



NASA Procedural Requirements

COMPLIANCE IS MANDATORY

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Request Notification of Change (NASA Only)

Subject: Protection of Human Research Subjects (Revalidated 6/26/14)

Responsible Office: Office of the Chief Health & Medical Officer

[| TOC](#) | [ChangeHistory](#) | [Preface](#) | [Chp1](#) | [Chp2](#) | [Chp3](#) | [Chp4](#) | [Chp5](#) | [Chp6](#) | [Chp7](#) | [Chp8](#) | [Chp9](#) | [Chp10](#) | [AppdxA](#) | [AppdxB](#) | [AppdxC](#) | [AppdxD](#) | [AppdxE](#) | [AppdxF](#) | [ALL](#) |

CHAPTER 7. Research Mishaps, Adverse Events, Injuries, Illness, and Disease and Medical Care

7.1 Mishap/Adverse Event Reporting and Investigation

7.1.1 In the case of an active research protocol being conducted at a NASA Center or facility, and/or using NASA hardware or equipment, and/or involving a NASA investigator, the PI shall inform the responsible NASA IRB within 24 hours of discovery of any injury, illness, disease, or death, whether expected or not, incurred by a research subject. Such an event is termed a research subject mishap.

7.1.1.1 An adverse event is any untoward or unfavorable medical occurrence involving a human research subject occurring while associated with the subject's participation in the research. An adverse event is not necessarily a mishap if the protocol-related documents or informed consent documents identify the potential for the medical occurrence.

7.1.1.2 An adverse event that causes death, hospitalization or serious injury or is deemed to place research subjects or others at greater risk or harm than what was previously known or anticipated, is classified as a research subject mishap.

7.1.1.3 The determination of whether an adverse event is classified as a research subject mishap will be made by the Chair of the responsible IRB.

7.1.2 Within 3 working days upon being notified, the IRB Chairperson shall notify the NASA Center Safety Officer, the ANO, the NASA Center Chief Medical Officer (where applicable), the relevant NASA research funding program, and the Crew Medical Officer in the case of crew involvement in the event of a reportable incident, of the incident.

7.1.2.1 When the injury results in a loss of life, a permanent disability, or when a person requires hospitalization, and/or a person requires extensive first aid or lost workday(s), the mishap will be reported to the ANO immediately.

7.1.3 For a research subject mishap involving a fatality, life threatening injuries, permanent or partial disability, or requiring hospitalization (i.e. Type A, Type B mishaps per NPR 8621 NASA Procedural Requirements for Mishap and Close Call Reporting, Investigating, and Recordkeeping) an investigation will be initiated as soon as possible per NPR 8621.1 by a board convened by the appropriate Appointing Official (AO).

7.1.3.1 For research subject mishaps occurring at a Center, the Center Director will serve as the AO, with concurrence from the CHMO.

7.1.3.2 For research subject mishaps involving a human research subject participating in NASA-funded research at a grantee site or at another offsite location involving a NASA investigator, and/or using NASA hardware or equipment, the CHMO will serve as the AO.

7.1.4 Research subject mishaps resulting in an injury or illness to an individual or individuals (i.e., Type C, D, or CC mishaps per NPR 8621.1) will be investigated in accordance to processes established by the Institutional Review

Board (IRB) approving the human research study, following the guidance provided in Appendix E.

7.1.4.1 If the IRB Chair and/or the CHMO believe that there is an inherent conflict of interest for the IRB to convene or perform the investigation, the convening authority defaults to the appropriate AO, as described above.

7.1.5 OCHMO will inform and/or seek concurrence through telephone or email contact with OSMA Mishap Investigation Program Manager on applicability and implementation of NPR 8621.1 requirements associated with all human research subject related mishaps.

7.1.6 Upon being notified of a mishap the IRB Chairperson shall determine whether the research should be immediately suspended with subsequent IRB concurrence.

7.1.6.1. Once a research protocol involving human subjects is suspended, IRB review and approval will be required before the experiment can resume.

7.1.7 During the mishap investigation all researchers shall cooperate with the NASA mishap investigators, grant interviews, and provide data as requested.

7.1.8 In the case of NASA funded research by a non-NASA PI at a non-NASA facility or institution, the PI shall notify all institutional IRB's that approved his or her proposal of any research subject mishap. The research subject mishap, and if the research has been suspended, will be reported to NASA as the funding agency by the PI, IRB and/or the entity responsible for the oversight of the grant or contract.

7.2 Medical Care and Reporting

7.2.1 For all occurrences requiring medical attention, the PI shall maintain a record of all pertinent information acquired through the research protocol, such as physiologic monitoring and/or imaging data that is acquired, and make them available to the subject's physician.

7.2.2 In the case of research being conducted at a NASA Center or facility, and/or using NASA hardware or equipment, and/or involving a NASA investigator, the PI shall inform the NASA IRB in the event of any change in the experimental environment or in the subject that could forecast medical problems.

7.2.3 In evaluating the research proposal the NASA IRB shall review the health care provisions provided to the research subject, and the availability of appropriate medical care for possible injury or illness that could occur during the course of the research.

7.2.4 To inform the research subject, the provisions for access to medical care shall be included in the consent form.

7.2.5 The medical care for astronaut research subjects shall include the assigned NASA flight surgeon who shall have access to all research data that pertains to the health of the astronaut research subject. The flight surgeon may use this data for the ongoing health monitoring of the astronaut.

| [TOC](#) | [ChangeHistory](#) | [Preface](#) | [Chp1](#) | [Chp2](#) | [Chp3](#) | [Chp4](#) | [Chp5](#) | [Chp6](#) | [Chp7](#) |
| [Chp8](#) | [Chp9](#) | [Chp10](#) | [AppdxA](#) | [AppdxB](#) | [AppdxC](#) | [AppdxD](#) | [AppdxE](#) | [AppdxF](#) |
| [ALL](#) |

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