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC), International. The ACF is located in Building 37, Room 1033, with a total of 803 square feet. The animal room (19.5' x 15.5') contains three free-standing cage racks which can accommodate a total of 48 cages. Three storage cabinets hold clean rat and mice cages and a bedding disposal station. The storage room (10.5' x 10.5') contains water bottles, sipper tubes, feed hoppers, a small desk, and one locked storage cabinet containing controlled drug supplies. The cage washroom contains a cage washer, cleaning materials and other supplies. Extra counter space is available for performing animal procedures. The temperature/humidity chart recorder is also located on the wall in this room. At the entry way to the cage washroom is an animal carcass freezer. An Eyewash system is located next to the sink by the cage washer.

To ensure proper controls and cleanliness in the ACF, the front door has a cypher lock. Authorization to use, visit or inspect the ACF must be obtained from the JSC Facility Manager. Authorized personnel are provided with the combination to this cypher lock.

6.3.1.1 Clinical Laboratory Services

If, in the course of monitoring procedures, the Attending Veterinarian finds an animal to have health problems, the Investigator will be notified in order to determine the most appropriate method of treatment.

6.3.1.2 Radiology/Radiography

The JSC Animal Care Facility does not offer this service at this time.

6.3.1.3 Surgery

In the ACF, surgery may be performed to prepare animals for experimentation, for diagnosis, and for corrective measures to maintain the health and well-being of animals. Before performing diagnostic or corrective surgery, the Attending Veterinarian consults with the Principal Investigator. In the case of emergencies where surgery is required to save the life or relieve the suffering of an animal, the Principal Investigator may have to be informed after the fact if he/she cannot be contacted in time.

Surgery should be scheduled early in the day and early in the week to allow the ACF staff sufficient time for preparation and for postoperative monitoring and care. Fridays, weekends and holidays should not be considered as options when scheduling surgeries.

Following surgery, the animal should be placed in a room that is free of drafts, odors, noise, traffic and other disturbances and should be monitored until it has recovered from anesthesia. Details regarding the animal's postsurgical recovery may be found in Section 6.11.5.3.

If the animal requires further postoperative attention, the Principal Investigator is responsible for assigning a qualified member of his staff to monitor after hours. This individual's qualifications must be made known to the Attending Veterinarian and included in the Animal Care and Use Protocol.

When surgery is performed for research purposes, the Principal Investigator must enter a description of the surgical procedure on a copy of the "Animal Health Record". (Because rodents do not have individual health records maintained in the ACF, a health record must be initiated.) The importance of documenting surgical procedures cannot be overemphasized, because the information may be critical to the effective diagnosis and treatment of postoperative complications. If complications do arise, Investigators should seek assistance from the Attending Veterinarian.

6.3.1.4 Euthanasia

ACF personnel do not routinely euthanize animals at the end of a research project. If an animal is in good health, every effort is made to place it with another investigator. Animals from control studies may be particularly useful to another investigator. Before these may be used, however, the new investigator must have an approved protocol on file in the ACF Office. Euthanasia must be accomplished following the recommendations of the 2000 AVMA Panel on Euthanasia and must *not* be done in animal holding rooms. During the procedure the animal must be handled gently and quietly and euthanized by a method that results in immediate death.

Any rodent found dead, euthanized, or sacrificed in an experimental procedure must be placed in a plastic bag and stored in the ACF freezer. Contaminated animals must be placed in a biohazard bag and stored on the bottom shelf of the freezer to help prevent cross-contamination of other carcasses. All bags must be labeled with study number, date and biohazard risk if applicable. The Radiation Safety Officer, (281-483-7082), will be responsible for directing the disposal of animals exposed to radioactivity. Disposal of any other contaminated animals will require special arrangements prior to the approval of the proposed study. Animals will not be terminated without prior written approval of the PI except in an emergency. The ACF Laboratory Associate makes arrangements periodically for frozen carcasses to be picked up by American 3CI. When possible, uncontaminated carcasses will be donated to a wildlife refuge park.

6.3.1.5 Necropsy and Histopathology

The Attending Veterinarian will make arrangements for these services if necessary.

6.3.2 Interactions with the Animal Care Facility

6.3.2.1 Access to Animal Facilities

To ensure proper controls and cleanliness in the ACF, the front door has a cypher lock. Entry is permitted only to properly badged ACF staff and Principal Investigators and their staff according to work requirements. Maintenance personnel and visitors without proper badges must be authorized by the ACF Laboratory Associate, ACF Facility Manager or Attending Veterinarian.

6.3.2.2 Maintenance Personnel and Visitor Access Policy

Access to the ACF is controlled to protect the health and safety of both animals and humans, and to safeguard the integrity of animal research projects. Arrangements for entry to the ACF during *off-hours must be made in advance* through the ACF Laboratory Associate.

Certain maintenance personnel (mechanical, electrical, HVAC, etc.), having prior approval for regular access to the ACF, need only inform the ACF Laboratory Associate, Attending Veterinarian, or ACF Facility Manager of the nature of their access and the area they will access. All other maintenance personnel must schedule their access with the ACF Laboratory Associate or ACF Facility Manager. The ACF personnel authorizing the access will determine if that access requires accompaniment by an ACF staff member.

It is JSC's policy to allow supervised visits to the ACF by visitors on a noninterference basis as time and personnel availability permit. Requests for visits by a member of Congress, members of the news media or the general public must be submitted through the External Affairs Office (Code DX). Visitors to the ACF will be accompanied by an ACF staff member at all times. It is the responsibility of the ACF Laboratory Associate or ACF Facility Manager for ensuring the availability of the ACF staff during the visit. Only an JSC photographer (request must be submitted with visit request) may take pictures within the ACF unless prior approval has been obtained from JSC Public Affairs Office. To allow for proper scheduling, requests for visits should be submitted fourteen (14) days in advance, but this does not assure that a request for a visit on a specific day can be accommodated. The request for visit must be submitted to the ACF Facility Manager who may act as the authorizing official for ACF visits. No changes may be made to the attendance list once approval for the visit has been granted. Visits during off-duty hours are strongly discouraged.

6.3.2.3 Use of Animal Vivarium Rooms. To avoid problems of communicable disease, no animals except those purchased or authorized by the ACF are permitted in buildings housing research animals. Similarly, the Attending Veterinarian only treats animals that are involved in JSC research projects. Investigators and their staffs are discouraged from performing tests on animals in the animal holding rooms. If such tests must be performed there, however, the investigator's staff is required to clean up the area afterward and remove all their equipment. If it is necessary to keep the equipment in the holding room overnight, approval must be obtained from the ACF Laboratory Associate. Major procedures may not be performed in animal holding rooms at any time. Euthanasia is not permitted in holding rooms, except in an emergency to relieve an animal's suffering.

Animals in the ACF are housed separately by species in order to:

- prevent transmission of infectious diseases that may not be apparent in one species but cause clinical signs in another;
- prevent anxiety among animals caused by interspecies antagonisms; and create appropriate research environments.

.4 Animal Care Facility and User Documentation

All instructions and/or requests from Principal Investigators to the ACF staff concerning all animal activities involving the ACF must be submitted in writing. **No verbal requests will be honored** except in the case of an animal emergency.

.4 Medical Examination for Animal Handlers

Zoonoses are those diseases that can be transmitted between man and other animals. Many of these zoonotic diseases can cause extremely serious illness in humans and, in a few cases, even death (rabies, ceriopitecene herpes virus). Of significant importance is the man-to-animal transmission of disease, where an animal handler infects an animal test subject, thereby negating, or severely interfering with, an experiment (e.g., tuberculosis). For these reasons it is imperative that all animal handlers participate in an active occupational health program designed to protect their health as well as the health of the animals.

JSC investigators and support workers working in the JSC Animal Care Facility will be required to complete an animal handler's physical in the JSC Clinic and fill out the Application for Access to JSC/NASA Animal Facility Laboratories. Please return the completed Application form to the ACF Laboratory Associate. Non-JSC investigators and other support workers must submit evidence of participation in an occupational health program at their home institute and also complete the Application form. Documentation of the physical examinations, home-institute occupational health participation and Application for Access will be retained in the master documentation folders for each approved protocol.

.4.2 Definitions

For purposes of this section, the following terms will be used:

- “Animal” means any vertebrate animal;
- “Animal Handler” includes all individuals who come in contact with vertebrate research animals, their unfixed tissues, excrement, soiled cages and equipment, or other potential biological hazards attributable to the animals.

.4.3 Applicability

These definitions apply to any:

- Federal Civil Service employee;
- NASA contractor, subcontractor, or grantee employee;
- Postdoctoral fellow, visiting scientist or visiting staff; and
- High school or college work-study student.

