



NASA Procedural Requirements

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2027**COMPLIANCE IS MANDATORY FOR NASA EMPLOYEES**

Care and Use of Animals

Responsible Office: Office of the Chief Health & Medical Officer

Table of Contents

Preface

- P.1 Purpose
- P.2 Applicability
- P.3 Authority
- P.4 Applicable Documents and Forms
- P.5 Measurement/Verification
- P.6 Cancellation

Chapter 1. Introduction

- 1.1 Animal Research at NASA
- 1.2 Policy Implementation
- 1.3 NASA Principles for the Ethical Care and Use of Animals Implementation
- 1.4 Memorandum of Understanding (MOU) Between Office of Laboratory Animal Welfare, Office of Extramural Research, Office of the Director, National Institutes of Health and National Aeronautics and Space Administration

Chapter 2. Responsibilities

- 2.1 CHMO, Flight IACUC IO, and Office of Research Assurance
- 2.2 Chief Veterinary Officer
- 2.3 Attending Veterinarians
- 2.4 Institutional Animal Care and Use Committee Chairs
- 2.5 Center Directors
- 2.6 Institutional Officials
- 2.7 Program Personnel

2.8 Principal Investigators

Chapter 3. Criteria for IACUC Approval

3.1 Introduction

3.2 Criteria for Research Sponsored or Funded by NASA, Conducted in NASA Facilities/Spacecraft, or Using NASA Resources.

3.3 Criteria for Research Sponsored or Funded by International Partners, Conducted at NASA Facilities/Spacecraft, or Using NASA Resources

3.4 Criteria for Research Sponsored or Funded by NASA, Conducted in International Partner Facilities/Spacecraft, or Using International Partner Resources

Chapter 4. NASA Specific Requirements

4.1 Introduction

4.2 Veterinary Care, Compliance, and Response

4.3 IACUC Responsibilities and Processes

4.4 Communication of Animal Health and Welfare

4.5 Vertebrate Animals and Higher Order Cephalopods Section Review

4.6 Standard Housing Guidelines for ISS

4.7 Photo Documentation Policy

4.8 Biospecimen Sharing Program

4.9 Flight Rules and Operational Documentation

4.10 Science Requirements

4.11 Engineering Requirements

4.12 Noncompliance, Unanticipated Adverse Events, and Corrective Actions

4.13 Emergency/Disaster Plan

4.14 Records Management

Appendix A. Definitions

Appendix B. Acronyms

Appendix C. NASA Principals for the Ethical Care and Use of Animals

Preface

P.1 Purpose

- a. NASA is committed to humane and responsible use of live vertebrate animals and higher order cephalopods (hereinafter, animals) in Agency-supported research, testing, teaching, and hardware development activities. When animals are required, the Agency will comply with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines and ensure the NASA Principles for the Ethical Care and Use of Animals, Sundowner Report, 1996, (see Appendix C) are incorporated into its programs.
- b. This directive describes the responsibilities and implementing requirements for the use of animals in research, testing, teaching, and hardware development activities funded or sponsored by NASA or conducted in NASA facilities, aircraft, or spacecraft, including commercial facilities, aircraft, and spacecraft that are funded or sponsored by NASA or use NASA resources.

P.2 Applicability

- a. This NPR is applicable to NASA Headquarters and NASA Centers, including Component Facilities and Technical and Service Support Centers. This language applies to the Jet Propulsion Laboratory (a Federally Funded Research and Development Center), other contractors, recipients of grants, cooperative agreements, or other agreements only to the extent specified or referenced in the applicable contracts, grants, or agreements.
- b. This NPR applies to Principal Investigators (PI) who are contractors, recipients of grants, cooperative agreements, or other agreements as specified or referenced in the applicable contract, grant, or agreement.
- c. This NPR applies to Payload Developers who are contractors as specified or referenced in the applicable contract.
- d. This NPR applies to NASA supported Animal Care Facilities who are contractors as specified or referenced in the applicable contract.
- d. This NPR is applicable to all activities involving animals that are funded or sponsored by NASA, use NASA resources, or are conducted in NASA facilities, aircraft, or spacecraft.
- e. This NPD is applicable to all activities involving animals conducted by public institutions or in commercial facilities, aircraft, and spacecraft that are funded or sponsored by NASA or use NASA resources. Activities involving animals by public institutions or in commercial facilities, aircraft, and spacecraft that are not directly or indirectly funded by NASA or do not use NASA resources are out of scope.

Note: NASA resources related to operation of the commercial facility, aircraft, or spacecraft having nothing to do with the animal activity does not constitute “use of NASA resources” for the actual animal activity. For example, if the institution or commercial provider only uses KSC services to load animals or launch the vehicle, this NPR would not apply.

f. This NPR does not apply to livestock, domesticated animals, or wildlife under non-NASA control that are permitted to be at NASA Centers or Facilities for other than research purposes (e.g., cattle leases, guide dogs, and wildlife management), nor does it apply to animals used by NASA, contractors, or other agencies for law enforcement and security purposes.

g. In this directive, all mandatory actions (i.e., requirements) are denoted by statements containing the term “shall”. The terms “may” or “can” denote discretionary privilege or permission, “should” denotes a good practice and is recommended, but not required, “will” denotes expected outcome, and “are/is” denotes descriptive material.

