Langley Research Center

LPR 7100.10

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PROTECTION OF HUMAN RESEARCH SUBJECTS

National Aeronautics and Space Administration

Responsible Office: Safety and Mission Assurance Office

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PREFACE

P.1 Purpose

1.1 This Langley Procedural Requirements (LPR) describes how Langley Research Center (LaRC):

a. Implements Federal and NASA regulations covering research involving human subjects.

b. Ensures the safety, health, and welfare of human test subjects associated with research conducted for, with, by, or at Langley Research Center.

P.2 Applicability

2.1 This LPR is applicable to NASA Headquarters and NASA Centers, including Component Facilities and Technical and Service Support Centers.

2.2 This LPR applies to research involving human subjects that meets any of the following conditions:

a. Is funded by Langley Research Center.

b. Involves Langley Research Center personnel, either civil servant or contractor, in their official, professional roles.

c. Is conducted at Langley Research Center.

d. Utilizes Langley Research Center's equipment or facilities.

P.3 Authority

14 CFR 1230 – Protection of Human Subjects

P.4 Applicable Documents

a. NPD 7100.8, "Protection of Human Research Subjects"

b. NPR 7100.1, "Protection of Human Research Subjects"

c. LAPD 1150.2, "Councils, Boards, Panels, Committees, Teams, and Groups"

d. Langley Research Center Employee Safety Pocket Guide

e. LF 193, LaRC Institutional Review Board (IRB) Checklist

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f. LF 229, Human Subject Research Volunteer Informed Consent Statement

g. LF 368, NASA Langley Research Center Institutional Review Board (IRB) Application for Review of Human Subject Research

P.5 Measurement/Verification

None

P.6 Cancellation

LPR 7100.10, Protection of Human Research Subjects dated June 20, 2005

Original signed on file

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Distribution:
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1. Introduction

1.1 This document describes how Langley Research Center (LaRC) shall protect the safety, health, and welfare of human research subjects and implement the regulations and policies prescribed by:

a. 14 CFR 1230 – Protection of Human Subjects.

b. NPD 7100.8 – Protection of Human Research Subjects.

c. NPR 7100.1 – Protection of Human Research Subjects.

1.2 The contents of this LPR complement the information contained in 14 CFR 1230, NPD 7100.8, and NPR 7100.1.

1.3 This LPR shall not be used in a stand-alone manner.

1.4 Parties associated with research involving human subjects must refer to and understand the contents of all these governing documents in order to fulfill their responsibilities.

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2. Principles

2.1 LaRC shall apply the following principles to research involving human subjects:

a. Any person who participates as a test subject in human subject research shall do so on a voluntary basis.

(1) No coercion will be used.

(2) Before agreeing to participate, test subjects shall be given a description and explanation of the test, their roles, their risks, and the potential benefits of the research.

(3) The description and explanation shall be presented in language and terminology that the test subject can understand.

b. Research tests involving human subjects shall not be conducted unless the risks are reasonable in relation to the accumulated benefits to the test subjects and to the importance of the knowledge to be gained.

c. Selection of test subjects shall be equitable and reasonable.
(1)The burden and benefits of the research shall be fairly distributed.

d. The Principal Investigator (PI) shall establish and conduct tests in a manner that protects the safety, health, and welfare of the test subjects.

e. Personally Identifiable Information (PII) about test subjects shall be protected and will not be released without prior written consent of the test subject.

f. An Institutional Review Board (IRB) shall provide independent review, approval, and oversight of all research involving human subjects.

g. Research involving human subjects shall be conducted in accordance with:

(1) 14 CFR 1230 – Protection of Human Subjects

(2) NPD 7100.8 – Protection of Human Research Subjects

(3) NPR 7100.1 – Protection of Human Research Subjects

h. The objective of LaRC is to avoid loss of life, personal injury and illness, property loss or damage, or environmental harm and to ensure safe and healthful conditions for all parties involved in its research activities.

(1) While conducting research involving human test subjects, LaRC shall protect the test subjects from harm or injury (physical, psychological, social, or economic).

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i. All persons participating in research involving human subjects shall report any potential hazards or any unanticipated problems encountered during the research.

j. If unsafe conditions or work practices present imminent danger to personnel or property during the conduct of research involving human subjects, all parties involved are vested with the right and obligation to promptly stop the work and report the condition to the PI, the responsible supervisor, or the LaRC Safety Office.

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3. Key Responsibilities

3.1 All parties involved with human subject research shall:

a. Safely conduct the research.

b. Follow approved procedures.

c. Report safety hazards to the PI, their supervisor, or the LaRC Safety Office.

d. Exercise the stop-work authority if they detect an imminent danger to personnel or property.