6.4.3 Compliance Identification: Animal Access Authorization

Preprinted card identifiers shall be utilized as a means of compliance identification. These card identifiers, titled “Animal Access Authorization”, shall be signed by the JSC Clinic Physician, shall be laminate-finished and punched for easy assembly with a JSC NASA badge, and shall identify the:

- Individual's name
- Individual's Affiliation (NASA or Contractor organization)
- Organizational Code and Mail Stop
- Examination: Animal Handler ____ Primate ____
- Effective Date _____ Expiration Date _____

6.4.4 Obtaining an Animal Access Authorization Card

Animal handlers at JSC must obtain an Animal Handler physical examination from the JSC Health Clinic. The ACF Laboratory Associate will prepare a Johnson Space Center Job-Related Physicals form and submit it to the Health Clinic. The Health Clinic will contact the individual requesting examination to schedule an appointment. Based on the results of the examination, the Health Clinic physician will sign and date the card and send it to the ACF Office.

6.4.5 List of Animal Handlers

Presently, only ACF Staff have Animal Handler badges and these badges are renewed annually.

6.4.6 Accidents, Injuries, Illnesses Documentation Repository

The JSC Health Clinic will complete Federal industrial accident reports on animal handler injuries, bites and scratches and will, in addition, send written notification of the accident to the ACF Facility Manager, the Attending Veterinarian, the Chief Veterinary Officer and the Animal Handler's Supervisor. The JSC Health Clinic will maintain documentation of animal handler injuries, bites and scratches in accordance with current procedures governing industrial accidents and medical records.

Sections 6.6 and 6.7 of this Handbook detail the procedures to be followed in the case of accidents and injuries incurred in the course of animal handling and in the case of illnesses of those who have intimate contact with animals.

6.4.7 Animal Handler's Examination

This examination is required annually. It consists of the following:

- Physician conducted medical history/physical exam (or interim history exam)
- Blood draw for serum storage (on initial visit only);
- Intra-dermal TB test. If positive, chest X-ray every four (4) years (may be declined by patient);
- SMAC/CBC/Urine (4098) on initial visit, then every four (4) years;
- Height, weight, blood pressure;
- Tetanus and diphtheria toxoids (0.5 cc) every four (4) years for maintenance

6.4.8 Primate Handler's Physical Examination

Currently, there are no primates at JSC.

6.5 Animal Acquisition and Transfer

All arrangements for acquiring and housing live vertebrates from any source must be made through the ACF Laboratory Associate.

Animals may not be purchased or otherwise acquired until a fully approved protocol is on file.

If exotic or other wildlife are to be used, arrangements for any necessary quarantine must be made through the ACF Office before animals are acquired. The Investigator is responsible for determining if permits (such as U.S. Fish and Wildlife) are required, and any necessary permits must be obtained **before** animals are acquired. The ACF Office can help investigators to determine whether permits are needed and assist in obtaining them.

The Federal Government recognizes more than 400 species worldwide as endangered or threatened. These animals cannot be brought into the United States alive, as parts of manufactured items, or as hunting trophies. Exceptions may be granted by Federal permit for limited scientific or breeding purposes. For further information and a current list of prohibited species, please contact the Attending Veterinarian.

.1 Ordering Animals

To initiate a rodent purchase, the Principal Investigator notifies the ACF Laboratory Associate of the quantity, species, gender, age and preferred delivery date for the rodents. Any special instructions/requirements for ordering and/or housing of the animals should also be indicated. The Principal Investigator should be aware that the delivery date requested might not always be possible to achieve. Consequently, in determining the date the rodents should be available for protocol procedures, the Investigator should allow sufficient time for delivery and 3-5 days after delivery for the rodents to acclimate to their environment. Authorization to order rodents will be made by the ACF Laboratory Associate based on verification of an approved protocol and animal numbers still available under the protocol. The ACF Laboratory Associate will confirm the purchase to the Investigator and advise them as to the date of delivery. In general, common laboratory species and strains can be obtained within ten (10) working days. Delivery of animals is affected by vendor location and by vendor shipping policies. Orders are placed for delivery on Monday through Thursday whenever possible to prevent problems associated with delivery on weekends and holidays.

Note: Arrangements for animals coming from other institutions (whether they are purchased or not) must first have the approval of the ACF Facilities Manager and the Attending Veterinarian **before** delivery can be made. In all cases, a *Protocol for Animal Use* will be necessary.

.2 Transfer of Animals

Upon completion of the protocol, Principal Investigators should inform the JSC ACF staff in writing whether the rodents should be euthanized or are no longer required for his/her specific needs along with the experimental and treatment conditions to which they have been subjected. The JSC ACF staff and/or Attending Veterinarian will determine whether the latter group can be reassigned to another Investigator with an approved protocol.

.6 Handling of Animals by Investigators and Their Staff

All animal laboratories are considered controlled areas. Only individuals who have had the animal handler's medical examination and the orientation program on experimental animals are permitted in laboratories and the immediately surrounding areas when animals are present.

The legal requirements for appropriate care and humane treatment of experimental animals apply not only to animals housed in the ACF, but also to animals when they are in Investigators' laboratories. Thus, in the laboratory, all of the requirements outlined in this manual apply.

Federal law also requires that Investigators use anesthetics, analgesics, and tranquilizers to effectively minimize the pain and discomfort of the animal while under experimentation. Guidelines are provided as to the type and dosage of drug to be administered.

Investigators who plan experiments that cannot be conducted effectively using anesthesia, analgesics, or tranquilizers to relieve all pain and distress in animals must state this in their research protocols and justify the withholding of these measures on scientific grounds. The IACUC pays particular attention to this matter in its protocol reviews. If the research is permitted, ***the Principal Investigator must directly supervise all animal procedures that entail pain or discomfort., throughout the study*** Moreover, the Attending Veterinarian may terminate a procedure if, in his/her opinion, it is unduly stressful to the animal.

In addition to protecting animals from pain and distress, Investigators must provide them with a clean, healthful and safe environment while they are in the laboratory. The ACF provides cages in which the animals must be kept at all times except during experimentation or training.

The following conditions are necessary in the laboratory just as they are in the animal holding rooms:

Animals must be housed in cages suitable to their species and size (based on the recommendations of the *NRC Guide*);

Ambient temperatures and noise must be maintained at appropriate levels (based on recommendations of the *NRC Guide*);

Appropriate light/dark cycles must be provided according to the requirements of the approved research protocol;

Food that meets veterinary standards and clean drinking water must be available according to the requirements of the species and the research protocol;

Animal foods and bedding must be stored in closed containers of suitable composition;

Areas around cages, including workbenches and cabinets, must also be kept clean;

There must be **no** eating, drinking, smoking, chewing gum, or human food or beverages in the areas where animals are housed or used during experimental procedures.

There must be no routine housing of animals in laboratories without the approval of the ACF Laboratory Associate or the Attending Veterinarian. Should such housing (in the laboratory) be required for an experimental reason as stated in the protocol, the Principal Investigator should appoint one member of his/her staff to be responsible for overseeing feeding, watering, and environmental control, and a second individual should be appointed to assume those responsibilities when the first is not present. Provisions should also be made for care of the animals on weekends and holidays. Finally, all animals in the laboratory must be observed at least daily, by a member of the ACF staff, for their well-being. Illness or injury should be reported to the Attending Veterinarian as soon as it is discovered for determination of any necessary action.

6.7 Disease Control

At JSC, every precaution is taken to minimize disease transmission between animals and humans and among animals. Risks from injury or radiation exposure are likewise kept to a minimum.

6.7.1 Protective Clothing and Hygiene

When working with most animals, laboratory coats offer adequate protection but must be supplemented with disposable gloves and a mask as needed. This protective clothing should be worn only where animal activities are taking place. Personal cleanliness is the hallmark for control of transmissible disease and is obligatory. After handling animals or soiled or contaminated equipment in the ACF, hands should be washed thoroughly with soap and warm water. Hands should also be washed before leaving either the laboratory or an animal holding room.

6.7.2 Human Health and Safety

All individuals who will work with animals must undergo an initial medical examination and immunizations before they are permitted to handle any animals.

To further protect the health of persons who come in contact with laboratory animals, ***JSC regulations strictly prohibit smoking, chewing gum, drinking and eating or bringing food/beverages for human consumption into areas where animals are housed or used.***

Furthermore, all ACF and research personnel who handle animals, their unfixed tissues or wastes are required to have a medical examination periodically.

All personnel should also inform their personal physicians that they are working with animals. Further, if the individual or his personal physician suspects that an illness or allergy may be animal-related, the JSC Clinic should be notified immediately.

Animal scratches and bites should be thoroughly cleansed immediately and reported to the ACF Lab Associate, ACF Facility Manager or Toxicology Supervisor.

.3 Radiation Hazards

If this service is required, please contact the Attending Veterinarian or the ACF Facility Manager.