Note: Care should be taken when reading NASA policy versus policy and guidance from external organizations as terminology is used differently. The above definitions are relevant to NASA policy. The Department of Agriculture and Department of Health and Human Services use different terminology in their policies and guidance. Refer to their documents for specific terminology usage.

h. In this directive, all document citations are assumed to be the latest version unless otherwise noted.

P.3 Authority

- a. Animal Welfare Act of 1966, 7 U.S.C. § 2131 et seq.
- b. National Aeronautics and Space Act, 51 U.S.C. § 20113 (a).
- c. Care and Use of Animals in the Conduct of NASA Activities, 14 CFR, pt. 1232.
- d. NPD 1000.3, The NASA Organization.
- e. NPD 8910.1, Care and Use of Animals.

P.4 Applicable Documents and Forms

- a. c. Animal Welfare, 9 CFR ch. 1 subch. A pts. 1-3.
- b. NPD 1050.7, Authority to Enter into Partnership Agreements.
- c. NPD 1440.6, NASA Records Management.
- d. NRRS 1441.1, NASA Records Retention Schedules.
- e. Guide for the Care and Use of Laboratory Animals (The Guide), Eighth Edition, 2011, National Academy Press, Washington D.C.
<https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-use-of-laboratory-animals.pdf>
- f. International Guiding Principles for Biomedical Research Involving Animals, Council for International Organization of Medical Sciences and International Council for Laboratory Animal Science, December 2012. https://grants.nih.gov/grants/olaw/Guiding_Principles_2012.pdf
- g. Memorandum of Understanding (MOU) Between Office of Laboratory Animal Welfare, Office of Extramural Research, Office of the Director, National Institutes of Health and National Aeronautics

and Space Administration, March 24, 2020. <https://olaw.nih.gov/NASA.html>

h. NASA Principles for the Ethical Care and Use of Animals, Sundowner Report 1996. https://www.nasa.gov/sites/default/files/atoms/files/the_sundowner_report-3.pdf

i. Occupational Health and Safety in the Care and Use of Research Animals, 1997, National Academy of Sciences Institute for Laboratory Animal Research. <https://rcb.tamu.edu/bohp/forms/ilar>

j. OCHMO-550, Standard Housing Guidelines for the International Space Station.

k. OCHMO-551, Vertebrate Animals and Higher Order Cephalopods Review Process.

l. SSP 50521, Return, Processing, Distribution and Archiving of Imagery Products

m. Policy and Guidelines for the Use and Care of Animals in Space-borne Research, Committee on Space Research (COSPAR) Information Bulletin: Space Research Today, Number 169, August 2007. <https://www.sciencedirect.com/science/article/pii/S1752929807800326>

n. Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), US Department of Health and Human Services, Revised 2015, NIH Publication No. 15-8013. <https://olaw.nih.gov/sites/default/files/PHSPolicyLabAnimals.pdf>

o. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, 85 FR 12059, (May 20, 1985). <https://olaw.nih.gov/policies-laws/gov-principles.htm>

P.5 Measurement/Verification

a. The Chief Health and Medical Officer (CHMO) will measure and verify compliance with this directive by assessing:

(1) Regulatory required Institutional Animal Care and Use Committee (IACUC) semi-annual Program Review and Facility Inspection reports.

(2) Regulatory required OLAW, AAALAC, and United States Department of Agriculture (USDA), PHS and AAALAC reports for all facilities operated or leased by NASA.

(3) Animal Policy Review Board (APRB) reports.

P.6 Cancellation

NPR 8910.1C, Care and Use of Animals, dated December 02, 2011.

Chapter 1. Introduction

1.1 Animal Research at NASA

1.1.1 Research designed to advance our understanding of how the space environment affects living systems and to ensure the health, well-being, and productivity of humans in space often requires PIs to utilize on animal models. In some cases, basic research is conducted to understand how space conditions (e.g., microgravity, space radiation, isolation) affect different physiological systems (e.g., cardiovascular, musculoskeletal, neurological). In other cases, applied studies are conducted to understand the mechanisms that underlie adverse health effects that astronauts experience and to develop and evaluate potential interventions to mitigate these conditions. Studies may be conducted by scientists in spacecraft or aircraft, or on the ground in laboratories or specialized facilities that can simulate some aspects of the space environment.

1.1.2 The APRB is a mechanism for communication and discussion among the Agency's animal care community regarding planning, activities, processes, and methodologies, associated with the care and use of animals in scientific research funded or sponsored by NASA or conducted in NASA facilities, aircraft, or spacecraft, including commercial facilities, aircraft, and spacecraft that are funded or sponsored by NASA or use NASA resources.

1.1.3 An IACUC is a committee that oversees and evaluates research involving animals to ensure their humane care and use. There are four NASA IACUCs. Three of these IACUCs address ground and aircraft research: the Johnson Space Center IACUC, Ames Research Center IACUC, and Kennedy Space Center IACUC. The fourth IACUC, the Flight IACUC, established through NASA Headquarters, addresses spaceflight and aircraft research. In addition, NASA contracts with institutions to perform pre-launch services, ground control activities, and post-flight services. The NASA IACUCs responsible for addressing ground research and these institutional IACUCs are collectively known as Ground IACUCs.

