

completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 1230.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 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 ex-

pendent 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.

EFFECTIVE DATE NOTE: At 78 FR 76059, Dec. 16, 2013, part 1230 was revised effective Feb. 14, 2014. For the convenience of the user, the revised text is set forth as follows:

PART 1230—PROTECTION OF HUMAN SUBJECTS (Eff. 2-14-14)

Sec.

1230.101 Scope.

1230.102 Applicability.

1230.103 Policy.

AUTHORITY: 5 U.S.C. 301; 45 CFR part 46.

Pt. 1232

14 CFR Ch. V (1–1–14 Edition)

§ 1230.101 Scope.

This Part establishes general policy for the protection of human subjects, which is of primary importance in the conduct of any human research, as specified under 5 U.S.C. 301; 45 CFR part 46, subpart A.

§ 1230.102 Applicability.

This Part applies to NASA Headquarters and NASA Centers, including Component Facilities, and Technical and Service Support Centers for all research involving humans subjects conducted, supported, or otherwise subject to regulations by any Federal department or agency which takes appropriate administrative action to make the policy applicable to such research.

§ 1230.103 Policy.

It is the National Aeronautics and Space Administration's (NASA) policy to comply with 45 CFR part 46, subpart A, Protection of Human Subjects, which applies to all research conducted involving human subjects. To implement the provisions of 45 part 46, subpart A, NASA promulgated the following internal policies and requirements:

(a) NPD 7100.8, Protection of Human Research Subjects, describes the Agency's policy for human research conducted or supported, whether on the ground, in aircraft, or in space. NPD 7100.8 can be accessed at <http://nodis3.gsfc.nasa.gov/>; and

(b) NPR 7100.1, Protection of Human Research Subjects, describes the requirements for the Agency to conduct or support research involving human subjects. NPR 7100.1 can be accessed at <http://nodis3.gsfc.nasa.gov/>.

PART 1232—CARE AND USE OF ANIMALS IN THE CONDUCT OF NASA ACTIVITIES (Eff. until 2-14-14)

Sec.

1232.100 Scope.

1232.101 Applicability.

1232.102 Policy.

1232.103 Definitions.

1232.104 Implementation procedures by non-NASA institutions.

1232.105 Implementation procedures by NASA field installations.

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.

EFFECTIVE DATE NOTE: At 78 FR 76059, Dec. 16, 2013, part 1232 was revised effective Feb.

14, 2014. For the convenience of the user, the revised text will appear at the end of this part.

§ 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