NASA Procedural Requirements

NPR 8910.1A
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COMPLIANCE IS MANDATORY

Care and Use of Animals

Responsible Office: Office of the Chief Health & Medical Officer

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Preface

NASA management is committed to using live animals in Agency-supported research, testing, teaching, and hardware development activities only when necessary. When animals are required, the Agency will comply with all applicable laws, regulations, and guidelines. In addition, persons managing animal care and use programs will ensure that the "NASA Principles for the Ethical Care and Use of Animals" (Appendix A) are incorporated in their programs.

P.1 PURPOSE

This NPR 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.

P.2 APPLICABILITY

This NASA Procedural Requirements (NPR) applies to NASA Headquarters and NASA Centers, including Component Facilities, and to all activities involving animals funded by or sponsored by NASA, or conducted in or on NASA aircraft, and in or on NASA ground-based and space-borne facilities and platforms. Such activities include those conducted under a cooperative agreement or grant, reimbursable agreement, or other arrangement or agreement, entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity.

P.3 AUTHORITY

NPD 8910.1, Care and Use of Animals.

P.4 REFERENCES

a. 7 U.S.C. 2131 et seq., the Animal Welfare Act of 1966, as amended.

b. Public Law 99-158, Health Research Extension Act of 1985, "Animals in Research" (November 20, 1985).

c. 9 CFR, Subchapter A, Parts 1, 2, 3, and 4, U.S. Department of Agriculture (U.S.D.A.), Animal Welfare.

d. 14 CFR, Part 1232, Care and Use of Animals in the Conduct of NASA Activities.

e. U.S. Department of Health and Human Services, "Public Health Service Policy on Humane Care and Use of Laboratory Animals" (PHS Policy) (2002).

f. National Research Council, "Guide for the Care and Use of Laboratory Animals" (Guide) (1996).

g. United States Interagency Research Animal Committee, "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" (1985).

h. Council for International Organizations of Medical Sciences, "International Guiding Principles for Biomedical Research Involving Animals" (1985).

i. NPD 1440.6, NASA Records Management.

j. NPR 1441.1, NASA Records Retention Schedules.

P.5 CANCELLATION

NPR 8910.1A, Care and Use of Animals, dated May 7, 1999.

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CHAPTER 1. Definitions

The following definitions of terms are compatible with terminology in the Animal Welfare Act (AWA) and Public Health Service (PHS) Policy and apply to the conduct of all NASA activities related to the care and use of animals.

1.1. Activity includes research, testing, teaching, development of hardware for animal use, flight experimentation, and any other tasks involving the care and use of animals. This includes activities, such as those requiring primary tissue cultures derived from live animals.

1.2. Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International is a nongovernmental, non-profit organization established for the purpose of conducting elective, voluntary professional review and accreditation of laboratory animal care and use programs. Initial accreditation is achieved following a satisfactory onsite review by professionals knowledgeable of the field of Laboratory Animal Science and is maintained by submission of satisfactory annual reports and onsite re-reviews every 3 years.

1.3. Animal means any live or dead vertebrate animal that is being used or intended for use in research, teaching, testing, or experimentation or hardware development. Wildlife and agricultural animals are included only when they are used in nonagricultural research activities.

1.4. Animal Care Personnel are individuals directly involved in the care and monitoring of animal well-being, including animal or veterinary technicians or technologists, animal trainers, veterinarians, facility managers, and crewmembers.

1.5. Animal Facility and Study Area is any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal housing or holding, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment (including spacecraft, sounding rockets, aircraft, balloons, and related equipment during experimental activities) or ground-based facilities outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours. Vehicles used to transport animals between facilities must meet environmental control standards.

1.6. Animal Welfare Assurance is the document submitted by an institution to the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH) ensuring institutional compliance with the Public Health Service (PHS) Policy.

1.7 Assurance Number is a number issued by OLAW to institutions that have an approved Animal Welfare Assurance.

1.8 Attending Veterinarian is a person who graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates; has received training and/or is experienced in laboratory animal science and medicine, or in the care of the species being used, and who has direct or delegated authority and responsibility for activities involving animals.

1.9 Authorized NASA Official (ANO) is the NASA Administrator's representative responsible for all NASA activities involving animals. This individual is responsible for implementation of the provisions of this NPR and for ensuring that Agency programs involving animals comply fully with all applicable laws, regulations, and guidelines. NASA Policy Directive (NPD) 8910, Care and Use of Animals, designates the NASA Headquarters Chief Health and Medical Officer (CHMO) as the ANO.

1.10. Crewmember is any person assigned to a spacecraft or an aircraft mission.

1.11. Institute of Laboratory Animal Resources (ILAR) is a component of the National Academy of Sciences, National Research Council, dedicated to fostering the responsible care and use of laboratory animals in biomedical research. ILAR publishes various guidelines for animal care and use and is the responsible office for preparation and publication of the 1996 edition of the Guide.

1.12. Institution is any public or private organization, business or agency (including components of Federal, State, and local governments). In the case of NASA, an "institution" is a NASA Center.

1.13. Institutional Animal Care and Use Committee (IACUC) is a committee established in accordance with the requirements of the AWA and PHS Policy at each institution using animals in research, testing, or training activities.