.8 Animal Control and Safety

Every effort is made at JSC to handle animals in such a way as to ensure their health and safety, to prevent escapes, to prevent employee injury including exposure to chemical hazards, and to protect the validity of the ongoing research.

6.8.1 Animal Handling and Restraint

In accordance with federal legislation and guidelines for animal care, experimental animals must be handled humanely at all times, particularly with regard to restraint.

Each animal must be handled by methods that take into account diverse behavioral patterns and temperament of the species, as well as the personality and moods of the individual animal.

The physical condition and experimental preparation of the individual animal must also be considered when it is to be handled or restrained.

If an animal must be restrained or immobilized for research purposes, tranquilizers are useful in making the experience less stressful. The temperament of the individual animal is important in any decision to physically restrain it for experimental reasons. Some animals will not tolerate restraint under any circumstance and, therefore, a more tractable animal would be more suitable.

.2 Prevention of Injury

Injuries to laboratory animals may occur from mishandling, defects in cages, and exposure to other hazards. Injuries must be minimized.

To avoid cage-related injuries, cages and cage lids are inspected by ACF Staff. Research personnel are also expected to look for defects that could cause injuries when they are handling the animals and to report them to the Principal Investigator and to the ACF personnel.

Animals housed in groups of two (2) or more may fight. Since fighting can result in serious injury to the animals, every effort must be made to minimize it. However, sometimes, it is undesirable to house a rat alone due to the lack of companionship and 3 rats may be placed in one cage on a temporary basis. Problem animals that are either too aggressive or too submissive will be identified and will either be placed in individual cages or housed with pen mates that are compatible. If such behavior is strain specific, as in some inbred mice, individual caging is recommended. Investigators who find that their research animals exhibit behavioral problems should consult with the Attending Veterinarian to attempt to resolve the issue.

Hazardous substances, as defined in the JSC Health and Safety Manual, can also injure laboratory animals, as well as humans who work with them, and can damage equipment and facilities. Investigators planning to use such materials must give detailed information on their use in their protocols, including the techniques, processes, personnel, equipment, and facilities that will be involved and the experimental animals that will be affected. The procedures also must be submitted to the Environmental Health and Safety Committee for approval. Before work is begun, copies of approved procedures must be given to all personnel who will work on the project. The Principal Investigator must also inform his staff of the possible hazards associated with the research, the methods of containing or disposing of the materials, and the emergency procedures in case of an accident or exposure.

6.8.3 Animal Escape

Rooms where laboratory animals are housed must be closed at all times when animals are present. No animal may be permitted to run loose in a laboratory or holding room, and all animals that are removed from their cages for experimental purposes or treatment must be attended or restrained at all times. Cage lids should always be fastened securely.

Escaped rats and mice, when retrieved, should be separated by sex, checked for possible injuries, and then placed in clean cages. They must be kept separate from other animals, and the Investigator must be notified immediately so that he can determine their usefulness for his research and their ultimate disposition. Other species should be checked for identification and injuries before they are returned to a cage or enclosure.

All animals thought to be, or known to be, lost should be reported to the ACF Laboratory Associate as soon as possible (x38800). The ACF Laboratory Associate will then notify the attending Veterinarian and the ACF Facility Manager (x32846).

.9 Animal Housing

Animals are housed in cages designed to provide a comfortable environment that contributes to their well being while minimizing variables that can modify an animal's response during experimentation. Environmental factors such as temperature/humidity ranges, room air exchange rates, lighting, noise levels, and even odors are considered in housing the various species. Consultation on animal selection and use as well as routine veterinary care are provided without charge to the Investigator. Limited animal research services such as injections, blood collection, and anesthetic/surgical services are also provided.

.1 Husbandry Practices

.1.1 Caging

The ACF is responsible for the selection of appropriate cages for all animals, and for ensuring that housing conforms to *NRC Guide* standards and Animal Welfare Act requirements while also meeting research needs. The ACF contractor is responsible for maintaining cages in good repair. Investigators who require special housing should contact the ACF Laboratory Associate, Facility Manager, or Attending Veterinarian to discuss their needs.

Exceptions to *NRC Guide* standards must be justified in the protocol on the basis of experimental or species requirements.

.1.2 Feeding

Standardized commercial diets are available for most laboratory species. The ACF contractor is responsible for providing appropriate diets and for ensuring that food is fresh and free from contaminants. For special research needs, certified diets that have been assayed for commonly encountered environmental contaminants may be required. The ACF Laboratory Associate can assist with selection of specialized diets and provide information on their availability.

.3 Bedding

Harlan Teklad Sani-Chip and Harlan Tek-Fresh are the standard bedding materials provided by the ACF. Other types of bedding, such as laboratory corncob, paper bedding and Omega-dri Certified Bedding, are available upon request.

.2 Environmental Factors

.1 Temperature and Humidity

The *NRC Guide* defines requirements for the proper maintenance of laboratory animals. Environmental factors such as temperature and humidity must be carefully monitored because they affect metabolism and behavior and improper temperature and humidity levels may adversely affect research results. The ACF contractor is responsible for monitoring and maintaining appropriate temperature and has the capability for monitoring humidity in the animal facility.

.2 Microenvironments and Macroenvironments

The design of the cage or primary enclosure can greatly influence the animal's environment. The environment in the cage (microenvironment) may differ from the environment of the animal room (macroenvironment). For example, some of the newer caging systems for rodents incorporate a microbiological barrier. This may result in higher temperatures, humidity, carbon dioxide and ammonia levels in the cage than in the room. Since such factors may adversely affect research results as well as animal health, they should be considered in experimental design and animal housing.

.3 Ventilation

The purposes of ventilation are to supply adequate oxygen; remove thermal loads caused by animal respiration, lights and equipment; dilute gases and particulate contaminants; adjust the moisture content of room air; and where appropriate, create static-pressure differentials between adjoining spaces. The guideline of 10-15 fresh air changes per hour has been recommended by the *NRC Guide*.

Anyone noticing any departure from appropriate levels should report the information to the ACF Laboratory Associate immediately.

Facility problems noted after working hours should be reported to Work Control (x32038).

.4 Illumination

The lighting in an animal room must meet the animal's biological needs with regard to quantity and periodicity, and must also provide adequate illumination for daily observation and care of the animals. In addition, lighting should be sufficient to ensure safe working conditions for animal care personnel. The ACF contractor is responsible for establishing and maintaining light cycles in animal housing areas. Regular diurnal light cycles are provided by a time-controlled lighting system. Special research needs which require departures from normal light cycles can be arranged through consultation with the ACF Laboratory Associate.

.3 Sanitation

.3.1 Cleanliness

The Animal Welfare Act and the *NRC Guide* have guidelines established for the frequency of cleaning animal rooms and for changing cages. However, cleaning schedules can be altered to accommodate special research needs by arrangement with the ACF. Any deviations from the standards set forth by the *NRC Guide* must be addressed in the Animal Use protocol and approved by the IACUC.

.3.2 Waste Disposal

Radioactive and other bio-hazardous carcasses and animal wastes must be disposed of according to procedures established by the JSC Environmental Health and Safety Office. Investigators are responsible for cleaning their work area and all equipment after use and for storing carcasses (in plastic bags) in the freezer. These carcasses must be separated using red biohazard bags if chemically euthanized and white bags if non-chemically euthanized. Bags should be stored on separate shelves in the freezer according to their color. The ACF Laboratory Associate makes arrangements periodically for frozen carcasses to be picked up by American 3CI. When possible, uncontaminated carcasses will be donated to a wildlife refuge park.

.3.3 Vermin Control

The presence of vermin in the ACF rooms can result in contamination of feed and bedding, and the introduction of disease. The ACF contractor is responsible for coordinating the vermin control program in the animal facility with assistance of JSC. Pesticides are used in animal areas only when necessary, and then only after consultation with the Attending Veterinarian and the Investigator(s) whose animals will be exposed.

.10 Animal Identification and Record Keeping

The Animal Welfare Act and the *NRC Guide* require appropriate identification of animals and maintenance of animal records. Accepted methods of animal identification include cage cards; collars and bands; ear notches and tags; implantable microchips; tattoos. Toe clipping is only acceptable for infant rodents and lower vertebrates when other methods of identification cannot be used.

Toe clipping must be approved by the IACUC before it is attempted.

All animal records must be maintained for three (3) years following the death or disposition of the animal, or the end of the research protocol, whichever is longer, and are subject to inspection by the USDA, the granting agency (NIH, NSF, etc.) site visitors (AAALAC), and the IACUC.

.1 Standard JSC ACF Identification Procedures

As animals are received by the ACF, the following methods are used for their identification.

Rodents

Cage cards should include the following information: animal species, age, sex, date of arrival, protocol number, name of PI, and vendor.