1.2 Policy Implementation

1.2.1 NPD 8910.1 and this NPR combined with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines, Animal Welfare Act of 1966, 7 U.S.C. § 2131 et seq; Animal Welfare, 9 CFR, Ch. I, Subch. A, Pts. 1-3, Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), US Department of Health and Human Services, Revised 2015; The Guide; U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, 85 FR 12059, (May 20, 1985); Policy and Guidelines for the Use and Care of Animals in Space-borne Research, COSPAR Information Bulletin: Space Research Today, Number 169, August 2007; International Guiding Principles for Biomedical Research Involving Animals, Council for International Organization of Medical Sciences and International Council for Laboratory Animal Science, December 2012, form NASA's policy for research involving animals. NASA policy, NPD 8910.1 and this NPR, applies to all research involving animals conducted or supported by NASA or using NASA resources.

1.2.2 NPD 8910.1 details the policy and responsibilities of Headquarters and the Centers, while this NPR defines procedures and specific NASA requirements levied in addition to the applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines. The APRB

and IACUCs implement these requirements through charters and/or other Center documentation.

1.3 NASA Principles for the Ethical Care and Use of Animals Implementation

1.3.1 The NASA Principles for the Ethical Care and Use of Animals recognize that 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.

1.3.2 The bioethical principles of respect for life, societal benefit, and nonmaleficence provide a framework to consider the ethical challenges that arise from research using animals and they will be used by NASA to explicitly evaluate research protocols. The ethical review will be conducted at the time of IACUC review.

1.4 Memorandum of Understanding (MOU) Between Office of Laboratory Animal Welfare, Office of Extramural Research, Office of the Director, National Institutes of Health and National Aeronautics and Space Administration

NASA has entered into an agreement with OLAW to obtain services in general and comprehensive administration and coordination of the PHS Policy. These services will assist the IACUCs and Institutional Officials (IO) with negotiating Animal Welfare Assurances, evaluating allegations of noncompliance, advising the implementation and interpretation of the PHS Policy, authorizing waivers to the PHS Policy and conducting site visits.

Chapter 2. Responsibilities

2.1 CHMO, Flight IACUC IO, and Office of Research Assurance

2.1.1 The CHMO has appointed the Director, Medical Policy and Ethics as the Flight IACUC IO.

2.1.2 The CHMO is responsible for appointing the Chief Veterinary Officer (CVO).

2.1.3 The Flight IACUC IO, in addition to responsibilities detailed in Section 2.6, is responsible for:

- a. Appointing the Flight Attending Veterinarian (AV).
- b. Establishing the Flight IACUC, with charter.
- c. Coordinating appointments of Center personnel to the Flight IACUC with concurrence of the respective Center Director.

2.1.4 The Office of Research Assurance ensures compliance with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines. The Office of Research Assurance is responsible for:

- a. Ensuring the Administrator, appropriate Mission Directorate Associate Administrators, Office of Safety and Mission Assurance, NASA General Counsel, and NASA Inspector General (when appropriate) are well-informed, through official channels, of significant actions, problems, or other matters of substance related to the exercise of this authority.
- b. Assessing each IACUC's semi-annual Program Review and Facilities Inspection report and OLAW, AAALAC, and USDA reports for all facilities operated or leased by NASA, and APRB reports and submitting a summary to the IO.
- c. Establishing and maintaining mechanisms to obtain timely information and notify the CVO, IACUCs, Center Directors, IOs, and Program Managers of reports of unanticipated adverse events or noncompliance with any applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines received from non-NASA institutions where animal research is supported by NASA.
- d. Reviewing all corrective actions required by IACUCs, IOs, and CVO to determine if further actions are warranted and/or, at their discretion, initiating investigations of unanticipated adverse events or noncompliance with NASA policy.

2.2 Chief Veterinary Officer

2.2.1 The CVO is responsible for:

- a. Coordinating the Agency's veterinary and animal care and use activities.
- b. Advising the Office of Research Assurance, on any aspect of the Agency's and its international colleague's animal care and use programs.
- c. Designating a NASA representative for the COSPAR Panel on the Use and Care of Animals in

Space-borne Research.

d. Serving as Chair of the APRB.

e. Assessing each IACUC's semi-annual Program Review and Facilities Inspection report and OLAW, AAALAC, and USDA reports for all facilities operated or leased by NASA.

f. Ensuring an appropriate review is conducted for any NASA animal activity believed to be noncompliant with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines, and approved protocols.

g. Reviewing all corrective actions required by IACUCs and IOs, and recommending further actions, if warranted, and/or investigations of unanticipated adverse events or noncompliance with NASA policy to the Office of Research Assurance.

h. Representing NASA in the external laboratory animal science community and associations, such as the American Association for Laboratory Animal Science, the American Society of Laboratory Animal Practitioners, the International Council for Laboratory Animal Science, and COSPAR.

i. Informing participating international entities and individuals regarding technical requirements in accordance with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines, and veterinary standards, including information regarding the requirements and constraints for animal research flight activities.

j. Reviewing and concurring with newly developed hardware, modified hardware, and established hardware to ensure they meet the health, husbandry, and housing requirements of the research animal prior to its use in the flight program.

k. Assessing the Vertebrate Animals and Higher Order Cephalopods Section (VACS) as part of the VACS Review process to discuss and advise on NASA specific requirements and unique aspects of animal care and use in a microgravity environment.

l. Maintaining the Memorandum of Understanding (MOU) Between Office of Laboratory Animal Welfare, Office of Extramural Research, Office of the Director, National Institutes of Health, and National Aeronautics and Space Administration

2.3 Attending Veterinarians

2.3.1 The AVs are responsible for:

a. Directing the animal care and use program to ensure the health and wellbeing of all animals used in ground and inflight research.

b. Serving as a designated member of the IACUC.

c. Consulting with PIs and Payload Developers during the planning stages of any proposed research activity with the potential for pain and distress.

d. Working with the respective IACUC Chair and IO to seek and maintain AAALAC accreditation and PHS Assurance and file the required USDA annual report.