1.14. Institutional Official as used in the AWA refers to NASA Center Directors or the Center Director's designee.

1.15. Institutional Review Board (IRB) is a committee established, in accordance with NPD 7100.8, Protection of Human Research Subjects.

1.16. Interagency Research Animal Committee (IRAC) was established in 1983, by the Assistant Secretary for Health, U.S. Department of Health and Human Services. It is intended to be a focal point for Federal agencies to discuss issues involving animals used for research, testing, and training.

1.17. International Council for Laboratory Animal Science (ICLAS) is an international nongovernmental scientific organization that was founded in 1961, under the auspices of UNESCO and several scientific unions. The aims of ICLAS are to promote and coordinate the development of laboratory animal science throughout the world, to promote international collaboration in laboratory animal science, to promote the definition and monitoring of quality laboratory animals, to collect and disseminate information on laboratory animal science, and to promote the humane use of animals in research, testing, and teaching through recognition of ethical principles and scientific responsibilities. The U.S. representative is designated by ILAR.

1.18. Investigator is any person who uses or proposes to use animals in NASA-supported activities (see also Principal Investigator).

1.19. The NASA Animal Care and Use Policy Review Board (NACUPRB) is a board established by NASA to review the NASA animal care and use policy and procedures, including this NPR. The board is composed of the NASA Chief Veterinarian as Chair; Center veterinarians; Chairs of each Center's IACUC; other representatives of each Center as appointed by Center Directors; a public affairs, a legal, and a legislative representative; and other experts in animal care and use, as appointed by the ANO. The NASA Chief Veterinarian shall appoint the Executive Secretary.

1.20. The NASA Flight Animal Care and Use Committee (NF ACUC) is a committee established by NASA to review, approve or disapprove all protocols using animals that are associated with flight activities supported by NASA. Members of the committee shall include, as a minimum, the NASA Chief Veterinarian, representatives from IACUC's at NASA centers, an Attending or Duty

Veterinarian, a practicing scientist experienced in research involving animals, a public member to represent the general community interest, and one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, or member of the clergy).

1.21. Office of Laboratory Animal Welfare (OLAW) is the division of National Institutes of Health (NIH) responsible for overseeing implementation and enforcement of the PHS Policy on Humane Care and Use of Laboratory Animals.

1.22. Principal Investigator (PI) is an investigator who has overall responsibility for all aspects of a NASA-supported animal activity and has received authorized funding (either government or corporate, as applicable) to conduct such activities.

1.23. PHS includes, among others, the Centers for Disease Control; the Food and Drug Administration; the Health Resources and Services Administration; and NIH.

1.24. Research or Flight Program Manager is the person designated by NASA Headquarters to manage each program in which NASA has a research or payload interest. Programs may consist of several projects.

1.25. Research or Flight Project Manager is the person designated by a Center Director to manage individual projects.

1.26. NASA Selection Official is any person authorized to make final selections of programs or projects to be supported by the Agency.

1.27. NASA Chief Veterinarian is a veterinarian appointed by the ANO to coordinate veterinary and animal care and use activities on an Agencywide basis. The NASA Chief Veterinarian may be a NASA civil servant or one appointed under the Intergovernmental Personnel Act (IPA) provision. He/she also serves as Chairperson of the NACUPRB.

1.28. Support means activities involving animals funded by or sponsored by NASA, or conducted in or on NASA facilities, aircraft, or spacecraft. Such activities include those conducted under a contract, cooperative agreement or grant, reimbursable agreement, or other arrangement or agreement, entered into by NASA and another Government agency, private entity, nonfederal public entity, or foreign entity.

1.29. Duty Veterinarian is a veterinarian appointed by the NASA Chief Veterinarian to serve as the Attending Veterinarian responsible for animal care and use issues associated with a flight mission in progress.

CHAPTER 2. Responsibilities

2.1. ANO is responsible for the following:

2.1.1. Implementing the provisions of this NPR and ensuring that all Agency programs and activities involving animals comply fully with all applicable laws, regulations, and guidelines.

2.1.2. Designating a NASA representative for the Interagency Research Animal Committee (IRAC).

2.1.3. Establishing and maintaining mechanisms for obtaining timely information from OLAW of all cases in which the Assurance of an institution involved in NASA research has been withdrawn by the PHS; and notifying NASA Institutional Animal Care and Use Committees (IACUC), Center Directors, Institutional Officials (IO), and Research and Flight Program Managers of such revocations so that they can determine if NASA awards involving the use of animals are affected and take appropriate actions.

2.1.4. Reviewing all sanctions imposed by Center Directors or IACUCs' to determine if further sanctions are warranted, or, at his or her discretion, initiating investigations of alleged noncompliance with this NPR and imposing sanctions when warranted.

2.1.5. Appointing the NASA Chief Veterinarian, who shall be a NASA civil servant or appointed under the IPA provision and shall report to the ANO.

2.1.6. Establishing and maintaining mechanisms to notify the NASA Chief Veterinarian, NASA IACUC, Center Directors, IO, and Research and Flight Program Managers of reports of noncompliance with the AWA, PHS, and this NPR that are received from non-NASA institutions where animal research is supported by NASA.