.2 Animal Identification by Investigator

Investigators may wish to further identify animals for their own purposes. The Investigator should be aware that the identification method he/she wishes to employ should be described in the protocol submitted for review by the JSC IACUC.

6.11 Special Procedures Involving Animals

.1 Preventive Medicine

- .1.1 Newly acquired animals can trigger an outbreak of disease into established colonies. In addition, production colonies maintained by suppliers occasionally experience outbreaks of disease. To minimize the possibility of introducing disease into ACF, all arrangements for acquiring and housing live vertebrates must be made through the ACF Laboratory Associate.

6.11.1.2 Quarantine and Stabilization

It is desirable to quarantine or allow a stabilization period for all newly received animals for various periods, depending upon the species, source, and condition of the animals. The quarantine period allows the Attending Veterinarian to determine whether or not an animal has a contagious disease and permits the animal to become acclimated to the new environment. New arrivals of animals, regardless of source, should be allowed a stabilization period before use (usually a period of three to five [3-5] days). Such a period allows the animal to recover from shipping stress, adapt to its new surroundings, and become physiologically stable, thus improving its suitability as a biological model.

6.11.1.3 Separation of Species

Physical separation of animals by species is required. This separation can be accomplished by housing different species in micro-isolator cage units on different cage racks. When animals of the same species are obtained from multiple sources, their microbiological status may differ, in which case separate housing is advisable.

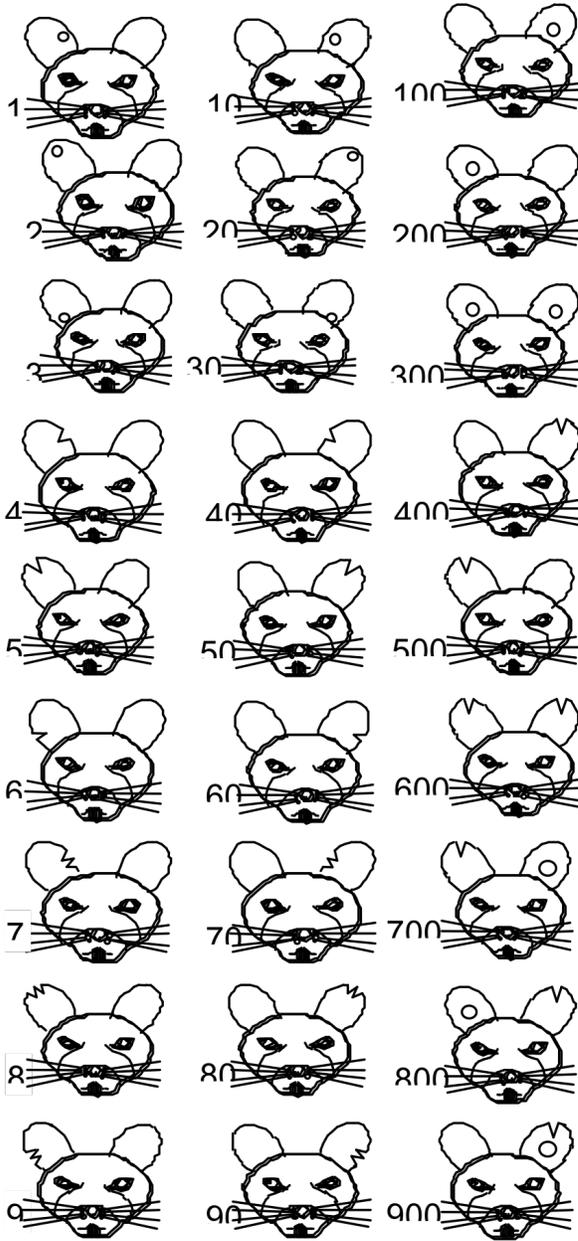


Figure 1 Rodent Identification by Ear Marking

Notes:

1. This Ear-punching system was adapted from the AALAS Manual.

2. The animal is viewed from the front. The right ear is on your left.

a.) The right ear is the "1's" digit. The left ear is the "10's" digit.

b.) The punch rotation is Medial to lateral for increasing digits.

c.) This system can theoretically number to 999. In practice, past 399, the placement of the punch must be very precise.

ACF personnel check all animals daily, including weekends and holidays, for signs of illness, injury or abnormal behavior. Observations of illness, injury, and abnormal behavior are reported to the Attending Veterinarian, who, along with the Investigator, decides on what course of action to take. In cases where such observation will interfere with experimental objectives, prior arrangements may be made with the ACF Laboratory Associate to ensure adequate monitoring of animals and environmental systems.

.3 Emergency Care

Any health problem noted by anyone at anytime, including evenings, weekends and holidays, should be immediately reported to the Attending Veterinarian or other ACF personnel. The ACF staff must also be notified of facility malfunctions (e.g., excessively hot or cold animal rooms) that may or may not appear to directly threaten animal health.

.4 Anesthesia and Analgesia

The Attending Veterinarian and the IACUC must review animal procedures to ensure that proposed anesthetics and analgesics are appropriate for the species and research objectives. The Attending Veterinarian is available to provide consultation about, assistance with, or training in the proper administration and use of anesthetics and analgesics. See Appendix B-4 on controlled drug use in the ACF.

NASA-JSC policy requires written documentation of all survival surgical procedures, including the types and amounts of anesthetic or tranquilizing drugs used. This documentation is generally part of the *Protocol for Animal Use* and is subject to inspection by the IACUC during its semiannual inspection of the animal facility and animal study areas. **In addition, all manipulation and drug use in all animals will be recorded directly on the animal's health record, or otherwise made available to the ACF for inclusion in the appropriate records.**

The Animal Welfare Act requires the use of anesthetics/analgesics to minimize pain and discomfort to an experimental animal. PIs must seek the advice of the veterinarian regarding appropriate anesthetics/analgesics. Muscle relaxants and paralytic drugs are not anesthetics and should not be used alone for surgical restraint. They may be used in conjunction with anesthetics. If an experimental procedure is to be done without using anesthetics, analgesics, or tranquilizers, the proposal must be justified and approved by the IACUC.

All survival surgeries should be recorded on a Procedure Records/Post-Operative Observations log sheet (See Appendix D). These log sheets are kept in a binder in the ACF storeroom.

Although strict aseptic technique during surgery is not required with rodents, it is important to follow aseptic practices. This will help to reduce the numbers of microbes exposed to the incision and, therefore, minimize

infection. Research technicians performing survival surgery must wear a disposable lab coat and gloves. The animal should be properly prepped for surgery including shaving and cleaning the surgical site. Surgical instruments should be sterilized prior to surgery and used on only one animal at a time. The surgical area should be straightened and cleaned between animals.

All animals that have undergone surgery will be appropriately monitored until they have awakened and are able to maintain an upright position. The research technician should observe post-op animals periodically and record these post-op observations on the log sheet. Following surgery, the animal should be placed in a room that is free of drafts, odors, noise, traffic, and other disturbances and should be monitored until it has recovered from anesthesia. If the animal requires further postoperative attention, the Investigator is responsible for assigning a qualified member of his staff to monitor after hours. This individual's qualifications must be made known to the Attending Veterinarian and included in the Animal Care and Use Protocol. The *NRC Guide and Animal Welfare Act* require that to conduct painful procedures without anesthesia or analgesia must be scientifically justified in the protocol and approved by the IACUC. Such procedures must be supervised directly by the responsible Investigator. Guidelines for anesthesia, analgesia and tranquilization can be obtained from the Attending Veterinarian.

.5 Surgery and Post Surgical Care

.5.1 Survival Surgery

Survival surgery is defined as surgery on an animal that is expected to recover from anesthesia.

Major surgery is defined as any surgical intervention that penetrates a body cavity or has the potential for producing a permanent handicap in an animal that is expected to recover.

Minor surgery is any operative procedure in which only skin or mucous membrane is incised (e.g., vascular cut down for catheter placement or implanting devices in subcutaneous tissue).

All surgical procedures require IACUC approval.

.5.2 Presurgical Care

The JSC ACF which currently houses rodents only, does not require Presurgical care.

.5.3 Postsurgical Care/Recovery

All animals that have undergone surgery will be appropriately monitored until they have awakened and are able to maintain an upright position. The research technician should observe post-op animals periodically and record these post-op observations on the log sheet. It is advisable that surgeries be performed early in the day so the animals have ample time to recover from anesthesia prior to being left alone for the evening.

(Caution: Use of heat lamps and electric heating pads can result in burns or hyperthermia in animals that are anesthetized or otherwise unable to escape from the heat. Close observation is required, and use of circulating warm water blankets or hot packs is recommended whenever possible.)