3.2 Principal Investigators (PIs) shall:

a. Follow the provisions of 14 CFR 1230, NPD 7100.8, NPR 7100.1, and this LPR.

b. Design and conduct research experiments in a manner that safeguards the safety, health, and welfare of the test subjects.

c. Report accidents, unexpected events, close calls, and safety concerns to the LaRC Safety Office.

d. Obtain the review and approval of the LaRC IRB before commencing any experiments involving human research subjects or implementing changes or modifications to previously approved research.

e. Maintain current and required training status for the protection of human subjects as directed by the Chief Health and Medical Officer.

f. Ensure that the subject or the subject's beneficiaries receive compensation by means of insurance, worker's compensation, or the like in the event that the subject suffers illness, disease, injury, loss, or death as a direct result of LaRC funded research.

    (1) The lack of this provision shall serve as a basis for disapproval of the research. This applies to all studies performed at a NASA Center, using NASA equipment or facilities, or having a NASA employee or on-site contractor as the principal investigator.

g. Be responsible for contracts on which task orders are placed to provide human subjects as volunteers to participate in research.

    (1) Contract shall include language to ensure that the contractor provides for the human subject to receive compensation by means of insurance, worker's compensation, or the like in the event that the subject suffers illness, disease, injury, loss, or death as a direct result of the research.

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3.3 LaRC line managers shall assure that:

a. PIs are adequately trained and qualified to perform research involving human subjects.

b. PIs follow applicable regulations, policies, and procedures.

c. The LaRC IRB is properly staffed and has any other resources needed to comply with its responsibilities.

d. Federal funds are not expended for research involving human subjects unless the provisions of 14 CFR 1230, NPD 7100.8, and NPR 7100.1 are met.

3.4 Test Subjects shall:

a. Read and sign the informed consent statement after requesting clarification of anything they do not fully understand.

b. Alert the PI should any situation arise that may affect their ability to participate in the study.

c. Report accidents, illness, changes in their health, close calls, and safety or health concerns.

d. Initiate the stoppage of work in case of imminent danger.

3.5 Persons who prepare statements of work for research involving human subjects shall:

a. Include requirements mandating adherence to applicable Federal regulations (14 CFR 1230, NPD 7100.8, NPR 7100.1, and this LPR).

b. Transmit a copy of the statement of work to the LaRC IRB Secretary.

c. Forward a copy of the performing institution's certification to the LaRC IRB Secretary.

3.6 Persons who review and recommend acceptance of unsolicited proposals for research involving human subjects shall:

a. Ensure that they contain a requirement that mandates adherence to applicable Federal regulations (14 CFR 1230, NPD 7100.8, and NPR 7100.1) or a certification from the proposing institution indicating that the proposed research has been reviewed and approved by a Federally-approved IRB.

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b. Provide a copy of unsolicited proposals that are recommended for funding to the LaRC IRB Secretary.

c. Send a copy of the performing institution's certification to the LaRC IRB Secretary.

3.7 The LaRC IRB shall:

a. Provide, review, approve, and oversee research experiments involving human test subjects to ensure that:

(1) The safety, health, and welfare of human subjects are adequately protected.

(2) Applicable regulations, policies, and practices are followed.

b. Maintain current and required training status for the protection of human subjects as directed by the Chief Health and Medical Officer.

c. Screen procurement solicitations that would involve the use of NASA research funding with the requirement to use human subject volunteers.

3.8 LaRC Safety Office shall:

a. Notify LaRC and NASA Headquarters officials of accidents and unexpected events in accordance with established policies.

b. Forward reports of unexpected events to the LaRC IRB Chairperson.

c. Assure that adequate actions are taken to investigate and address accidents, safety hazards, and safety or health concerns.

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4. Conducting Research Involving Human Subjects

4.1 Authority and Obligation To Stop A Test

4.1.1 If unsafe conditions present an imminent danger to any person or equipment, all associated personnel, including test subjects, are vested with the right and obligation to stop the testing.

4.1.2 When anyone involved in a test senses an imminent hazard, they shall notify the PI (or the person in charge of the test) of the danger and declare they are exercising the stop work authority. Testing shall promptly be halted. T he hazard shall then be assessed and appropriate corrective actions taken.

4.1.3 All parties associated with the test shall comply with and support this policy.

4.2 Application for IRB Review

4.2.1 The PI shall prepare an Application for IRB Review of Human Subject Research, LF 368 and submit it electronically to the LaRC IRB Secretary. (See LAPD 1150.2, “Councils, Boards, Panels, Committees, Teams, and Groups,” for identification of the IRB Secretary.)