2.2. The NASA Animal Care and Use Policy Review Board (NACUPRB) is responsible for meeting in person at least once per year and convening via a teleconference at least once each calendar quarter to accomplish the following:

2.2.1. Reviewing and reaffirming that animal research, testing, and training are activities necessary for the achievement of NASA goals and objectives.

2.2.2. Reviewing and reaffirming the "NASA Principles for the Ethical Care and Use of Animals."

2.2.3. Reviewing animal care and use policies and procedures, issues, and this NPR.

2.2.4. Cooperatively developing common procedures, guidance, training, documentation, and forms which provide uniform and progressive application of professionally accepted standards at NASA Centers involved in animal care and use activities (such as Ames Research Center (ARC), Dryden Flight Research Center (DFRC), Johnson Space Center (JSC), Kennedy Space Center (KSC), and Marshall Space Flight Center (MSFC)).

2.2.5. Reviewing each Center's Animal Care and Use program at least once annually, through a review of the Center's semiannual IACUC reports and other information as needed.

2.2.6. Coordinating the ARC, JSC, KSC, and MSFC Animal Care and Use Handbooks, IACUC Reference Manuals, animal care and use protocol form, and Animal Care and Use Standard Operating Procedures Workbooks to maximize commonality.

2.2.7. Exchanging information regarding issues and practices pertaining to animal care and use.

2.2.8. Recommending changes in NASA policies and procedures to the ANO, and Center Directors, as appropriate.

2.2.9. Serving as a source of expertise and advocacy on animal care and use issues for the ANO, IACUC's, and NASA management.

2.2.10. Assisting the ANO in developing responses to public, organizational, and legislative inquiries and comments about NASA animal activities.

2.3. The NASA Flight Animal Care and Use Committee (NF ACUC) is responsible for the following:

2.3.1. Reviewing, approving or disapproving all protocols using animals that are associated with flight activities supported by NASA. No NASA-supported flight activity using animals shall be conducted without such approval by the NF ACUC.

2.3.2. Providing assurance to the ANO that all animal research conducted in flight meets the requirements of all applicable federal regulations, and that a comprehensive review of benefits and risks has been completed.

2.4. Center Directors are responsible for the following:

2.4.1. Signing the Center's Animal Welfare Assurance, making a commitment on behalf of the Center that the requirements of this NPR will be met. Center Directors may delegate authority for the day-to-day management of their Center's Animal Care and Use Program but they retain the ultimate responsibility for ensuring compliance with the AWA, PHS Policy, the Guide, and this NPR at their Centers. In addition, only Center Directors may appoint personnel to the IACUC.

2.4.2. Serving as the Center's IO, or delegating, in writing, an IO who meets the requirements of the PHS Policy and AWA, to perform the following:

2.4.2.1. Establishing and supervising the functioning of their Centers' IACUC. This responsibility may be accomplished through the use of another Center's IACUC via a formal intercenter agreement.

2.4.2.2. Signing and submitting to OLAW the Animal Welfare Assurance, committing the Center to the requirements of the PHS Policy and this NPR in all Center activities involving animals. Providing copies of the approved Animal Welfare Assurance, OLAW letter of approval and any OLAW correspondence to the ANO.

2.4.3.3. Approving the application for AAALAC International Accreditation and the annual AAALAC International reports. Providing copies of the AAALAC International Accreditation letter, the annual reports, and any correspondence from AAALAC International to the ANO.

2.4.3.4. Approving the annual report to the U.S. Department of Agriculture (USDA) and providing copies of the report and any comments from USDA to the ANO.

2.4.5.5. Deciding and administering sanctions in cases of noncompliance with this NPR, in accordance with the AWA, its implementing regulations, PHS Policy, and NASA personnel policies; and notifying appropriate funding officials and the ANO.

2.4.6.6. Providing the ANO with copies of all IACUC minutes and reports.

2.5. NASA Chief Veterinarian is responsible for the following:

2.5.1. Coordinating veterinary and animal care activities across NASA institutions. In accomplishing this responsibility, the NASA Chief Veterinarian is specifically authorized to halt any animal activity he or she believes to be noncompliant with applicable laws, regulations, this NPR, and approved protocols. Following halting of any activity, the NASA Chief Veterinarian will initiate action, including IACUC re-review, to resolve the situation.

2.5.2. Guiding, as Chairperson, the activities of . the NACUPRB.

2.5.3. Advising the ANO on any aspect of the Agency's Animal Care and Use Program.

2.5.4. Representing NASA in the external Laboratory Animal Science community and associations.

2.5.5. Participating in the development, review and approval of requirements for all animal facilities and equipment for flight as related to animal care and use.

2.5.6. Developing and implementing a program to foster and encourage the use of alternate methods of research that reduce the numbers of animals used, refine the procedures used to minimize or eliminate animal pain or distress, or encourage the use of procedures that do not require the use of animals. As part of this effort, the NASA Chief Veterinarian will establish and maintain liaison with organizations working in this field and will develop and maintain mechanisms for dissemination of information regarding new methods and protocols to potentially interested parties.

2.5.7. Developing and implementing for non-NASA investigators an education program intended to inform them regarding the requirements and constraints for flight animal research activities in-flight.

