



Subject: Protection of Human Research Subjects

Responsible Office: Office of the Chief Health & Medical Officer

1. POLICY

a. This directive establishes policy for the protection of human research subjects, recognizing NASA's responsibility for the ethical treatment of research volunteers. These principles include respect for person, beneficence, and justice.

b. It is NASA's policy that all human research conducted, sponsored, or supported by NASA will follow all Federal laws, regulations, including Protection of Human Subjects (Common Rule), 14 CR pt 1230, and guidelines, as well as, NASA policy.

2. APPLICABILITY

a. This NID is applicable to NASA Headquarters and NASA Centers, including Component Facilities and Technical and Service Support Centers. This language applies to the Jet Propulsion Laboratory (a Federally Funded Research and Development Center), other contractors, recipients of grants, cooperative agreements, or other agreements only to the extent specified or referenced in the applicable contracts, grants, or agreements.

b. This NID is applicable to all research involving human subjects conducted, sponsored, or supported by NASA.

c. In this directive, all mandatory actions (i.e., requirements) are denoted by statements containing the term "shall." The terms: "may" or "can" denote discretionary privilege or permission, "should" denotes a good practice and is recommended, but not required, "will" denotes expected outcome, and "are/is" denotes descriptive material.

d. In this directive, all document citations are assumed to be the latest version unless otherwise noted.

3. AUTHORITY

The National Aeronautics and Space Act, 51 U.S.C. § 20113 (a).

4. APPLICABLE DOCUMENTS AND FORMS

a. Protection of Human Subjects, 14 CFR pt. 1230.

5. RESPONSIBILITY

a. The Chief Health and Medical Officer (CHMO) and the Office of Research Assurance ensure all Agency programs and activities involving human research subjects comply fully with applicable Federal laws, regulations, and guidelines, as well as NASA policy.

- b. The Institutional Official (IO) obligates NASA to the terms of the Federalwide Assurance for the protection of human subjects by providing the resources and support necessary to comply with all requirements applicable to research involving human subjects.
- c. The NASA Institutional Review Board (IRB) Chair oversees the development, coordination, and implementation of protocol and program reviews and facility inspections for the IRB in compliance with Federal laws, regulations, and guidelines, as well as, NASA policy.
- d. Center Directors ensure all Center programs and activities involving human research subjects comply with Federal laws, regulations, and guidelines, as well as, NASA policy.
- e. Program Managers ensure all human subject research funded within their program is compliant with Federal laws, regulations, and guidelines, as well as, NASA policy.
- f. Principal Investigators (PI), including civil service and non-civil service (i.e., contractors, grantees, etc.), conduct human subject research in full compliance with NASA and Center/Institution policy and procedures.

6. DELEGATION OF AUTHORITY

None.

7. MEASUREMENT/VERIFICATION

None.

8. CANCELLATION

None.

ATTACHMENT A: DEFINITIONS

Federalwide Assurance. Assurance of compliance approved by OHRP for NASA use, to ensure institutions engaged in non-exempt human subjects research conducted or supported by NASA, commit to complying with the requirements set forth in the Common Rule.

Institutional Official – An individual who has administrative and operational authority to commit institutional resources to ensure compliance with Federal laws, regulations, and guidelines, as well as, NASA policy.

Office of Research Assurance. Office of the Chief Health and Medical Officer office that ensures all Agency programs and activities involving research subjects comply fully with applicable Federal laws, regulations and guidelines, as well as, NASA policy.

Principal Investigator - A civil servant or non-civil servant (e.g., grantees, contractors and parties to agreements) researcher who has overall responsibility for all aspects of the funded and/or sponsored research project. Responsibilities for non-civil servant researchers are implemented through grants, contracts, agreement etc.

Program Manager – The person designated by NASA to manage each program in which NASA has a research or payload interest. Programs may consist of several projects.

ATTACHMENT B: ACRONYMS

CHMO – Chief Health and Medical Officer

IO – Institutional Official

IRB – Institutional Review Board

PI – Principal Investigator