

National Aeronautics and Space Admin.

§ 1232.103

1232.106 Management authority and responsibility.

1232.107 Sanctions.

AUTHORITY: 42 U.S.C. Sec. 2451; Pub. L. 89-544, as amended; 7 U.S.C. Sec. 2131; 39 U.S.C. Sec. 3001; 9 CFR subchapter A parts 1, 2, 3, and 4; and Pub. L. 99-158, Sec. 495.

SOURCE: 54 FR 35870, Aug. 30, 1989, unless otherwise noted.

§ 1232.100 Scope.

This rule establishes the policy, implementation procedures, and management authority and responsibility for the care and use of vertebrate animals (hereinafter referred to as "animal subjects") in the conduct of NASA activities.

§ 1232.101 Applicability.

This rule applies to NASA Headquarters and NASA field installations and will be followed in all activities using animal subjects that are supported by NASA, conducted in NASA facilities, aircraft, or spacecraft, or which involve NASA to any degree. All activities using animal subjects conducted under a contract, grant, cooperative agreement, memorandum of understanding, or joint endeavor agreement entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity are included within the scope of this rule.

§ 1232.102 Policy.

(a) It is NASA policy to require its laboratories and the institutions performing NASA-supported activities using animal subjects to comply with the Animal Welfare Act of 1966 (Pub. L. 89-544), as amended (Pub. L. 91-579, Pub. L. 94-279, and Pub. L. 99-198), 7 U.S.C. 2131 et seq., and 39 U.S.C. 3001, and with the regulations promulgated thereunder by the Secretary of Agriculture (9 CFR subchapter A parts 1, 2, 3, and 4) pertaining to the care, handling, and treatment of animal subjects held or used for research, testing, teaching, or other activities supported by the Federal government. Investigators shall follow the guidelines described in the National Institutes of Health (NIH) Publication No. 85-23 (Rev. 1985), "Guide for the Care and Use of Laboratory Animals" (the Guide) or

subsequent revisions. Attention is called to the U.S. Government "Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" on pp. 81-83 of the Guide. In order to implement these guidelines and principles, investigators will comply with the revised Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (hereinafter referred to as PHS Policy) effective November 1, 1986.¹

(b) This rule authorizes NASA to have the same authority for NASA-supported programs as that delegated to PHS by the PHS Policy, including the functions and responsibilities of the Animal Care and Use Committees (ACUC's).

(c) All research supported by NASA that involves activities using animal subjects shall be conducted under protocols that conform to this rule and that are reviewed and approved as prescribed in this rule.

§ 1232.103 Definitions.

The following definitions of terms comply with the PHS Policy and apply to the conduct of all NASA activities related to the care and use of animal subjects.

(a) *Activity* includes research, testing of hardware for animal use, flight experimentation, and any other tasks involving the use of animal subjects.

(b) *Animal* is any live vertebrate animal.

(c) *Animal Care and Use Committee* (ACUC) is the committee established at each institution and NASA field installation involved in research with animal subjects. It is responsible for evaluating the care and use of animal subjects at the facility and for ensuring that the care and use of animal subjects at the facility is in compliance with this rule and PHS Policy.

(d) *Authorized NASA Official* is the Director, Life Sciences Division, NASA Headquarters, or designee, who is the NASA Administrator's representative

¹Available from the Office of Protection from Research Risks (OPRR), National Institutes of Health, 9000 Rockville Pike, Bldg. 31, Room 5B59, Bethesda, MD 20892, Telephone 301-496-7005.

and is responsible for all NASA activities involving animal subjects. This individual is responsible for implementation of the provisions of this rule and for ensuring that agency programs involving animal subjects comply fully with all applicable laws, regulations, and guidelines.

(e) *Field Installation Director* is the Director of a NASA Field Installation, or designee, who is the institutional official responsible for the care and use of animal subjects in research conducted at that field installation and for ensuring compliance with this rule at that field installation.

(f) *Investigator* is any person who uses or proposes to use live animal subjects in NASA-supported activities, e.g., receives funds, salaries, or support under a grant, award, agreement, contract, or direct employment by NASA, or the use of any NASA facilities, aircraft, or spacecraft for the purpose of carrying out research, tests, or experiments using animal subjects.

(g) *PHS Assurance* is a document prepared by an awardee institution assuring its compliance with PHS Policy.

(h) *Research of Flight Program Manager* is the NASA Headquarters manager of each program in which NASA has a manifest interest.

(i) *Supported* pertains to activities either funded in part or in whole by NASA or an approved activity that is not funded by NASA but that utilizes NASA facilities, including spacecraft and aircraft.

(j) *Veterinarian* is the NASA attending veterinarian, a person who has 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 experience in the care and management of the species being attended, and who has direct or delegated authority and responsibility for activities involving animal subjects at the NASA field installation.

§ 1232.104 Implementation procedures by non-NASA institutions.

(a) *Proposal Information.* No animal subjects may be utilized unless a pro-

posal justifying and describing their use is submitted to NASA for approval. The required proposal information is outlined in the PHS Policy (IV.D.1.a.-e.).

(b) *Proposal Approval by the Institutional ACUC.* Before a proposal for research involving the use of animal subjects will be considered for NASA support, the NASA Headquarters Research or Flight Program Manager must receive a statement that the research has been reviewed in accordance with the PHS Policy (IV.C.) and approved by the appropriate ACUC at the participating institution.

(c) *Proposal Approval for Flight Experiments.* In addition to the institution's ACUC review, activities involving animal subjects to be flown on NASA spacecraft will be subject to review and approval by the Ames Research Center (ARC) ACUC. The ARC ACUC will submit each evaluation report to the ARC Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters. Animal activities to be flown onboard NASA manned spacecraft may also be subject to review by the Human Research Policy and Procedures Committee (HRPPC) at the Johnson Space Center (JSC). Animal activities utilizing the facilities of any NASA field installation are also subject to approval of that field installation's ACUC (§1232.105(d)).

(d) *Institutions with PHS Assurance on File.* The institution, by an approved or provisionally acceptable Assurance on file at the NIH Office for Protection from Research Risks (OPRR), Department of Health and Human Services (HHS), assures NASA that it will comply with the PHS Policy. The Assurance file number must be included in the research proposal submitted to NASA.

(e) Institutions with no PHS Assurance on File. Proposals from institutions without an approved Assurance on file with the NIH OPRR will first be peer-reviewed for scientific merit. If the proposed research is deemed worthy of support, NASA will arrange for a special Assurance to be negotiated by the Director, Life Sciences Division, NASA Headquarters. The arrangements for a special Assurance review by NIH