

field installation's Assurance of compliance shall be submitted in the manner prescribed in §§1232.104(c) and 1232.105 (b), (c), (d), and (f).

(2) At least once every 12 months, the ACUC, through the Field Installation Director, shall report in writing to the Authorized NASA Official:

(i) Any change in the field installation's program or facilities that would affect the AAALAC accreditation status;

(ii) Any change in the description of the field installation's program for animal care and use;

(iii) Any changes in the ACUC membership;

(iv) Notice of the dates that the ACUC conducted its semiannual evaluations of the field installation's program and facilities and submitted the evaluations to the Field Installation Director;

(v) A statement that the field installation has no changes to report as specified in §1232.105(h)(2) (i), (ii), or (iii) of this rule, if there are no changes.

(3) The ACUC, through the Field Installation Director, shall promptly provide the Authorized NASA Official with a full explanation of the circumstances and actions taken with respect to:

(i) Any serious or continuing non-compliance with this rule and PHS Policy;

(ii) Any serious deviation from the provisions of the Guide; or

(iii) Any suspension of an activity by the ACUC.

(4) Reports filed under § 1232.105 (h) of this rule shall include any minority views filed by members of the ACUC.

(5) A copy of the U.S. Department of Agriculture (USDA) Annual Report will be furnished to the Authorized NASA Official.

§1232.106 Management authority and responsibility.

(a) *Authorized NASA Official.* The Authorized NASA Official is the NASA Administrator's representative 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.

(b) *Field Installation Director.* The Field Installation Director is responsible for and has the authority to:

(1) Sign the field installation's Assurance, making a commitment on behalf of the field installation that the requirements of the PHS Policy and this rule will be met in all field installation activities involving animal subjects;

(2) Create and oversee the functioning of the field installation ACUC;

(3) Decide and administer sanctions in cases of noncompliance with this rule;

(4) Fulfill the reporting requirements assigned to this individual in §1232.105(h); and

(5) Sign the annual USDA report.

(c) *NASA Field Installation(s) ACUC Responsibility.* Each NASA Field Installation ACUC is responsible to its Field Installation Director for the activities described in §§1232.104(c) and 1232.105 (b), (c), (d), (e) and (h).

(d) *Research or Flight Program Manager Responsibility.* The Research or Flight Program Manager is responsible for ascertaining the presence of the required PHS Assurance file number for proposals involving animal subjects received from non-NASA institutions, and a statement of ACUC review and approval of all NASA and non-NASA proposals involving animal subjects. No awards for activities involving animal subjects can be made without this documentation [see §§1232.104 (b) and (d) and 1232.105(b)].

(e) *NASA Veterinarian(s) Responsibility.* NASA veterinarian(s) have direct or delegated authority and responsibility for activities involving animal subjects at their field installation. Such authority and responsibilities shall include recommending approval or disapproval of procedures involving animal subjects as a member of the ACUC, continual monitoring of these activities, surveillance of the health and condition of animal subjects, and reporting any observed deviations from approved procedures involving animal subjects to the Field Installation Director and the ACUC. In the case of deviation from ACUC-approved practices or procedures, the veterinarian shall have the authority to immediately halt

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such procedures until they are reviewed and resolved by the ACUC. In cases of a conflict concerning animal usage by an investigator that cannot be resolved between him/her and the veterinarian, the matter may be brought to the attention of the Field Installation ACUC for review and recommendation for action as set forth in this rule. Whereas the performance of the veterinarian's duties can be delegated to other qualified individuals, the ultimate responsibility rests with the veterinarian. This responsibility extends not only to the Animal Care Facility (ACF), but also to other locations where animal subjects are used.

Other specific areas of responsibility and authority vested in the veterinarian are:

(1) *Entry of personnel into the ACF.* The veterinarian has the responsibility to develop access procedures to the ACF and submit them to the ACUC for approval.

(2) *Personnel Training.* The veterinarian will participate in the training of personnel in the handling of animal subjects and in specimen sampling procedures.

(3) *Animal Training.* The veterinarian will monitor all schedules and procedures involving the training and acclimation of animal subjects.

(4) *Surgery and Surgical Procedures.* The veterinarian will monitor all surgical procedures and verify that the principles of the Guide with regard to aseptic surgery are employed. Post-surgical recovery procedures are included. If necessary, training will be provided by the veterinarian to bring procedures conducted by investigators to the level of these standards.

(5) *Veterinary Medical and Engineering Procedures.* The veterinarian will monitor all veterinary medical and engineering procedures performed on animal subjects and verify their appropriateness. The veterinarian will actively participate in identifying and/or establishing the design requirements and adequacy of animal facilities for ground and spaceflight-related activities.

(f) *NASA Representative to the Interagency Research Animal Committee (IRAC).* The NASA representative to the IRAC will obtain information of all

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cases in which an institution's Assurance has been revoked by the PHS. The NASA IRAC representative will notify NASA ACUC's, Field Installation Directors, the Authorized NASA Official, and all Headquarters Research and Flight Program Managers so that they can determine which NASA awards involving the use of animal subjects are affected and can take appropriate sanctions.

§ 1232.107 Sanctions.

(a) *Non-NASA Institutions.* Principal investigators not employed by NASA whose activities are supported by NASA but whose activities using animal subjects are restricted to non-NASA facilities shall be subject to the control of their institution's ACUC and responsible institutional official. Notification of noncompliance with this rule shall be made either as described in § 1232.106(f) or by the non-NASA institution to the Director of the NASA Field Installation through which the activity has been supported and to the Authorized NASA Official. Any continued noncompliance may be caused for termination of funding or support.

(b) *NASA Field Installations.* (1) Inappropriate procedures on animal subjects by NASA principal investigators shall be halted by the NASA Field Installation Veterinarian or line management and brought to the attention of the ACUC if the issue cannot be immediately resolved. The ACUC will review the activity and report any noncompliance with this rule to the Field Installation Director. Principal investigators not employed by NASA, whose activities using animal subjects are performed in NASA facilities, aircraft, or spacecraft, are subject to similar action. Such noncompliance will be cause for sanctions. The principal investigator can contest, in writing, these decisions to the ACUC.

(2) The ACUC as the agent of the Field Installation Director 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 Animal Welfare Act, the Guide, PHS Policy requirements, or this rule.

(3) Any suspension or termination of approval will include a statement of