2.3.2 The Flight AV is also responsible for:

- a. The care of the research animals during all flight animal research activities.
- b. Designating a Duty Veterinarian who has full authority in the absence of the Flight AV.
- c. Advising PIs and Payload Developers on technical feasibility regarding the ability to complete proposed flight research to ensure animal welfare and achievement of scientific objectives.

2.4 Institutional Animal Care and Use Committee Chairs

2.4.1 The NASA IACUC operates in accordance with Federal regulations, laws, and guidelines. The NASA IACUC Chair is responsible for overseeing the development, coordination, and implementation of research protocol reviews, program reviews, and facility inspections. In addition, the IACUC Chairs are responsible for:

- a. Ensuring availability of all IACUC minutes to the IO and CVO.
- b. Developing and submitting each IACUC's semi-annual Program Review and Facility Inspection report to their IO and the CVO.
- c. When applicable and in consultation with the IO and AV, submitting to the OLAW, the PHS Animal Welfare Assurance; committing the Center to the requirements of the PHS Policy in all Center activities involving animal use; and providing the approved assurance, the OLAW letter of approval, and any correspondence with OLAW to the CVO.
- d. When applicable and in consultation with the IO and AV, seeking and maintaining AAALAC accreditation, approving the annual AAALAC reports and providing the AAALAC accreditation letter, the annual reports, and any correspondence with AAALAC to the CVO.
- e. When applicable and in consultation with the IO and AV, ensuring the submission of the USDA Annual Report of the Research Facility, and providing the report, and any correspondence with USDA, to the CVO.

2.5 Center Directors

2.5.1 The Center Directors are responsible for:

- a. Serving as the Center's IO. The IO's duties may be delegated, in writing, to a senior level official with administrative and operational authority, however, Center Directors retain the ultimate responsibility for ensuring compliance with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines. See Section 2.6 for specific IO responsibilities.
- b. Establishing a Center IACUC, with charter.
- c. Ensuring Center personnel conducting animal research at any another research location are doing so under IACUC approved protocols.
- d. Concurring on appointments of their Center's personnel to the Flight IACUC.

2.6 Institutional Officials

2.6.1 The IOs are responsible for:

- a. Establishing, supporting, and overseeing the functions of their IACUC consistent with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines.
- b. Committing their organization to compliance with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines in all center activities involving animal care and use.
- c. Ensuring adequate funding for their animal care and use program, AAALAC accreditation, IACUC functions, IACUC member training, and travel of APRB members to the annual meeting.
- e. Appointing IACUC members, including the chair, with concurrence of the respective Center Director.
- f. In consultation with the corresponding IACUC and the Office of Research Assurance, determining, administering, and reporting to the appropriate federal authorities, corrective actions associated with suspensions of animal activities, serious or continuing noncompliance or serious deviation from NASA policy or applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines.
- g. In coordination with the IACUCs, submitting required reports to the OLAW, AAALAC and USDA.

2.7 Program Personnel

2.7.1 The Program Managers who fund or sponsor animal research are responsible for:

- a. Ensuring compliance with NASA Policy through verification of flight or ground IACUC protocol approval and completion of the VACS Review or other peer review.
- b. Ensuring IACUC approval at the institution receiving NASA funding prior to initiating animal research.
- c. Ensuring peer review and technical implementation feasibility assessments have been performed for planned flight experiments using animals, and the AV has been consulted on the assessment prior to selection of an experiment for flight.
- d. Notifying the CVO of any reports of noncompliance or unanticipated adverse events with respect to their funded or sponsored animal research.
- e. Ensuring this policy is incorporated into the governing contracts, grants, or agreements for activities involving the use of animals.
- f. Ensuring all research performance sites hold a PHS Animal Welfare Assurance.

2.7.2 Payload Developers, via their funding mechanism, are responsible for:

- a. Communicating Flight AV recommendations and directions to the onboard crew.
- b. Obtaining concurrence from the Flight IACUC, Flight AV, and CVO for all Flight Rules, Operational Interface Procedures (OIP), and other operational documentation that have the potential to impact the health and welfare of animals.
- c. Obtaining concurrence from the AV and IACUC overseeing the research for all science

requirements documents that may impact animal health and welfare.

d. Obtaining concurrence from the AV for housing, facilities, and/or experiment unique equipment designs or changes prior to submittal to the IACUC for approval.

e. Informing the Flight AV of flight emergencies that may result in delayed or no interventions for animal welfare.

2.8 Principal Investigators

2.8.1 PIs, including civil service and non-civil service (i.e., contractors and grantees), via their governing contracts, grants and agreements, are responsible for:

a. Familiarizing themselves and complying with relevant Agency and Center/institution policies and procedures for the conduct of animal research.

b. Consulting with the relevant attending veterinarian during the planning phase of any proposed research activity with the potential for pain and distress.

c. Describing proposed use of animals in grant applications.

d. Obtaining IACUC approval prior to using animals and prior to implementing significant changes to the protocol.

e. Ensuring research is conducted according to the IACUC approved protocol.

f. Complying with institutional policies and procedures.

g. Addressing significant changes to the use of animals in progress reports.

h. Addressing changes in the care and use of animals that may be a potential change in scope, including changes in performance site.

i. Reporting to the IACUC any noncompliance or unanticipated adverse events that occur during the conduct of their research and how these issues have been addressed.

j. Implement corrective actions required by the IACUC to mitigate a noncompliance or unanticipated adverse events.