2.5.8. Informing international entities and individuals about the technical requirements in accordance with U.S. laws, regulations, guidelines, standards, and this NPR. This will include information regarding the requirements and constraints for flight animal research activities.

2.5.9 Serving as Executive Secretary of the NF ACUC.

2.6. Institutional Animal Care and Use Committee (IACUC) is responsible for the following:

2.6.1. Performing responsibilities in accordance with provisions given in the Animal Welfare Act, its implementing regulations, PHS policy, and the Guide. Unless another IACUC is specifically designated by the ANO, the NF ACUC is responsible for protocols, and procedures involving animals for all flight vehicles, facilities, and hardware. When animals are housed at a NASA Center in preparation for flight activities, the host Center's IACUC is responsible for their care and use and for reviewing and approving or disapproving those parts of proposals that call for the use of the host Center's facilities housing the animals.

2.6.2. Approving, disapproving, or requiring modifications to be made in those components of proposed activities involving the care and use of animals that are submitted by investigators. In addition, IACUC's have the authority to suspend previously approved activities involving animals. All decisions shall be based on the response of a majority of a quorum of the members present and shall be accurately recorded in the minutes of the meeting. In conducting the reviews of proposed activities involving animal care and use, IACUC members will ensure that the "NASA Principles for the Ethical Care and Use of Animals" are met.

2.6.2.1. Animal activities that have been approved by the IACUC may be subject to further review by the Center Director, ANO, or other NASA officials, as appropriate. These officials may disapprove animal activities but may not approve an activity related to the care and use of animals if

the activities have not been approved by the IACUC.

2.6.3. Including in its membership, in accordance with the AWA its implementing regulations, and PHS Policy, at least one Doctor of Veterinary Medicine with training or experience in Laboratory Animal Medicine and who has direct or delegated program authority for activities involving animals, a practicing scientist experienced in research involving animals, an individual not affiliated with the institution in any way other than as a member of the IACUC, and at least one member whose primary concern is in a nonscientific area such as an ethicist, lawyer, or member of the clergy.

2.6.4. Approving personnel qualifications and training.

2.6.5. Reviewing the Center's program for humane care and use of animals, at least once every 6 months, and inspecting all of the Center's animal facilities (including satellite facilities), using the AWA its implementing regulations, PHS Policy, and the Guide as a basis for evaluation. The report, signed by a majority of the IACUC members, must be submitted to the ANO through the IO .

2.6.5.1. Although in-flight spacecraft may contain facilities which are, by definition, "Animal Facilities," it is recognized that IACUC inspections of such facilities are impractical, and often impossible. However, to meet the intent of the AWA in regards to monitoring animal facilities, the NF ACUC will review all in-flight and postflight crewmembers reports regarding animal hardware performance. Any reported deficiency or failure must be evaluated by the NF ACUC in regards to the welfare of animals being maintained in-flight. Any deficiency or failure determined to potentially impact animal well-being negatively, will be reported immediately to the appropriate Center Director, the NASA Chief Veterinarian, and the ANO. OLAW will also be notified of such deficiencies or failures if the in-flight animal activities involve PHS funding.

2.6.5.2. Reports of the reviews and inspections must contain a description of the nature and extent of the Center's adherence to the AWA, its implementing regulations, PHS Policy, the Guide, and this NPR. They must specifically identify any departures from the provisions of the Guide and this NPR and must state the reasons for each departure. In addition, they must contain specific reference to the Committee's efforts to incorporate bioethical considerations in their reviews of proposed animal care and use activities.

2.6.5.3. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that, consistent with PHS Policy definitions, and, in the judgment of the IACUC and the Center Director, is or may be a threat to the health or safety of the animals. The IACUC, through the IO, will report promptly any such deficiencies to OLAW.

2.6.5.4. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.

2.6.6. Reviewing and approving, requiring modifications in (to secure approval), or withholding approval of those components of proposed activities or significant changes to ongoing activities related to the care and use of animals. Once approved, no significant changes can be made until a written request with appropriate justification is submitted to and approved by the IACUC.

2.6.7. Conduct continuing reviews of approved animal activities at appropriate intervals as determined by the IACUC, but at least once every 12 months.

2.6.8. Establishing mechanisms for ensuring the reporting, receipt, and review of concerns involving the care and use of animals.

2.6.9. Making recommendations to the IO regarding any aspect of the Center's animal program, facilities, or personnel training.

2.6.10. Providing copies of meeting minutes and reports of semiannual inspections and reviews to the IO who will forward copies, with any recommendations pertaining to Agencywide issues, to the ANO and the NASA Chief Veterinarian.

2.6.11. Reporting, in writing, the following to the ANO, as well as USDA, the Animal and Plant Health Inspection Service (APHIS), and OLAW as required, through the IO, at least once every 12 months:

2.6.11.1. Changes in the description of the Center's program for animal care and use.

2.6.11.2. Changes in the Center's program or facilities that would affect the AAALAC International accreditation status.

2.6.11.3. Changes in the IACUC membership.

2.6.11.4. A statement that the Center has no changes to report, if there are no changes.

2.6.11.5. Any recommendations, including minority views, for changes in NASA-wide facilities, policies, or procedures.

2.6.12. Promptly provide, through the IO, the ANO, as well as USDA, APHIS, and OLAW as appropriate, with a full explanation of the circumstances and actions taken, with minority views, if any, with respect to the following:

2.6.12.1. Any deviation resulting in serious or continuing noncompliance with the provisions of the Guide, AWA, its implementing regulations, PHS Policy, or this NPR.

