NASA Policy Directive

NPD 7100.8G
Effective Date: August 12, 2022
Expiration Date: August 12, 2027

COMPLIANCE IS MANDATORY FOR NASA EMPLOYEES

Printable Format (PDF)

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 or supported by NASA will follow all Federal laws, regulations, including Protection of Human Subjects (Common Rule), 14 CFR pt. 1230, and guidelines, as well as, NASA policy, including NPD 7170, Use of Human Research Genetic Testing and NPR 7100.1, Protection of Human Research Subjects.

2. APPLICABILITY

a. This NPD is applicable to NASA Headquarters and NASA Centers, including Component Facilities and Technical and Service Support Centers. This language applies to contractors, recipients of grants, cooperative agreements, or other agreements only to the extent specified or referenced in the applicable contracts, grants, or agreements.

Note: The applicability of this NPD to the Jet Propulsion Laboratory is being re-assessed by NASA. This applicability statement will be updated as necessary when that re-assessment is completed.

b. This NPD is applicable to all research involving human research subjects conducted or supported by NASA. This includes, but is not limited to, all human research subject activities conducted by non-federal institutions or in commercial facilities, aircraft, and spacecraft that are funded or supported by NASA or use NASA resources. Human research subject activities by non-federal institutions or in commercial facilities, aircraft, and spacecraft that are not funded by NASA or do not use NASA resources are out of scope.

Note: NASA resources related to operation of the commercial facility, aircraft, or spacecraft having nothing to do with the human research activity does not constitute "use of NASA resources" for the actual human research activity. For example, if the institution or commercial provider only uses KSC services to launch the vehicle, this NPD would not apply.

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. 14 CFR pt. 1230, Protection of Human Subjects (Common Rule).

b. NPD 7170, Use of Human Research Genetic Testing.

c. NPR 7100.1, Protection of Human Research Subjects.

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 Federallaws, regulations, and guidelines, as well as NASA policy.

f. Principal Investigators (PI), including civil service and non-civil service (e.g., contractors, grantees, and parties to agreements, etc.), ensure human subject research is conducted in full compliance with Agency, Center, and home institution policy and procedures.

6. DELEGATION OF AUTHORITY

None.

7. MEASUREMENT/VERIFICATION

None.

8. CANCELLATION

a. NPD 7100.8F Protection of Human Research Subjects.

b. NID 7100.134 Protection of Human Research Subjects.

/s/ Bill Nelson
Administrator

ATTACHMENT A: DEFINITIONS

Federalwide Assurance. An assurance of compliance with the U.S. Federal regulations for the protection of human subjects in research. Institutional Official. An individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance.

Office of Research Assurance. Office within the Office of the Chief Health and Medical Officer ensures all Agency programs and activities involving research subjects comply fully with applicable Federal, state, and local laws, regulations and guidelines, as well as, NASA policy. Principal Investigator. A civil service or non-civil service (e.g., grantees, contractors, and parties to agreements) researcher who has overall responsibility for all aspects of the funded and/or supported research project. Responsibilities for non-civil service 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 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

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