Chapter 3. Criteria for IACUC Approval

3.1 Introduction

NASA makes every effort to comply with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines. However, due to the nature of spaceflight, it may not be possible to meet some requirements. In these cases, the IACUC reviews the justification for the “departure” from the requirement, and if satisfactory, approves the departure and reports it to the IO via the semi-annual Program Review and Facility Inspection report as allowed by the 9 CFR Ch. I, Subch. A, Pts. 1-3 and the PHS Policy. This chapter addresses spaceflight unique IACUC criteria.

3.2 Criteria for Research Sponsored or Funded by NASA, Conducted in NASA Facilities/Spacecraft, or Using NASA Resources

3.2.1 All research, to the greatest extent possible, will comply with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines, to ensure animal welfare. When not possible, the IACUC will review the specific scientific justification for the departure from the requirement, and if satisfactory, may approve the departure.

3.2.2 All research will be conducted in accordance with Section 4.6, Photo Documentation Policy, to ensure animal health and welfare.

3.2.3 Inflight Research, to include ground controls, will be conducted in accordance with DOC XXX, NASA Standard Housing Guidelines for ISS, to ensure animal welfare unless a scientifically justified departure from the requirements is approved by the Flight IACUC.

3.2.4 Inflight Research will be subject to a bioethical review as part of the Flight IACUC review.

3.3 Criteria for Research Sponsored or Funded by International Partners, Conducted at NASA Facilities/Spacecraft, or Using NASA Resources

Note: The term International Partner is being used in a broad sense, A non-U.S. entity (government, non-government, academic, commercial, etc) with whom NASA collaborates as per NPD 1050.7, vs the more strict definition used for the International Space Station, NASA’s partners; CSA, ESA, JAXA, and Roscosmos.

3.3.1 Research will follow requirements stated in this NPR.

3.3.2 In compliance with NPD 1050.7, Authority to Enter into Partnership Agreements, research that is sponsored or funded by an International Partner and that is conducted at a NASA facility or on NASA spacecraft or using NASA resources, will be documented and affirmed in a legally binding agreement between NASA and the International Partner, which is negotiated, drafted, and finalized by the Office of International and Interagency Relations (OIIR).

3.4 Criteria for Research Sponsored or Funded by NASA, Conducted in International Partner Facilities/Spacecraft, or Using International Partner Resources

3.4.1 Research will, to the greatest extent possible, follow requirements stated in this policy. As this research is conducted internationally, the laws and regulations of the country where the activities occur will also be followed. The minimum requirement should be the International Guiding Principles for Biomedical Research Involving Animals.

3.4.2 Unless departures have been scientifically justified and approved by the IACUC or equivalent oversight committee of the Agency responsible for the funded PI, NASA requires compliance with The Guide.

Note: Not all International Partners have an IACUC per se. For Example, Russia has a bioethical committee that reviews human and animal research which serves the same function as an IRB and IACUC.

3.4.3 In compliance with NPD 1050.7, research that is sponsored or funded by NASA and that is conducted at an International Partner facility or on International Partner spacecraft or using International Partner resources, will be documented and affirmed in a legally binding agreement between NASA and the International Partner, which is negotiated, drafted, and finalized by the OIIR.

Chapter 4. NASA Specific Requirements

4.1 Introduction

NASA's mission to explore, use, and enable the development of space for human enterprise is unique. NASA's program of animal care and use complies with all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines. Some aspects of NASA's program of animal care and use implementation are specific to spaceflight, and, therefore, justified departures must be reviewed and approved by the appropriate IACUC.

4.2 Veterinary Care, Compliance, and Response

4.2.1 Veterinary responsibilities and processes are defined in Federal, state, and local animal welfare laws and regulations, policies, and guidelines. NASA has some unique aspects that require additional definition of responsibilities and processes.

4.2.2 In addition to all applicable Federal, state, and local animal welfare laws and regulations, policies, and guidelines for veterinary care, compliance, and response the Flight AV, or in their absence, the designated Duty Veterinarian shall:

a. Coordinate veterinary support during flight.

Note: The Flight AV interfaces with the Center and institution AVs where work is being conducted pre-flight and interfaces with Center and institution AVs until animals are returned to the host institution or COR post-flight for data collection.

b. Assess and respond to all animal care and use issues arising inflight.

c. Be the sole point of contact for the Mission Control Center Flight Director, Payload Developer, Payload Investigator and others on the science team, and Payload Operations and Integration Center Payload Operations Directors for all inflight animal care and welfare issues.

d. Ensure the proper storage, use, and disposal of controlled substances inflight.

e. With sole authority, intervene in and/or terminate any animal activity to ensure animal health and welfare.

f. With sole authority, direct unplanned euthanasia of animals during inflight animal research. The CVO will be notified of an unplanned euthanasia decision.

4.3 IACUC Responsibilities and Processes

4.3.1 IACUC responsibilities and processes are defined in Federal, state, and local animal welfare laws and regulations, policies, and guidelines. NASA has unique aspects that require additional definition of responsibilities and processes.