2.6.12.2. The reasons for any suspension or termination of approval will be documented in writing with copies provided promptly to the PI, the Center Director, OLAW, and the ANO. If an IACUC suspends a research activity that has already been approved, the PI will be given written documentation regarding the reason for such action and will be afforded the opportunity to take corrective actions to resolve the situation.

2.6.12.3. Any adverse actions by, or communication from OLAW, AAALAC International, or USDA.

2.7. The IRB, if the experiment involves the exposure of the crewmembers to research animals, at JSC must review and approve the proposal and modifications to ensure the protection of the crew from exposure to zoonotic risk and other health-related concerns. The IRB may also review proposals and modifications to ensure that the orbiter and flight hardware will not be chronically contaminated by zoonotic agents potentially carried by research animals. Copies of documents indicating IRB action in regards to projects involving animals will be provided to the ANO and the responsible IACUC (normally, the NF ACUC).

2.8. Animal Care and Use Personnel are responsible for the following:

2.8.1. Maintaining animals in accordance with contemporary standards, laws, and regulations.

2.8.2. Obtaining and maintaining, through training and experience, proficiency in regards to the procedures they perform involving animals.

2.8.3. Reporting any deficiencies in procedures for animal care and use activities or issue of noncompliance with applicable laws, this NPG, and IACUC approvals to the veterinarian, IACUC chairperson, NASA line management, or NASA Inspector General.

2.9. Principal Investigators, including those resident at NASA Centers, are responsible for the following:

2.9.1. Complying with, and ensuring their research staff comply with, those responsibilities applicable to all animal care personnel described above in section 2.8.

2.9.2 Obtaining IACUC approval from each institution where research will be conducted for all successfully peer-reviewed proposals requesting the use of animals. NASA will not provide support for proposals that have passed peer review until proof of IACUC approval is submitted. In the case of international investigators, proof of approval for the use of animals must be provided by a governmental or agency level equivalent of an IACUC.

2.9.3. Including the PHS Animal Welfare Assurance number from OLAW for the institution at which the research is to be conducted. Proposals from U.S. and foreign institutions without an approved Assurance on file with the NIH OLAW must provide one of the following: 1) proof of current accreditation from the Association for Assessment and Accreditation from AAALAC International; 2) documentation of institutional animal care and use ensuring compliance with the PHS Policy; or 3) documentation of institutional animal care and use ensuring compliance with the Council for International Organization of Medical Sciences (CIOMS), "International Guiding Principles for Biomedical Research Involving Animals."

2.9.4. Conducting all animal activities in accordance with approved Animal Care and Use Protocols.

2.9.4.1. NASA employees who wish to conduct research using animals at a non-NASA facility must provide documentation to the IACUC at their Center that the research has been approved by the IACUC at the institution where the work will be conducted.

2.9.5. Providing results to the IACUC, particularly those results, outcomes, and assessments of animal condition and health that will allow the IACUC to continually monitor the adequacy of animal well-being and unintended consequences which adversely affected animal well-being.

2.9.6. Using experimental designs and procedures that accomplish the following:

2.9.6.1. Minimize the numbers of animals necessary to obtain scientifically valid results.

2.9.6.2 Incorporate refined techniques that eliminate or minimize animal pain and distress.

2.9.6.3. Replace animals with no animal systems whenever possible.

2.9.6.4. Notifying Program/Project Managers and the responsible IACUC, in writing, of deviations, unexpected outcomes, or proposed significant changes in approved protocols.

2.10. PIs and NASA personnel working in non-U.S. laboratories under NASA sponsorship are responsible for the following:

2.10.1. Conducting all animal activities in accordance with the animal care and use standards as defined in this NPR, the PHS Policy, the AWA, its implementing regulations, or as defined by the host country, whichever is the more demanding.

2.10.2. Not participating in animal activities if the standards defined in this NPR, the PHS Policy, the AWA its implementing regulations, or the standards of the host country cannot be met.

2.10.3. Reporting as soon as possible, with follow-up hard copy, their decision that they cannot participate in animal activities to the NASA Program Manager, appropriate Center Director, the appropriate IACUC, the NASA Chief Veterinarian, and the ANO.

2.11. Program and Project Managers are responsible for the following:

2.11.1. Determining that Investigators and PIs comply with subsections 2.8 and 2.9 of this NPR and

withholding funding from those that do not.

2.11.2. Ensuring that NASA has received documentation that proposals requesting NASA support for activities comply with subsection 2.9 of this NPR; and certifying compliance to the Selection Official prior to providing NASA support.

2.11.3. Ensuring that flight activities comply with Chapter 5 of this NPR; and certifying compliance to the Selection Official prior to selection for NASA support.

2.12. Attending Veterinarians at NASA Centers are responsible for the following:

2.12.1. Managing and providing the clinical veterinary care program to include all requirements specified as "Adequate Veterinary Care" in the AWA its implementing regulations, and PHS Policy.

