

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

should be undertaken in consultation with the NASA representative to the Interagency Research Animal Committee (IRAC) and will be handled on a case-by-case basis.

(f) Foreign institutions must comply with the PHS Policy (see Section II Of PHS Policy) and this rule before being supported by NASA for any activities involving animal subjects.

§ 1232.105 Implementation procedures by NASA field installations.

(a) *Proposal Information.* The information required for proposals involving the use of animal subjects is identical to that described in §1232.104(a).

(b) *Proposal Approval by the NASA 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 PHS Policy (IV.C.) and approved by the ACUC at the appropriate field installation.

(c) *Proposal Approval for Flight Experiments.* In addition to the Field Installation ACUC review, activities involving animal subjects to be flown on NASA spacecraft will be subject to review and approval by the 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 HRPPC at JSC.

(d) *Approval for Use of Field Installation Facilities.* The NASA Field Installation ACUC will review and approve or disapprove those parts of proposals that call for the use of their facilities to conduct any activity involving animal subjects (e.g., Kennedy Space Center or ARC Dryden facilities used to support experiments using animal subjects). The ACUC will submit each evaluation report to the Field Installation Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters.

(e) *NASA Animal Care and Use Committees.* (1) The Director of each NASA Field Installation that is involved in

animal research activities will establish an ACUC to ensure compliance with the policies and provisions of this rule. The membership of the ACUC shall be in accordance with PHS Policy.

(2) The NASA Field Installation ACUC's will review and approve or disapprove all proposals using animal subjects. In accordance with the PHS Policy (IV.C.), the ACUC will submit each report to the Field Installation Director who will, upon request, transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters.

(3) NASA ACUC's have the authority to approve, disapprove, or require changes to be made in those components of proposals involving the care and use of animal subjects that are submitted by NASA investigators. All decisions shall be based on the response of a majority of a quorum of the members. A minority opinion including abstentions should be recorded; this record should include a justification for the opinion.

(4) The ACUC shall conduct continuing review of proposals at appropriate intervals as determined by the ACUC, but not less than once every 3 years.

(5) Proposals that have been approved by the ACUC may be subject to further appropriate review by the Authorized NASA Official, NASA Headquarters. However, the official may not approve those sections of a proposal related to the care and use of animal subjects if they have not been approved by the ACUC.

(6) Once experimental procedures are approved, no substantial changes can be made unless a formal request with appropriate justification for such a request is submitted to and approved by the appropriate ACUC. If the experiment involves exposure of the flight crew to the animal subjects, the HRPPC at JSC must review and approve the proposed modifications. Copies of ACUC approval of the proposed modifications shall be submitted to the Field Installation Director who will, upon request, transmit the report to the Authorized NASA Official, NASA Headquarters.