.5.3.1 The Four Stages of Recovery from Anesthesia

A. Level 4 –Animal unconscious or semiconscious and unable to sit or maintain sternal recumbency.

1. Examine and record findings frequently.

Examples of notations include:

- a. body temperature;
- b. heart rate;
- c. respiratory rate;
- d. capillary refill time (record in seconds);
- e. jaw tone (record resistance or no resistance)
- f. response to toe pinch (record withdrawal or no withdrawal); and
- g. time of extubation.

2. The animal should be turned from side to side frequently to prevent dependent pulmonary congestion and edema.

3. Ambient temperature should be adjusted (warming pad) to bring body temperature to normal. Care must be taken not to burn or overheat the animal. The animal should be kept dry.

The state of hydration should be assessed and fluids should be provided as necessary.

B. Level 3 – Animal conscious and can maintain sternal recumbency or sit, but cannot stand.

1. Examine and record findings frequently. Examples of notations include:

- a. body temperature until it becomes normal ($\pm 2^{\circ}\text{F}$);
- b. capillary refill time; and
- c. condition of the operative site.
- d. Examine closely for other abnormalities.

2. Keep the animal dry and adjust the ambient temperature to bring the body temperature to normal.

3. If required by the protocol or the Veterinarian, analgesics must be used.

C. Level 2 – Animal can stand and move about but is not eating and drinking normally.

1. Examples of notations include:

- a. hydration;
- b. attitude (alert or depressed);
- c. activity (active or inactive);
- d. food consumption;
- e. water consumption; and
- f. condition of operative site.
- g. examine closely for other abnormalities.
- h. consider use of analgesics.

D. Level 1 – Animal active, alert, eating and drinking normally.

Pertinent information after this point should be transferred to a Daily Animal Health Record Sheet and the animal observed daily.

.5.3.2 Non-survival Surgery

Non-survival surgery is defined as any surgery in which the animal will not regain consciousness. Such procedures may be performed in a suitably located and equipped laboratory.

.12 Euthanasia

NASA-JSC euthanasia guidelines follow those established in 2000 by the American Veterinary Medical Association Panel on Euthanasia (<http://oacu.od.nih.gov/ARAC/euth/avmaeu1.htm>). Proposed euthanasia techniques must be evaluated and approved by the Attending Veterinarian and the IACUC during review and approval of animal use protocols.

Euthanasia must be carried out by properly trained personnel. While decapitation on small rats and cervical dislocation on mice may be humane when administered by properly trained personnel, animal use protocols proposing these techniques without sedation or anesthesia must include the rationale justifying such techniques. Measures should be taken to ensure that euthanasia is performed in a way that minimizes reactions among other animals that may be present. Proper euthanasia technique includes a follow-up examination to confirm the absence of a heartbeat for a designated period of time. Cessation of breathing is not considered sufficient since with some euthanasia techniques heartbeat may be maintained after visible respiratory movements have ceased. Decapitation, cervical dislocation or thoracotomy should be used after injection of euthanizing drugs, or use of CO₂ to ensure that animals do not revive. Instruction on proper euthanasia techniques can be arranged through the Attending Veterinarian.

.13 Animal Waste and Carcass Disposal

.1 Animal Bedding

All soiled animal bedding material is recovered from cages and pans using the Viking Medical bedding disposal unit and disposed of in the JSC waste dumpster. Any animal bedding exposed to hazardous materials must be rendered safe by sterilization, decontamination or other appropriate measures before disposal. It is the Investigator's responsibility to ensure that the ACF staff is aware if bio-hazardous agents are being used.

.2 Carcass Disposal

Radioactive and other bio-hazardous carcasses and animal wastes must be disposed according to procedures established by the JSC Environmental Health and Safety Office. Investigators are responsible for cleaning their work area and all equipment after use and for storing carcasses (in plastic bags) in the freezer. These carcasses must be separated using red biohazard bags if chemically euthanized and white bags if non-chemically euthanized.

Identification (name of person responsible for animal and IACUC Protocol Number), and date must be included on the bag.

Bags should be stored on separate shelves in the freezer according to their color. The ACF Laboratory Associate makes arrangements periodically for frozen carcasses to be picked up by American 3CI. When possible, uncontaminated carcasses will be donated to a wildlife refuge park.

Syringes, needles, petri dishes, scalpels or razor blades, and cardboard must not be placed in the bags with the carcasses.

Under no circumstances are any animal carcasses or preserved animals to be put into the general trash collection system of NASA-JSC.

6.14 Transportation of Animals on Johnson Space Center

The regulations and standards for proper care and humane treatment of laboratory animals also apply during transportation of the animals. Newly purchased animals are delivered directly to the ACF by the vendor or the contractor vehicle. Regardless of the delivery method, animals are transported in their shipping containers and transferred to cages upon arrival at the ACF.

With rare exceptions, the ACF receives animals only during the hours of 10:00 AM to 3:00 PM, Monday through Friday. Before the animals are accepted, a qualified ACF staff member must examine them. Animals may be rejected if they do not meet the requirements of the Principal Investigator, who should be advised of their condition as soon as possible. The Principal Investigator, in conjunction with the Attending Veterinarian will determine what further actions will be taken.

Animals must be transported in approved containers that will prevent their escape and minimize stress. Carrying animals in your arms or in open boxes is not acceptable. For transportation of rodents to other buildings, it is recommended that micro-isolator cage units be used whenever possible.

6.15 Removal of Animals from JSC

When rodents are to be shipped, all shipments, regardless of whether or not they are to be returned, must be coordinated through the ACF Laboratory Associate who will make the necessary shipping arrangements and will see that approved shipping containers are used.

.16 Animal Bites or Other Animal-Related Injuries

In the event of an animal bite or other animal-related injury, administer first aid (wash the wound thoroughly with soap and water) and report the injury promptly to the JSC Health Clinic (x34111) for further evaluation. In the event of an animal bite after-hours or weekends, notify the JSC Clinic and ask that they inform the ACF Facility Manager and the Attending Veterinarian.

.17 Pets in Animal Facilities, Labs or Offices

Pet animals are not allowed in buildings housing research animals.

.18 Reporting Deficiencies in Animal Care and Treatment

The IACUC has the obligation to address concerns involving the care and use of animals. Any complaint regarding the care and use of animals in instruction or research or charges of animal abuse at NASA-JSC should immediately be reported to (in priority order) the Chief Veterinary Officer or Attending Veterinarian and the Chairperson of the IACUC.

Anonymity and confidentiality of anyone requesting it will be provided.

Investigation of the alleged incident will proceed according to the following flow diagram. The IACUC Chairperson will keep persons expressing concerns informed of investigations. The Chief Veterinary Officer, Attending Veterinarian or IACUC Chair will conduct an initial review of the concerns. After notification of and discussion with the Director, Space and Life Sciences (designated by the Center Director as the official responsible for the JSC animal care program) and/or the IACUC Chair, the problem may be taken to the IACUC.

The IACUC has the authority to stop ongoing research if the above steps have not resulted in a correction of the deficiency. The Veterinarian(s) have the authority to immediately halt any procedure in which the life or well-being of an animal is in jeopardy. The IACUC will decide on a plan of action to ensure that the concerns expressed by the Veterinarian(s) or other individuals are met and that the research conforms to the *NRC Guide*, *PHS Policy* and *the Animal Welfare Act*. The Director's Office will maintain a file documenting the complaint, the review, and action taken to rectify any problem(s) identified, and will also file the required reports, if necessary, to government agencies.