2.12.2. Serving as a voting member of the Center's IACUC.

2.12.3. Ensuring that all animal care and use activities are monitored and the attending veterinarian is aware of the results of such monitoring.

2.12.4. Maintaining surveillance of the health and condition of animals in the animal colony and those being used in research activities.

2.12.5. Reporting any unresolved deficiencies in animal care, use, and treatment, or any activity that is not being conducted in accordance with the description of that activity provided by the PI and approved by the IACUC, to the Center Director, IACUC, and the NASA Chief Veterinarian.

2.12.6. Immediately halting activities deviating from IACUC-approved practices or procedures, or from professionally accepted animal care and use practices. In cases where the differences between the Investigator or Animal Care Provider and the Veterinarian cannot be resolved within 24 hours, the matter must be immediately brought to the attention of the IO and IACUC Chair for review and resolution.

2.12.7. Participating in the training of personnel in the handling of animals and in specimen sampling procedures and other professionally accepted standards of animal care and use.

2.12.8. Overseeing all schedules and procedures for training and acclimating animals.

2.12.9. Reviewing presurgical, surgical, and postsurgical procedures to verify that the principles of the Guide for survival surgery are used. When necessary, the Veterinarian will provide or arrange for training necessary to qualify investigators and other animal users.

2.12.10. Reviewing and verifying the appropriateness of all veterinary medical and experimental procedures performed on animals.

2.12.11. Reviewing and approving, in consultation with the NASA Chief Veterinarian, the design requirements and changes of local animal facilities for support of ground and space flight animal activities.

2.13. Selection Officials, as the individuals selecting or approving grants, contracts, agreements, awards, and reimbursable arrangements are responsible for the following:

2.13.1. Ensuring that investigators have IACUC approval from their home institution and that, if applicable, their home institution has an approved OLAW Assurance or meets the criteria of section 2.9.3 prior to funding of any animal-related activities.

2.13.2. Including a copy of this NPR with each request for proposal and notification of selection.

2.14. Crewmembers serving as the animal care personnel during a flight activity are responsible for the following:

2.14.1. Participating in assigned preflight training to gain proficiency in accomplishing activities and procedures involving animals.

2.14.2. Providing scheduled status reports to the Duty Veterinarian or NASA Chief Veterinarian on animal health and well-being during in-flight operations.

2.14.3. Reporting promptly to the Duty Veterinarian or NASA Chief Veterinarian any problems affecting animal welfare during space flight, such as deficiencies in hardware or in procedures for animal care and use.

2.14.4. Providing the NASA Chief Veterinarian with in-flight and postflight reports regarding hardware performance and animal care and use procedures.

2.14.5 Ensuring that animal welfare requirements receive priority during the conduct of flight activities.

2.15. The Duty Veterinarian or NASA Chief Veterinarian will have the responsibility and authority to serve as the Attending Veterinarian during space flight activities.

CHAPTER 3. Recordkeeping Requirements

3.1. Each NASA Center involved in activities using animals shall manage the following records in accordance with NPR 1441.1, NASA Records Retention Schedules to ensure their proper maintenance, safeguarding, and disposition:

3.1.1. An approved Animal Welfare Assurance.

3.1.2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.

3.1.3. Records of proposals, protocols, and proposed changes in the care and use of animals and whether IACUC approval was given or withheld.

3.1.4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official.

3.1.5. Copies of USDA Annual Reports and any USDA correspondence pertaining thereto.

3.1.6. Records of AAALAC International accreditation, including application, acceptance notification, annual reports, and any AAALAC International correspondence.

3.1.7. The NASA NPD and NPR on Animal Care and Use, and the Animal Care Facility Work Instruction.

3.1.8. All records for at least 3 years after completion of animal activities.

3.1.9. All records pertaining to the acquisition and dispersion of controlled substances in accordance with DEA requirements.

3.2. Animal records shall be maintained on all animals used in NASA facilities, aircraft, and spacecraft. While it may be appropriate to maintain only group records for some animals (such as rodent) used in ground-based studies, to the extent possible, individual records will be established and maintained for all animal mammalian species and, when practical, for all vertebrate animals that are candidates for in-flight space flight experiments and can be individually identified, regardless of species. NASA-sponsored investigators at non-NASA institutions are expected to maintain similar animal records for animals used for space flight baseline studies.

3.2.1. Information to be included in these animal records includes, but is not limited to, a description of the animals (such as species, breed/strain, sex and age); receipt and quarantine data, including transportation information such as waybill numbers and means of transportation; administration of prophylactic vaccinations or treatments; history, diagnosis, clinical test results, treatments, and outcomes of any illnesses; any observations regarding the animals' behavior or physical abnormalities; documentation of all experimental manipulations, including detailed surgical and postsurgical reports; and disposition information, including the results of any necropsy performed (animals dying of unknown causes should be necropsied by a qualified veterinarian as appropriate). Other information that is appropriate for inclusion in these animal records are technician

observations regarding the animals' overall condition and appetite, the animals' standing within a group's dominance hierarchy, and documentation of the animals' involvement in cases of human injury (from biting and scratching).