4.3.2 The Flight IACUC and Ground IACUCs both have cognizance of the entire research study and work closely together to ensure all activities are reviewed. During flight research, the Ground

IACUC and Flight IACUC will be in close coordination as the flight animals will be in space and the controls at the ground facility. The authority to act will reside with the IACUC in possession of the research animals.

4.3.2.1 The Ground IACUCs shall oversee all activities occurring at their institution and be authorized to act in the event of an adverse event, noncompliance, veterinary intervention or significant modification, until handover to another ground IACUC or, with respect to flight animals, handover at the launch pad when the transport facility is integrated into the vehicle.

4.3.2.2 The Flight IACUC shall oversee all activities occurring on the launch pad, during launch, on-orbit operations, through euthanasia or return, including health check and/or handover at the receiving institution, and be authorized to act in the event of an adverse event, noncompliance, veterinary intervention or significant modification.

4.3.2.3 In the event of an adverse event, noncompliance, veterinary intervention or significant modification, the authorized IACUC shall inform any other IACUC that reviewed and approved the research proposal. 4.3.3 Protocols for animal activities may need to be modified inflight as research design and procedures are refined to satisfy operational constraints or experimental variation.

4.3.3.1 When this occurs, the Flight IACUC, by Full Committee Review, Designated Member Review or Veterinary Verification Consultation, shall review and approve significant modifications to animal care and use activity prior to implementation.

4.3.3.2 Likewise, if corresponding modifications to ground activities are necessary, the responsible Ground IACUC and/or the Flight IACUC shall review and approve significant modifications to animal care and use activity prior to implementation.

4.3.4 The Flight IACUC cannot conduct in person inspections of animal facilities in space, however, the Flight IACUC shall, to the greatest extent possible, conduct the required inspections of animal facilities in space.

4.3.5 For Research Sponsored or Funded by NASA, Conducted in International Partner Facilities/Spacecraft, or Using International Partner Resources:

a. The NASA sponsored or funded PIs shall obtain a letter, prior to award initiation, from the International Partner IACUC or equivalent oversight body stating it has reviewed and approved the research to be conducted using International Partner spacecraft and/or resources and provide this letter to the CVO and, in the case of flight research, also the Flight IACUC.

b. The PI shall also obtain Flight IACUC approval for flight research

c. The CVO shall review the letter to ensure NASA's interests for ground research.

4.4 Communication of Animal Health and Welfare

4.4.1 The health and welfare of research animals used during spaceflight are of the greatest importance to NASA for both ethical and scientific reasons. Health assessments can be conducted by trained and qualified individuals other than a veterinarian. Therefore, a mechanism for direct and frequent communication will be established to ensure timely and accurate information is conveyed to the responsible veterinarian concerning issues associated with animal health, behavior, and wellbeing, and that appropriate treatment or euthanasia is directed and administered.

4.4.2 Mission Control Center personnel shall provide realtime voice and video communication links for the Flight AV and crew to communicate to ensure animal health and welfare. Communication can be requested by either the Flight Attending Veterinarian or the crew.

4.4.3 Crewmembers may request a voice and/or video consultation with the Flight AV to discuss animal health and welfare should unexpected or critical conditions exist which warrant immediate action.

4.4.4 The Flight AV shall communicate, via the Payload Developer, or directly, when necessary, with the crew caring for research animals regarding the animals' condition. The Flight AV may also consult with the Project Scientist, Project Manager, and PI whose research may be affected regarding the circumstances and impact of the decision.

4.5 Vertebrate Animals and Higher Order Cephalopods Section Review

4.5.1 For each grant application or contract proposal that uses animals in research, NASA requires that a VACS be submitted and reviewed. The VACS provides a justification for using animals and of the species to be used, describes animal procedures and the minimization of pain and distress, and indicates the method of euthanasia.

4.5.2 A peer review panel shall conduct a VACS Review in accordance with the process described in the OCHMO-551, Vertebrate Animals and Higher Order Cephalopods Review Process.

4.5.3 The Program Manager shall inform the CVO of the details and results of the VACS Review for proposals selected for funding.

4.5.4 When proposals have not completed a peer review process, lack a VACS, or there is insufficient information for an IACUC to determine if a research design is sound, the IACUC may:

- a. Request the PI complete the VACS and submit it with their IACUC application.
- b. Identify outside consultants to review the scientific design proposed.

4.6 Standard Housing Guidelines for ISS

4.6.1 Conducting animal research in space requires specialized housing that can support animal welfare in the unique environment of space (e.g., microgravity).

4.6.2 Federal, state, and local animal welfare laws and regulations, policies, and guidelines require that the AV oversee the program of animal care, including housing conditions.

4.6.3 The Flight AV shall develop OCHMO-550, Standard Housing Guidelines for the International Space Station, for the animal enclosure module for research rodents that complies, to the greatest extent possible, with the 9 CFR Ch. I, Subch. A, Pts. 1-3, the PHS Policy, and The Guide for research animals.

4.6.4 PIs sponsored or funded by NASA, conducting research in NASA funded or sponsored facilities or using NASA resources shall:

- a. Comply with the OCHMO-550 to the greatest extent possible.

b. Request scientifically justified departures from the OCHMO-550 only when necessary.

4.6.5 The Flight IACUC shall review and approve departures from OCHMO-550, when sufficiently justified. Should the Flight IACUC not approve a departure, the PI and Payload Developer, may provide additional scientific justification and request, through the IO, the Flight IACUC reconsider their decision.