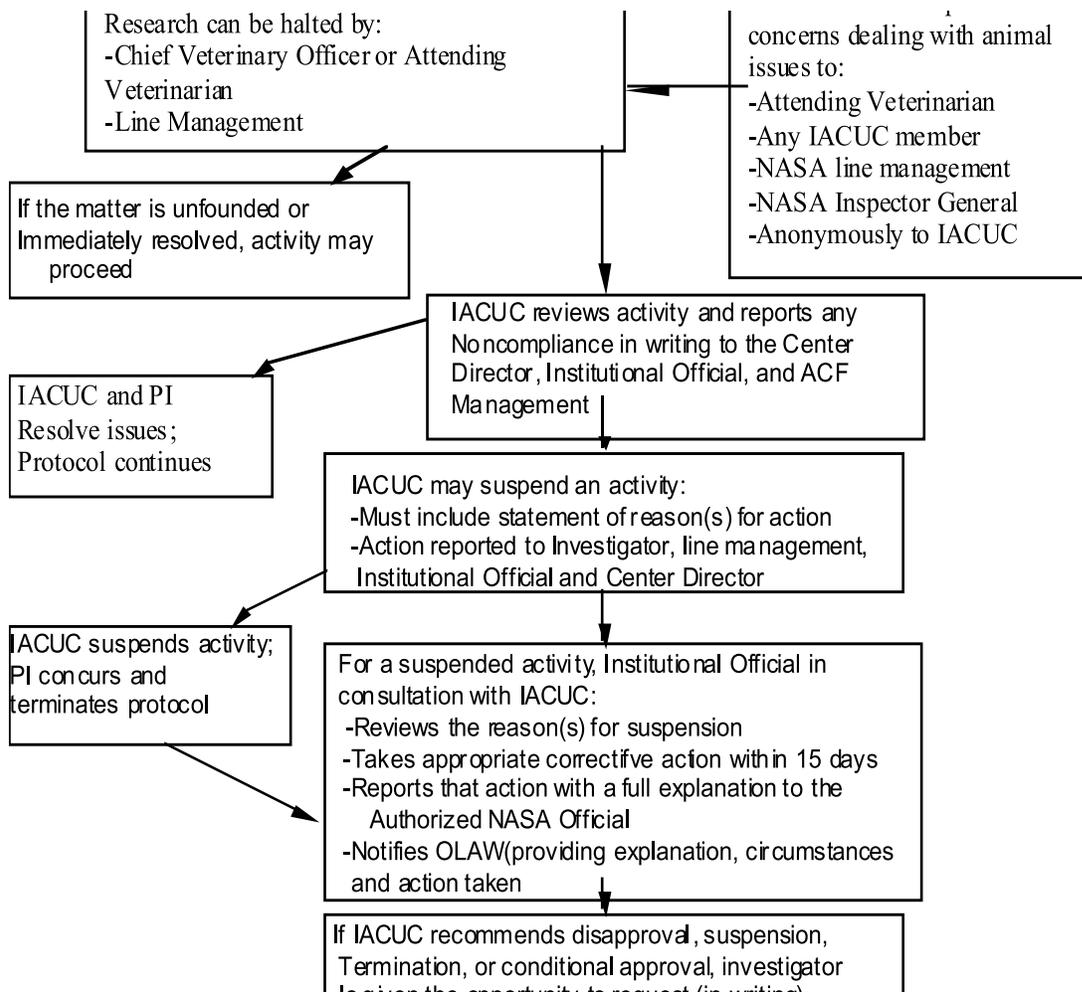
.19 Security

Certain security measures have been established to protect the animals used in instruction and research at NASA-JSC. Cooperation from all concerned in enforcing these measures is essential.

.19.1 Entrance into Animal Housing Facilities

Entrance into all Animal Care Facility areas is subject to the authorization of the ACF Facility Manager, the Attending Veterinarian or the Chief Veterinary Officer. Under no circumstances are Investigators, their staff or animal care personnel to give tours through the ACF facilities without the consent and approval of the ACF Facility Manager. To ensure proper controls and cleanliness in the ACF, the front door has a cypher lock. Authorized personnel are provided with the combination to this cypher lock.

.19.2 Visitors



In an effort to protect animals and minimize any possibility of disease transmission, visitors (including family members and friends) are not allowed in the ACF facilities without prior approval by the ACF Facility Manager. Children under the age of sixteen (16) are not allowed in the facility. Tours of the ACF facilities are scheduled and conducted by the ACF Facility Manager, and/or the Clinical Veterinarian or Chief Veterinary Officer when requested and approved.

6.19.3 Photographs or Videotapes of Animals

NASA Headquarters (HQ) Life Sciences Division has issued a policy on photo-documentation, including filming, photography, videotaping and/or downlink, of animals used in NASA research. It states that photo-documentation of life sciences research using animals may be permitted with the appropriate written rationale provided in the ACUC protocol. Prior approval from the NASA Chief Veterinary Officer and in some cases, concurrence from the Director of the Life Sciences Division, NASA HQ, is required. Unofficial or personal photos or videotaping of animal activities are not allowed.

Under no circumstances should photographic equipment be taken into ACF facilities without the specific prior approval of ACF Management.

.4 Inquiries Regarding Animal Use

Investigators, their staff and animal care personnel are advised not to attempt to answer questions from individuals not affiliated with NASA-JSC regarding animal care and use at this institution. All questions should be referred to the ACF Facility Manager, the Chief Veterinary Officer or the Attending Veterinarian. Inquiries from members of the media must be directed to the External Affairs Division, personnel who will clear interviews with the NASA-JSC researcher and staff. The Chief Veterinary Officer should be kept informed of all such requests for information and, when possible, provided with the name, address, telephone number, and affiliation of the individual(s) making the inquiry. The Chief Veterinary Officer or other designated personnel informed on the issues will answer questions from individual(s) and explain the institutional policy on the care and use of animals.

.5 Threats Related to Animal Use

All NASA-JSC Investigators and their staff and students, and all ACF personnel should *immediately* report all threats, whether written or verbal, to JSC Security (x33333) and the ACF Laboratory Associate.

.6 Demonstrations

In the event of a demonstration related to research animal use, all NASA-JSC personnel should avoid any activity that would jeopardize the health and safety of the animals and avoid any action that may result in or encourage belligerence or the disruption of routine animal care activities, and follow the directions of the NASA/JSC Protective Services Branch.

.7 Break-Ins, Theft and/or Acts of Vandalism

Anyone discovering a break-in, theft and/or act of vandalism in the ACF should inform the JSC Security Office (x33333). The JSC Security Office will notify the ACF Facility Manager and the Institutional official. The area should not be disturbed until permission is received from the individual responsible for the investigation.

7 Animal Health and Veterinary Services

.1 Routine Health Care

Veterinary care is an essential part of an animal care program. Adequate veterinary care consists of:

observing all animals daily to assess their health and welfare;

using appropriate methods to prevent, control, diagnose, and treat diseases and injuries;

providing guidance to users regarding handling, restraint, anesthesia, analgesia, and euthanasia; and

monitoring surgery programs and postsurgical care.

Veterinary care is the responsibility of a veterinarian who has training and experience in laboratory animal science and medicine. Qualified members of the ACF contractor staff perform daily observations of the rodents. Information or questions concerning animal health, behavior and well being are promptly conveyed to the Attending Veterinarian who decides on the course of action to be taken, usually after consultation with the Principal Investigator.

.2 Emergency Health Care

A mechanism has been established to provide emergency care at any time an animal health problem is noted. Emergency contact numbers for ACF Management and Attending Veterinarian are posted on the front door to the ACF.

.3 Reporting Sick Animals

An animal observed to be ill or exhibiting abnormal behavior should be reported to ACF personnel as soon as possible so that it may be examined by the Attending Veterinarian.

Inconsistent experimental results *may* suggest an underlying disease problem in the animal(s) used. In addition to seeking possible causes for the inconsistencies, please consult with the Attending Veterinarian for additional help.

.4 Zoonotic Diseases

About two hundred (200) diseases are transmitted from animals to humans or are common to man and animal such as toxoplasmosis, lymphocytic choriomeningitis, salmonellosis, rabies, tetanus, hemorrhagic fever, chlamydiosis, typhus, leptospirosis, plague, mycoses, etc. However, the chances for contracting these diseases are almost eliminated by the ACF's policy of purchasing disease-free animals from reliable vendors, following good sanitation and hygiene practices, and following a comprehensive veterinary care program which includes a quarantine/stabilization period, disease prevention and control, and an animal health surveillance system.

.5 Quarantine Procedures

Animals are quarantined upon arrival at the ACF for a period of time dependent upon the species, source, and health status, and the use for which they are intended. They are released from quarantine at the discretion of the Attending Veterinarian. Principal Investigators should allow for this quarantine period when ordering animals.

.6 Necropsy and Diagnostic Laboratory Services

Investigators who plan to have necropsy or diagnostic services performed on animals in conjunction with their research should discuss these plans with the Attending Veterinarian at the time they are writing their protocols. Laboratory diagnostic work can be arranged for by consultation with the Attending Veterinarian.

.7 Technical Assistance and Veterinary Services

All requests for technical assistance and veterinary services are to be submitted *in writing* to the ACF Laboratory Associate. Requests for these services should be submitted in a timely manner to ensure that the animal(s) are correctly identified and the necessary drugs and supplies are on-hand. Requests for support submitted with less than seventy-two (72) hour notice will be completed if schedules permit.

8 The Johnson Space Center Training Program

In order to meet legal requirements while also serving broad educational objectives, the ACF has instituted a three-tiered training program on animal use in instruction and research. This training program is structured as follows.

8.1 The Core Training Program

All managers, investigators, their staff and ACF personnel involved with the care and use of animals are *required* to complete a self-study program of the following material:

JSC Animal Care and Use Handbook;

the NRC Guide for the Care and Use of Laboratory Animals;

the Animal Welfare Act (Code Fed. Reg. Title 9 subchapter A);

And view the following:

“The Humane Care and Use of Laboratory Animals” Laboratory Animal Training Association, 1990, (35 minutes),

“Resources of Today for Research of Tomorrow” Animal Welfare Information Center, National Agricultural Library(United States Department of Agriculture), 1989 (18 min.), and

The New Research Environment” Foundation for Biomedical Research, 1987 (30 min).

