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NASA Procedural Requirements

COMPLIANCE IS MANDATORY

NPR 7100.1

Effective Date: March 28,
2003

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2013

[Printable Format \(PDF\)](#)

Request Notification of Change (NASA Only)

Subject: Protection of Human Research Subjects (Revalidated 7/7/08)

Responsible Office: Office of the Chief Health & Medical Officer

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CHAPTER 1. Responsibilities

The purposes of this NPR is to comply with the following:

1.1 Authorized NASA Official (ANO):

The ANO shall be responsible for the protection of human subjects and is empowered, subject to conditions and limitations imposed by immediate superiors, to authorize research involving human subjects. All or part of the authority may be redelegated, without power of further redelegation, to (a) a senior NASA HQ employee who reports to the ANO, or (b) the NASA Center Director(s).

1.2 Inform the Administrator:

The ANO shall ensure that the Administrator, the appropriate Associate Administrators (AA) sponsoring research involving humans, and the AA for the Office of Safety and Mission Assurance (OSMA), are kept fully and currently informed, through official channels, of significant actions, problems, or other matters of substance related to the exercise of this authority.

1.3 Approval of Multiple Project Assurances (MPA):

The ANO is responsible for approving all NASA Center MPA's or Single Project Assurances (SPA), indicating that NASA-conducted or -sponsored research complies with NASA policy and the body of existing law pertaining to research involving human subjects. The ANO is responsible for approving each NASA Center's annual summary of the research and Institutional Review Board (IRB) activities for the preceding year including review of compliance activities, membership, initial and continuing education, and an updated IRB membership list.

1.4 NASA Center Directors

NASA Center Directors shall be responsible for ensuring that their MPA is filed with the ANO. For NASA Center Directors not filing an MPA or SPA, the Center Director must certify to the ANO that research involving human subjects will not be conducted or sponsored by that Center during the following calendar year.

1.5 Establish IRB:

The NASA Center Directors may establish a Center IRB to review all ground-based, aerospace, and aeronautical flight research that their respective Centers conduct or that utilize NASA facilities, equipment, or personnel (NASA-conducted or -sponsored research). If this is not done, then another NASA IRB, by prior arrangement, shall review the research proposals using human subjects.

1.6 Protection of Rights:

The NASA Contracting Officers (NCO) shall ensure that all research proposals involving human subjects (including grants, contracts, cooperative agreements, memoranda of understanding, or other similar legal arrangements) are reviewed by an approved IRB prior to funding. The NCO shall maintain a record of all such IRB approvals.

1.7 Other Institutions Responsibilities:

Academic institutions, nonprofit institutions, or business enterprises performing NASA-funded research involving human subjects at non-NASA facilities, and not involving NASA permission to use Government equipment are responsible for obtaining approval for their proposed research from an approved IRB, which will generally be the IRB at the institution performing the research. NASA reserves the right to have all such research reviewed by a NASA IRB prior to funding or implementation of this research involving human subjects.

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