4.7 Photo Documentation Policy

4.7.1 NASA reviews and approves the collection and distribution of photo documentation of animal research at all of its facilities, including spacecraft and aircraft, to assure the collection is justified for scientific or operational purposes and supports animal health and welfare.

4.7.2 Photo documentation involving research animals related to the requestor's specific function and responsibility may be obtained by authorized individuals for purposes of scientific data collection, operational verification of hardware or procedures, education, training, public outreach purposes, and animal welfare.

4.7.3 In addition to SSP 50521, Return, Processing, Distribution and Archiving of Imagery Products from the International Space Station, the following applies specifically to animal research photo/video.

a. Approval to collect photo documentation.

(1) PIs shall obtain approval from the IACUC responsible for overseeing the research prior to collection of photo documentation by submitting requests using the Photo Documentation of Animal Activities Form that describes the photo documentation to be collected, the intended use of the photo documentation, and the potential release of the images.

(2) The IACUC and CVO may, if necessary, place conditions on the collection of photo documentation.

(3) PIs, Payload Developers, and members of their teams

(a) Shall not collect unofficial or personal photo documentation.

(b) Shall use NASA assets when collecting photo documentation.

b. Archival photo documentation.

Photo documentation from NASA missions will be archived in the Life Sciences Data Archive (LSDA) website, <https://lsda.jsc.nasa.gov>.

c Release of photo documentation.

(1) Principal Investigators shall request new uses of photo documentation not previously approved by the IACUC by submitting requests using the Photo Documentation of Animal Activities form.

(2) Requests to use photo documentation archived in the LSDA will comply with the LSDA process.

(3) The IACUC and CVO may require, as a condition of approval, an opportunity to review, prior to their release, images that will be used in publications or presentations or that will be provided to the media.

(4) Some intended uses of images (e.g., for media reports) may require additional approvals, but in no case can images be used that have not been approved for release by the Rodent Research Data Release Board and CVO, and in some situations with the approval of the Public Affairs Office.

(5) Release of unapproved images is prohibited.

4.8 Biospecimen Sharing Program

4.8.1 A Biospecimen Sharing Program (BSP) provides an opportunity for tissues not utilized by the PI from a primary investigation to be collected and made available to other investigators. In addition to increasing the scientific return from animals used in the primary study, tissue sharing may enable other scientific questions to be answered without using additional animals, or may help investigators to refine their studies and animal number estimates for future studies, thus meeting NASA's goals to reduce, replace, and refine the use of animals in research. A BSP is particularly valuable when research is conducted in novel environments and/or facilities (e.g., spaceflight, radiation, environmental chambers, and centrifuges).

4.8.2 Program Managers may establish BSPs for funded research.

4.8.3 PIs shall comply with Program BSP requirements.

4.9 Flight Rules and Operational Documentation

4.9.1 Flight rules and operational documentation are developed for space missions to establish rules and procedures on how specific nominal and off-nominal conditions will be addressed in order to preserve the success of the mission and experiment as well as ensure the health and welfare of the animals being used.

4.9.2 Payload Developers shall consult with the CVO during the development, design and modification of flight rules, OIPs, and other operational documentation that have the potential to impact the health and welfare of animals on spacecraft.

4.9.3 Payload Developers shall obtain approval from the Flight IACUC, Flight AV, and CVO for all Flight Rules, OIPs, and other operational documentation that have the potential to impact the health and welfare of animals on spacecraft prior to submitting to the Payload Operations Integration personnel.

4.9.4 Payload Developers shall coordinate with the program science sponsor during the development, design and modification of flight rules, OIPs, and other operational documentation that have the potential to impact the animal research science return.

4.10 Science Requirements

4.10.1 Conducting research in space, and in some specialized ground facilities, requires principal investigators, project scientists, payload developers, and/or facility personnel to work together to successfully plan and implement research in unique and constrained environments that are typically very different than standard laboratory conditions. The planning process results in numerous products designed to assure appropriate resources are in place to complete the research, verify

animal welfare and safety standards will be maintained, and document how the PI's scientific objectives will be achieved, among others.

4.10.2 PIs and Payload Developers shall consult with and obtain concurrence from the Attending Veterinarian, who will notify the CVO, and IACUC overseeing the research to be conducted on any products (e.g., science requirement documents, flight rules, launch commit criteria, operations interface procedures, facility plans, and implementation schedules.) that may impact animal health and welfare.

4.10.3 When signing and submitting the IACUC protocol, the PI is ensuring that they understand the details of the research design and that the scientific objectives are achievable.

4.11 Engineering Requirements

4.11.1 Developing hardware that can adequately perform through the rigors of launch and landing and in the space environment requires compliance with NASA engineering standards. Hardware being developed for use with animals requires additional consideration to assure animal care and welfare standards are met and maintained.

4.11.2 PHS and NASA policy require that the AV have the authority to implement the veterinary care program and to oversee the adequacy of all other aspects of animal care and use (e.g., animal husbandry, nutrition, sanitation practices, zoonosis control, and hazard containment).

4.11.3 Payload Developers who develop housing, facilities and/or experiment unique equipment that will be used for animal care and use (including specialized diets) shall consult with the appropriate AV:

- a. Early in the development process to ensure animal welfare requirements and standards are met.
- b. Prior to implementing changes to existing hardware (housing, facilities, and experiment unique equipment) and specialized diets.
- c. For concurrence prior to submittal of plans to the IACUC for functional evaluation.