All animal users are expected to review this material (use of the ACF Reference Library is encouraged) and sign a "Statement of Compliance" (Appendix A) acknowledging:

completion of the Core Training Program;

responsibility for knowing the applicable rules and institutional policies; and

responsibility for ensuring that all staff and students under their supervision also know and comply with these rules and policies.

8.2 Animal or Procedural Training

Animal users will be required to provide assurance of training/experience in the animal species and procedures they will be using. This information must be included in the summary of personal qualifications in the Animal Care and Use Protocol, and is subject to review by the Attending Veterinarian.

8.3 Annual Users Training

All ACF staff are provided 6 hours of training at the University of Texas – Houston Health Science Center in an Introduction to Laboratory Animal Science course. This course covers ethical issues, national and regional policies, regulations and standards relating to the care and use of laboratory animals, a tour of the facility, and courses in rodent anesthesia and recognition and treatment of pain in rodents.

IACUC members are offered training at IACUC 101 seminars, SCAW Conferences, and are provided copies of the OPRR Institutional Animal Care and Use Committee Guidebook, the NRC Guide to the Care and Use of Laboratory Animals, and a subscription to Lab Animal magazine.

Investigators undergo assessment by the Attending Veterinarian regarding their qualifications and experience. If necessary, they will be referred to the appropriate person or institution to receive further training. Proof of training must be submitted to the ACF office.

APPENDIX A - Statement of Compliance

I, the undersigned, have completed the self-study program outlined in this Handbook. In signing this Statement, I acknowledge responsibility for knowing the applicable rules and institutional policies, and for ensuring that all staff and students under my supervision also know and comply with these rules and policies. I also understand that this Statement will be kept on file with the IACUC and is a prerequisite for the use of animals in the JSC ACF.

I am also aware that certain animal users will be required to obtain additional certification for the use of certain species or groups of species (e.g., rodents, rabbits, primate etc.), or for the use of specific procedures (e.g., injections, restraint, blood sampling, etc.), and that certain animal users employing specialized procedures (e.g. anesthesia, surgery, implantations, etc.) will be required to demonstrate proficiency in these procedures by means of an individualized review conducted by the Attending Veterinarian or a person approved by the IACUC.

SIGNATURE

PRINT NAME

DATE

The privilege of using animals will be withheld pending the filing of this "Statement of Compliance" with the IACUC.

**Please return this signed page to the
Institutional Animal Care and Use Committee (IACUC)
in care of the ACF Laboratory Associate, BL37/P2.**

APPENDIX B

GENERAL CLEANING PROCEDURES FOR ACF

The cleaning of the ACF is performed by the Animal Caretaker. All floors, countertops, cabinets, and cage racks etc. are swept and mopped weekly to keep free of dirt and debris. Walls are cleaned every other month.

Exposed pipes, air conditioning vents etc. in the animal room are cleaned monthly. Equipment such as animal scales, restraint devices etc. are cleaned after each use.

Cleaning Agents Used in the ACF:

1. Roccal Disinfectant
Winthrop Veterinary Sterling Animal Health Products
New York, NY 10016
2. Bacdown Antimicrobial Hand soap by Curtin Matheson Scientific
P.O. Box 1546 Houston, TX 77251
3. Lime Away by Economics Laboratory (see #5)
Sales Office - 4 Corporate Park Dr. White Plains, NY 10604
4. Stera-Wash Cage & Rack Detergent by Merss Corporation
1017 W. 23rd St. Indianapolis, IN 46208 (317) 632-7299
5. Cormatic Soap, Ultima Liquid Soap by Georgia-Pacific
Contact: Tolman,
Attn: Arthur Callahan, 281-483-9564
6. Bio-Clean Laboratory Detergent
Stanbio Lab, Inc. 2930 E. Houston Street, San Antonio TX 78202
7. SO-F-105, FL-70 Detergent Biodegradable
Fisher Scientific Co. Chemical Manufacturing Division, Fairlawn, NJ 07410

APPENDIX B-1

Operation of Cage Washer

The cage washer is manufactured by Girton Manufacturing (see yellow Girton binder in ACF Records area). The model number is 794. For repairs during regular working hours, contact Work Control x32038.

The operation of the cage washer is as follows:

1. Switch master voltage box lever to "ON".
2. Turn fan switch to "ON"
3. Turn key to cage washer microcomputer box to "ON"
4. Turn water valve "ON"
5. Turn steam valve completely "ON"
6. Place cages on roll out tray of washer.
7. Close and secure access door.
8. Wait for "READY" light to come on.
9. Press "START" button (washer cycles automatically).
10. On completion of 2nd rinse, open access door.
11. Remove clean cages.
12. Repeat steps 6-11 for subsequent loads.
13. Drain cage washer by pressing "MANUAL DRAIN".
14. Turn steam valve completely "OFF".
15. Turn water valve "OFF".
16. Turn microcomputer key to "OFF".
17. Turn fan switch to "OFF".
18. Switch master voltage box lever to "OFF".

APPENDIX B-2

Microbiological Testing of the ACF

Microbiological testing is performed annually by the Wyle Laboratories Microbiology Laboratory in Building 37, Room 1022. The following samples are analyzed:

One sample of bedding directly from a new bag.

One sample of food from a new bag and one sample of food from the container.

Sample of 3 dirty cages prior to running through cage washer. Then a sample of the same 3 cages upon removal from washer.

Water sample from tap and from water bottle.

Final microbiological reports are kept on file. Rodac Press Plates are used on a quarterly basis for microbiological monitoring.

APPENDIX B-3

Cleaning Procedures for Animal Cages

The ACF Animal Caretaker is expected to provide animals with a clean cage, fresh water and fresh bedding at least twice a week or more often if cages become visibly soiled. Cages are changed every 3 days and the date the cage is changed is recorded on the cage card. Water bottles are replaced once a week. The ACF Animal Caretaker is responsible for sanitizing cages, cage card holders, feed hoppers, water bottles and sipper tubes in the Girton cagewasher. A temperature strip is used on the first wash of the day to ensure the cage washer is reaching the required 180° F. Cage filters, cage card holders and feeders should be changed bi-weekly. Face masks and gloves should be worn when handling cages with soiled bedding.

The process for changing cage bedding is as follows:

Add 1 heaping scoop of bedding material to an appropriate number of clean cages and stack on the platform truck. Remove one dirty cage from the rack at a time and place it on the truck next to the clean cages. Transfer the animals, feed holder, and cage card holder to the clean cage and return to the cage rack. Repeat this process until all cages have been replaced with clean ones.

All cages are to be transported to the cage wash room to dispose of soiled bedding in preparation for the cage washing process. The Bedding Disposal System will be moved into the Cage Wash Room for this procedure, plugged in and the hood turned on. Bags of animal waste are carried to the dumpster behind the building as soon as all cages are emptied. Excess waste and bedding is removed from the cages by rinsing the cages with hot water before they are placed in the cage washer.

APPENDIX B-4

CONTROLLED SUBSTANCES/DRUG POLICY

ORDERING AND RECEIPT

1. Orders must occur at least one month in advance of projected need.
2. Requests must be placed with the ACF Laboratory Associate who will order the drugs from the Medical Supply Officer of Kelsey-Seybold.
3. At delivery, drugs must be logged into inventory and locked in the drug cabinet.

STORAGE

1. All scheduled drugs must be locked in a substantially constructed cabinet. The cabinet must be contained by a locked area such as a room.
2. Access to the storage cabinet must be kept to a minimum.
3. Personnel using controlled substances must be trained as to their proper storage.

USE

1. Anesthetic cocktails made with controlled drugs must be appropriately labeled with expiration date (of earliest expiring component), date mixed and concentration of each ingredient.
2. All cocktails containing controlled substances must be under the control of a trained investigator or locked up when the investigator leaves the room.
3. Animal records should reflect the individual dose given to each animal.

INVENTORY

1. Inventory entries must be written in a bound ledger book.
2. Inventory for each controlled drug must be kept separately.
3. The log should indicate the name, address and DEA number of the registrant.
4. The log must be signed by the person taking the drug.
5. The amount taken and purpose must be listed in the log, including animals dosed (such as: 10 mice dosed for protocol #00-002).
6. Inventory of remaining drugs should be done monthly (biennially required).
7. Records of drug log must be kept at location for two years.

DISPOSAL

1. Disposal of unneeded or expired controlled drugs must be done in accordance with DEA guidelines.
2. The DEA field office can be contacted for specific instructions when controlled drugs are disposed.