Chapter 4. Approval for Use of NASA Facilities and Equipment

4.1 Each NASA Center IACUC will review and approve, require modifications in (to secure approval), or withhold approval of those parts of proposals that call for the use of their facilities or equipment to conduct any activity involving animals.

4.2 The NF ACUC will review and approve, require modifications in (to secure approval), or withhold approval of those parts of proposals that call for the use of NASA flight facilities or equipment to conduct any activity involving animals.

Chapter 5. Flight Activities

5.1. In addition to review by the Investigators' IACUCs, flight and supporting ground-based activities involving animals must be approved by the NF ACUC in accordance with the AWA, its implementing guidelines, PHS Policy, and this NPR. Associated ground-based activities shall also be reviewed by the IACUC at the Center where the work will be conducted. When ground-based activities are performed by an international partner, the laws and regulations of the country where the activities occur must be followed, with a minimum standard being the international guiding principles, "International Guiding Principles for Biomedical Research Involving Animals."

5.1.1. The process outlined in section 5.1 applies to all experiments flown on NASA flight platforms regardless of the sources of support, and to all experiments flown on non-NASA platforms, including international vehicles, if they are supported by NASA.

5.1.2. Animal activities to be flown on board NASA-crewed spacecraft must be reviewed by the IRB at JSC for areas related to crew health and safety associated with exposure to the animals.

5.2. Where multiple experiments approved individually are proposed to be conducted with the same experimental animal, an integrated proposal must be reviewed by the NF ACUC prior to commencement of integration studies.

5.3. Protocols submitted to the NF ACUC for proposed flight activities must include an animal use and disposition plan that incorporates all animals necessary to support any proposed flight activity, including those necessary to cover launch delays and other contingency planning. Also included in such plan shall be animals required to support any ground-based studies necessary to validate or integrate proposed in-flight animal-based activities and hardware. As part of the review of proposed animal care and use activities, Agency IACUC's will ensure that investigators and NASA program, project, and mission managers minimize the number of animals involved.

5.4. The NF ACUC will submit each evaluation report to the ANO.

5.5. Animal activities utilizing a NASA facility in support of flight activities must also be approved by that Center's IACUC and the NF ACUC, regardless of the institutional or national origin of the activities or the sources of support.

5.6. For veterinary care, compliance, and response to events during flight, the following guidelines apply:

5.6.1. The NF ACUC is responsible for approved animal care and use procedures and activities including preflight, flight, and postflight. In addition, the IACUC's at the ARC, JSC, KSC, and MSFC must also approve any animal activities conducted at their Centers. As previously noted, upon request from the ARC IACUC for cause, the ANO may officially transfer responsibility to an alternate IACUC on a case-by-case basis. However, protocols and results must be provided to the NF ACUC to facilitate their oversight and coordination of the animal flight research program and animal care and use decisions during flight activities.

5.6.2. The NASA Chief Veterinarian is responsible for veterinary support and for identifying a duty veterinarian available in person or by telephone at all times during flights that include animal activities.

5.6.3. It is recognized that protocols for animal activities may need to be modified in-flight as procedures are refined in response to operational constraints or experimental variation. Significant changes to protocols that become necessary during flight shall require the approval of the majority of a quorum of the NF ACUC or other designated IACUC. The IACUC chairperson or designee shall expeditiously seek this approval by designated review consistent with current acceptable procedures. The duty veterinarian has the authority to temporarily suspend activities or to grant a temporary approval to the requested change until the IACUC can review the request. The payload mission manager in the control room must immediately be told of this requested substantive change or temporary suspension of activities.

5.7. Mechanisms for interaction and coordination among NASA IACUC's and veterinarians with responsibilities for preparation, execution, and postflight animal activities will be developed and implemented by the NACUPRB, with concurrence and approval of the ANO.

5.8. Adequate resources must be provided and appropriate priority must be assigned to ensuring animal welfare requirements during the conduct of space flight research.

CHAPTER 6. Disposition of Research Animals

6.1. In order to consistently utilize animals in a humane and meaningful manner, animals which are no longer needed for research, including animals not used due to launch delays and other flight contingencies planning, should be utilized according to the following guidelines:

6.1.1. Animals that have had no surgical, chemical, or radioactive intervention will be returned to stock and assigned for use by any NASA-sponsored investigator who possesses an approved Animal Care and Use Protocol. Animals that have had surgical intervention may be assigned to other approved protocols; however, animals that have had major surgery may not be assigned to protocols that would require an additional major survival surgery.

6.1.2. The responsible IACUC may approve transfer of animals for use by other Federal institutions, NASA-funded non-Federal institutions, or other non-Federal institutions, that have OLAW or AAALAC International approved assurances, in that order of priority.

6.1.3. If no approved investigator or institution can be found, animals that have had no surgical, chemical, or radioactive intervention may be euthanitized and the carcasses may be provided to suitable organizations involved in the care and maintenance of endangered species or the care and rehabilitation of sick or injured animals, or they may be disposed of in accordance with procedures approved by the applicable IACUC.

6.1.4. Animals that have been exposed to a hazardous compound, experimental drug, radionuclides, or that have been subject to a major operative procedure as part of the experimental protocol may be returned to stock and assigned for use in other approved activities if determined by the applicable IACUC that such use is appropriate. Otherwise, they may be euthanized and disposed of in accordance with NASA guidelines governing the disposal of radioactive, biological, and chemical waste.

