

§ 1230.119

14 CFR Ch. V (1-1-06 Edition)

§ 1230.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ 1230.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 1230.121 [Reserved]

§ 1230.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 1230.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially

failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 1230.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

PART 1232—CARE AND USE OF ANIMALS IN THE CONDUCT OF NASA ACTIVITIES

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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 Ani-

mals (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 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

¹ Available 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.