APPENDIX B-5**JSC MEDICAL EXAMINATION FOR ANIMAL CONTACT**

All new employees assigned to the ACF are required to have an annual animal handler's physical. Hepatitis B immunization is offered to all employees working in laboratories. As part of the physical examination, they receive:

History of illness or actual immunity to the following:

- | | |
|------------------------------------|------------------------------|
| a. diphtheria | f. rubella |
| b. tetanus (booster every 4 years) | g. rubeola |
| c. polio | h. tuberculosis (tine test) |
| d. mumps | i. hepatitis |
| e. small pox | j. other infectious diseases |

Laboratory tests:

- complete blood count
- blood chemistries
- serology for CRP, SGOT, RPR
- TB Skin Tests
 - Chest x-ray if requested by physician

The health status of outside investigators must be confirmed in writing and filed in the ACF before they are allowed to work in the facility. The Application for Access to JSC/NASA Animal Facility Laboratories must also be completed by outside investigators and return to the ACF Lab Associate.

All animal bites and scratches should be cleansed immediately with soap and warm running water. Routine and emergency medical treatment is provided by the JSC Kelsey-Seybold Health Clinic (X3411 or emergency, after hours x33333). Emergency contact numbers are posted on the inside of the door to the Animal Facility.

APPENDIX B-6**BASELINE CARE AND HUSBANDRY CONDITIONS - RODENTS**

Standard Environmental Conditions for Rodents at JSC ACF

CAGES:	Rats – 19” x 10.5” x 8” microisolator cages Mice – 11.5” x 7.5” x 5” microisolator cages
BEDDING:	Harlan Teklad Sani Chips or Harlan Tek-Fresh
FOOD:	Harlan Teklad Rodent Chow Diet
WATER:	Ad libitum through polycarbonate H ₂ O bottle
TEMPERATURE:	72 ° ± 4°
HUMIDITY:	30 – 70%
LIGHT CYCLES:	12 hours light, 12 hours dark – timer in Animal Room
VENTILATION:	10-15 per hour

APPENDIX C

Protocol No. _____

Protocol for Animal Use

1. **Title** (Provide a descriptive title for the proposed study that includes the species to be used.)
2. **Investigator(s) and Professional Affiliation** (List PI(s) for the protocol, with their professional affiliation. Identify a single point of contact to whom the IACUC will direct correspondence).
3. **Protocol type**

new protocol: year 1

renewal for protocol: year 2

renewal for protocol: year 3

Scientific study

Pilot study

Proposal submittal

Education/training

Engineering test

4. **Funding Source and Peer Review**

Source: (current and proposed)

Title of Grant Submittal: (list all titles, if several funding sources)

Has this proposed activity undergone peer review? ___ Yes ___ No

If YES, who provided peer review and when? **(For new protocols include one copy of the approved grant proposal.)**

5. **Location of work:**

ARC

KSC

JSC

Other _____

6. **Principle Investigator Assurance**

To the best of my knowledge, the information contained herein is accurate.

I affirm that all procedures involving animals will be carried out humanely and will be performed by IACUC certified persons, and that as the designated Principal Investigator, I am responsible for all work conducted under this protocol.

I understand that federal regulations authorize the attending veterinarian to utilize his/her discretion in the implementation of the procedures herein described in order to assure the welfare of the animal

subjects. I further understand that any other variance from what is written in the protocol form would

10. Abstract and Rationale for the Study

Describe, **in language that will be understood by members of the general public**, the scientific aims of the project, what will be done, its significance and relation to previous studies. Justify the project in terms of its potential value.

11. Societal Benefit

Discuss the potential relevance to humans or animals (e.g. understanding of basic biological processes, maintenance and improvement of human or animal health and welfare, achievement of educational objectives).

12. Assurance of Non-Duplication

Provide a Statement of Assurance that this project is not unnecessarily duplicative.

13. Limiting Pain, Discomfort and Distress

List each procedure that has the potential for causing pain, discomfort, and/or distress, describe the methods used to assure that pain, discomfort and distress will be alleviated or minimized, OR provide a clear scientific justification for why such methods cannot be used.

For all painful and/or distressful procedures – regardless of the alleviation – provide a clear statement as to why painful and/or distressful procedures must be used and why less painful or distressful procedures are not available or appropriate.

• Statement of Assurance:

Provide a Statement of Assurance that the literature was reviewed for alternatives to these painful or distressful procedures.

Consider the “3Rs” (Replacement, Reduction, Refinement) to minimize pain and distress to the animals:

- Replacement of the animal model (i.e., use of tissue culture, computer models)
- Refinement of techniques
- Reduction in animal numbers

The narrative should be such that the IACUC can readily assess whether the search topics were appropriate and whether the search was sufficiently thorough.

• Databases used for search:

• Keywords:

• Date of search:

14. Animal Requirements

- Species Requirements:

Species	Sex	Strain	Age	Weight	Source/Vendor

- Justification of Species: (Please provide a thorough justification for utilizing the species noted. Statements that the planned species is traditionally used for the proposed research are not sufficient.)

- Animal Numbers:

Year 1	Year 2	Year 3	Total

- Justification of Animal Numbers: (Briefly describe the statistical justification for the number of animals requested. Include information on control groups and failure rates. Include a diagram if that will help the IACUC understand your justification.)

- Permits:

Are Special Permits required? Yes No

If Yes: Permit type:

Does JSC already have this permit? Yes No

15. Progress

If pilot studies were performed briefly state what was done, how many animals were used and what was learned.
 If this is a renewal, a brief statement of progress must be made. State what was done in the previous approval period, how many animals were used, what was learned and why additional animals are required to continue the study.
 Any incidents (unexpected animal illness or death) must be described here with an explanation as to how the issues were resolved.

16. Description of Experimental Plan

In **language that will be understood by members of the general public**, give a clear step by step description of the experiment. This description should allow the IACUC to understand the course of an animal from its entry into the experiment to the endpoint of the study. A diagram or chart may be helpful to explain what is being done.

17. Animal Procedures

Provide detailed information on each procedure named in the experiment plan **and the expected effects on the animals**.

This may include:

- Animal identification methods (e.g., ear notching, tattoos, collars cage card, implant, etc.)
- Experimental injections or inoculations
- Blood withdrawals (volume, frequency, sites, methodology)
- Surgical procedures (provide details in Section 11)
- Radiation (dosage and schedule)
- Restraint (Including restraint for routine procedures, ie blood draws. Prolonged restraint must be justified. Describe any sedation, acclimation or training.
- Other procedures (e.g., hindlimb suspension, centrifugation, microgravity exposure)
- Food or water restriction
- Endpoint criteria (e.g., percent body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology) must be listed.
- Veterinary care (plan of action in case of animal illness)
- Method of euthanasia

18. Endpoint Criteria and Contingency Plans

List criteria for removing an animal from the experiment or terminating the experiment due to adverse outcomes.

19. Surgery

• Type of surgery: ___ Nonsurvival (animal is euthanized without regaining consciousness)

 ___ Minor survival surgery (no penetration of a major body cavity, e.g. thorax, abdomen, cranium)

 ___ Major survival surgery (penetration of a major body cavity, e.g. thorax, abdomen, cranium, or surgical alteration that results in permanent physical impairment)

• Describe surgery in detail: (Include names and qualifications of participating personnel)

• Location: (Where will surgery be performed?)

• Surgical monitoring and supportive care: (pre-operative and intra-operative)

• Post-surgical monitoring and care: (during and following anesthetic recovery)

• Analgesics to be used:

20. Drug Table (List all drugs and euthanizing agents used in the protocol.)

Drug	Purpose	Dose	Route of Administration	Schedule

21. Disposition of Animals

What will happen to the animals at the end of the experiment?

Euthanasia

_____ AVMA approved (NASA/JSC recommends methods of euthanasia described in the AVMA 2000 Panel Report on Euthanasia) www.nal.usda.gov/awic/pubs/noawicpubs/avmaeuth.htm

_____ Other (If another method is used, provide scientific justification for the use of the alternative method)

Transfer of Live Animals

_____ “Transfer and Disposition of Surplus Animals”

_____ Other (describe transfer in detail)

22. Husbandry

Describe any special housing or husbandry requirements. Those that deviate from standard ACF practices must be described in detail; those that deviate from the NRC Guide must also be scientifically justified. www.nap.edu/readingroom/books/labrats

23. Safety Precautions

Protocols involving radiation or biosafety hazards must be approved by the appropriate officer.

Radiation Safety Officer

Biosafety Officer

(Print name and sign)

Date

(Print name and sign)

Date

24. Experience and Qualifications

List the experience and training of the PI and any personnel who will be supporting this protocol. Experience should be provided specifically as it relates to the procedures being performed in the animals. Training should include the date and title of training. All users must be current in the JSC Animal User Training Program.