CHAPTER 7. Sanctions

7.1. PIs not employed by NASA, whose activities are supported by NASA but whose activities using animals are restricted to non-NASA facilities, shall be subject to the control of their institution's IACUC, the responsible Center Director, and Program Manager when appropriate. Notification of noncompliance with the AWA its implementing guidelines, PHS Policy, and this NPR shall be made by the non-NASA institution to the Director of the NASA Center through which the activity has been supported and to the ANO. Any continued noncompliance may be cause for termination of funding or support.

7.2. At NASA Centers, the process for imposing sanctions is as follows:

7.2.1. Deficiencies in animal care and use at any NASA facility by anyone (such as investigators, animal care personnel, visiting scientists, support contractors) may result in the halting of such activities as directed by the NASA Chief Veterinarian, NASA Center Attending Veterinarian, or line management. If someone other than the Center's Attending Veterinarian has halted an activity, it must be immediately reported to the Attending Veterinarian. It must also be brought to the attention of the IACUC Chair within 2 business days. If the issue cannot be immediately resolved to the satisfaction of the Attending Veterinarian, the IACUC will review the activity.

7.2.2. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the AWA, its implementing regulations, PHS Policy, this NPR, or as described in the approved protocol. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. Any suspension of an approved activity will include a statement of the reasons for the action and will be promptly reported to the PI and the appropriate IO.

7.2.3. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW and the ANO. The IO will also formally report such actions to the PI, appropriate Center Director and Program or Project Manager responsible for supporting the activity. In the case of investigators from non-NASA institutions, notification shall also be sent to the management and IACUC at the investigator's institution.

7.2.4. If the PI fails to take appropriate corrective action, the IACUC can terminate a study.

7.2.5. In cases where an investigation is terminated, the Center Director, in consultation with the Center Chief Counsel, may also impose additional appropriate sanctions, and report his or her actions with a full explanation to the ANO.

7.2.6. The ANO, after reviewing the actions of the Center Director, may, in consultation with the NASA General Counsel, impose further sanctions, as appropriate.

Appendix A: NASA Principles for the Ethical Care and Use of Animals

A.1 Introduction

a. A strong allegiance to the principles of bioethics is vital to any discussion of responsible research practices. As reflected in the 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 the key 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.

b. It is generally agreed that vertebrate animals warrant 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. It is recognized that awareness of these principles will not prevent conflicts. Rather, these principles are meant to provide a framework within which challenges can be rationally addressed.

A.2 Basic Principles

a. The use of animals in research involves responsibility, not only for the stewardship of the animals but to the scientific community and society as well. Stewardship is a universal responsibility that goes beyond the immediate research needs to include acquisition, care, and disposition of the animals, 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.

b. 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.

(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 that the research should involve the minimum number of animals 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 models, computer simulation, and in vitro systems should be considered and used whenever possible.

(2) Societal Benefit

The advancement of biological knowledge and the 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, in cases where animals are used, the assessment of the overall ethical value of such use should include consideration of the full range of potential societal good, the populations affected, and the burdens that are expected to be borne by the subjects of the research.

(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.

Appendix B:Policy on Communication of Animal Health and Welfare During NASA Space Flight Missions

B.1 Policy

a. The health and well-being of experimental animals used during space flight is of the highest importance to NASA for both ethical and scientific reasons. Decisions made regarding the health status and fitness of experimental animals shall be made by qualified individuals with training appropriate to determine the type of interventions necessary to minimize pain and distress in the experimental animal and to maximize the return of scientific knowledge.

b. The need for voice communication during flight shall be at the request of the crewmembers and limited to circumstances, which extend beyond crew training, which affect animal health and well-being. Should unexpected or critical conditions exist which warrant immediate attention, at the commander's or payload commander's determination, a veterinary consultation with the NASA Chief Veterinarian or the Duty Veterinarian may be requested. Such communication may occur via an open or closed voice loop and shall be restricted to animal welfare issues, which require a decision to provide extraordinary intervention or to euthanize the experimental animals. Likewise, if conditions are detected from the ground which indicate imminent failure of the animal habitats or host systems and subsequent compromise of animal welfare, the NASA Chief Veterinarian or Duty Veterinarian may inform the crewmembers. The commander or payload commander may request authorization from the NASA Chief Veterinarian to down link relevant images of affected animals for review by the NASA Chief Veterinarian or the Duty Veterinarian to assist in a decision to euthanize the animals. Such a request will only be authorized when other means of communicating the animals' clinical status has been ineffective.

c. The decision to euthanize experimental animals shall be made by the NASA Chief Veterinarian with input from the crewmembers regarding the animals' condition. The Project Scientist, the Project Manager and the PI, whose work will be affected, shall be consulted regarding the circumstances and the impact of the decision. The NASA Chief Veterinarian will make the final decision to euthanize animals for humane reasons. The crewmembers will be informed of such decision for implementation. The NASA Chief Veterinarian shall be responsible for communicating the circumstances and procedures associated with the decision to NASA Headquarters, affected research teams and in a timely manner to the press through the Public Affairs Office.