4.11.4 The AV shall keep the IACUC and CVO informed of development activities.

4.11.5 The AV and CVO shall approve changes to existing hardware or specialized diets before any use of animals is permitted in new or modified hardware.

4.11.6 Program Managers shall inform the CVO of pending hardware development.

4.12 Noncompliance, Adverse Events, and Corrective Actions

4.12.1 Federal, state, and local animal welfare laws and regulations, policies, and guidelines defines responsibilities and processes for noncompliance, adverse events, and corrective actions. In addition, OLAW and the Office of Research Assurance, per the NASA/OLAW MOU, will evaluate allegations of noncompliance with the PHS Policy in conjunction with the IACUC and IO. Spaceflight is unique in that the PI is likely unaware of unanticipated adverse events or noncompliance occurring inflight until notified by NASA. All actions will be in compliance with Federal, state, and local animal welfare laws and regulations, policies, and guidelines.

4.12.2 The AV, shall inform the CVO, IACUC and PI of any noncompliance or unanticipated adverse events.

Note: Research misconduct is governed by NPR 1080.1, Requirements for the conduct of NASA Research and Technology.

4.12.3 The authorized IACUC shall notify the other IACUCs that reviewed and approved the research proposal, IO, CVO, the Office of Research Assurance, and OLAW of noncompliance and any immediate actions taken, including suspension of the activity.

4.13 Emergency/Disaster Plan

4.13.1 Federal, state, and local animal welfare laws and regulations, policies, and guidelines require an emergency disaster plan that address possible situations that could be encountered. The Guide requires animal facilities to have a plan to address disasters and emergencies in animal facilities including failures of critical systems or any event that jeopardizes or negatively impacts animal care and use.

4.13.2 Inflight spacecraft-based research activities will be suspended during life threatening emergencies; preservation of human life takes precedent over animal care during life threatening emergency operations. In flight disasters may result in significantly delayed or no interventions for animal welfare.

4.13.3 Payload Developers shall inform the Flight AV, who will notify the CVO of life-threatening emergencies that impact animal care and use activities. If time permits plans for emergency euthanasia of all research animals on orbit will be initiated.

4.13.4 Payload Developers shall consult with the Flight AV, or in their absence, the Duty Veterinarian, during an emergency that effects on-orbit animals to develop a plan concerning animal health and welfare. Such plans will not increase risk to the crew.

4.14 Records Management

4.14.1 In accordance with NPD 1440.6, NASA Records Management, Animal Care and Use records retention requirements are documented in NRRS 1441.1, NASA Records Retention Schedules.

4.14.2 All personnel producing animal care and use records shall comply with NPD 1440.6, NASA Records Management and NRRS 1441.1, NASA Records Retention Schedules, to ensure proper maintenance, safeguarding, and disposition of animal care and use records.

Appendix A. Definitions

Animal. Any live or dead vertebrate or higher order cephalopod that is being used or intended for use in research, teaching, testing, or experimentation or hardware development. Wildlife research and agricultural animals used in biomedical research are included.

Attending Veterinarian (AV). A veterinarian who has training or experience in laboratory animal science and medicine, or in the care of the species being used, and has authority to ensure adequate veterinary care is provided and to oversee the adequacy of other aspects of the animal care and use program. An Attending Veterinarian is a voting member on each IACUC. The Flight AV is the AV responsible for all activities involving animals in spaceflight and is a voting member of the Flight IACUC.

Chief Veterinary Officer (CVO). A veterinarian appointed by the CHMO to oversee and coordinate veterinary and animal care and use activities and ensure animal health and welfare on an Agency-wide basis. The CVO also serves as Chairperson of the APRB.

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

Flight IACUC. The NASA IACUC responsible for spaceflight and aircraft research.

Ground IACUC. A NASA or NASA contracted IACUC responsible for ground and aircraft research.

International Partner. A non-U.S. entity (government, non-government, academic, commercial, etc) with whom NASA collaborates as per NPD 1050.7.

Payload Developer. A person, assigned by the program manager, to assist the PI in developing flight specific hardware and operation of the research onboard NASA's space vehicle.

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

Program Manager. The person designated by NASA Headquarters to manage each program in which NASA has a research or payload interest.

Office of Research Assurance. OCHMO office responsible for coordinating and centralizing responsibilities, education, compliance, policy development, and oversight for protection of all research involving human or animal subjects.

Appendix B. Acronyms

APRB	Animal Policy Review Board
AV	Attending Veterinarian
BSP	Biospecimen Sharing Program
CHMO	Chief Health and Medical Officer
COSPAR	Committee on Space Research
CVO	Chief Veterinary Officer
IACUC	Institutional Animal Care and Use Committee
IO	Institutional Officer
LSDA	Life Sciences Data Archive
MOU	Memorandum of Understanding
OLAW	Office of Laboratory Animal Welfare
PHS	Public Health Service
PI	Principal Investigator
USDA	United States Department of Agriculture
VACS	Vertebrate Animals and Higher Order Cephalopods Section

Appendix C. NASA Principals for the Ethical Care and Use of Animals

C.1 “Introduction - 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. 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 Federal, state and local animal welfare laws and regulations, policies, and guidelines 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.”

C.2 “Basic Principles - 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. 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 non-maleficence.”

C.3 “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.”

C.4 “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.”

C.5 “Non-maleficence - 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.”