4.2.1.1 An electronic copy can be obtained online through the Langley Management System at the web site: https://lms.larc.nasa.gov/forms_list.cfm.

4.2.2 Proposed research involving human subjects and any proposed changes or modifications to previously approved research involving human subjects must be reviewed and approved by the LaRC IRB before the PI can involve test subjects in the research activities or implement changes.

4.3 Informed Consent

4.3.1 Participation as a test subject in human subject research shall be strictly on a voluntary basis. No coercion will be used.

4.3.1.1 Research test subjects shall be provided an Informed Consent Statement that thoroughly and completely discloses all relevant risks and benefits associated with their involvement in the research.

4.3.1.1.1 Prospective test subjects shall read and sign the Informed Consent Statement prior to their participation as a test subject.

4.3.1.1.2 The PI or designee shall also brief the perspective subjects as to the content of the informed consent as part of the continuous informed consent process.

4.3.2 It is LaRC policy to inform and obtain documented consent from test subjects before their involvement in any research activity.

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4.3.3 The PI shall prepare a proposed Informed Consent Statement.

4.3.3.1 The Informed Consent Statement shall be clearly written and use language and terminology that the test subjects can understand.

4.3.4 The required contents of the Informed Consent Statement are contained in 14 CFR 1230 and NPR 7100.1. LF 229 sets forth a summary of these requirements.

4.3.4.1 Informed Consent Statements used for research involving LaRC personnel, facilities, or equipment shall also contain the required text noted in LF 229.

4.3.4.2 If necessary, this required text may be tailored to the proposed research.

4.3.5 The proposed Informed Consent Statement shall be submitted to the IRB Secretary along with the Application for IRB Review of Human Subject Research.

4.3.6 To obtain Informed Consent, PIs shall:

a. Provide a complete copy of the Informed Consent Statement to the prospective test subject for his or her permanent records.

b. Allow the prospective test subject time to read the statement.

c. Discuss the test, the test subject's role in the test, the risks, and the benefits with the prospective test subject.

d. Give the prospective test subject an opportunity to ask questions and provide answers to any questions asked.

e. Permit the test subject to sign a copy of the Informed Consent Statement.

4.4 Privacy of Data and Research Records Retention

4.4.1 NASA and the PI shall protect all private information obtained during the course of research involving human test subjects.

4.4.2 The PI shall develop and implement a plan to:

a. Protect the private information associated with test subjects.

b. Prevent the improper disclosure of private information about any test subject without the test subject's previous written permission.

4.4.3 All records that contain private information shall be clearly labeled Sensitive But Unclassified (SBU).

4.4.4 Provisions shall be made to protect private information that is stored electronically.

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4.4.5 The PI shall maintain and retain all records associated with research activities in accordance with NPR 1441.1D.

4.4.5.1 Human Research Data Records are covered under Chapter 8, Item 105.

4.4.5.2 Pursuant to that Chapter and item, Human Research Data Records shall be maintained between 2 and 15 years after conclusion of the research program or project

4.4.5.3 Human Research Data Records shall be retained no longer than the life of the program or project plus 5 years, not to exceed 15 years after conclusion of the research program or project.

4.5 Pre-Test and/or Post Test Screening

4.5.1 The PI shall decide whether pre-test and/or post-test screenings are needed to:

a. Assure the validity of experimental results.

b. Protect the health and safety of the test subjects.

4.5.2 When screenings are employed, the PI shall determine whether to use questionnaires, debriefings, or medical examinations.

4.6 Appropriate Monitoring or Medical Coverage

4.6.1 The PI shall determine whether:

a. The health or medical condition of test subjects shall be monitored during the course of the research.

b. Special medical coverage is needed to provide quicker-than-normal response to potential injuries or health problems.

4.6.2 The PI shall take steps to implement the health monitoring and medical coverage determined to be appropriate.

4.7 Responding To and Reporting Unexpected Events

4.7.1 Personnel involved with human subject research shall promptly respond to and subsequently report the following unexpected events:

a. Accidents involving death, injury, property damage, or environmental damage.

b. Death, illness, or unforeseen medical problems of a test subject.

c. Any change in a test subject’s health or the test environment that could forecast a medical problem.

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d. Unscheduled medical care for a test subject that could be related to the research test.

e. Close calls.

f. Safety hazards.

g. Safety or health concerns.

h. Cases of non-compliance with federal regulations, NASA policies, or IRB approvals for human subject research.

4.7.2 The test subject shall notify the PI of any accident, injury, illness, changes in their health condition, hazards, safety concerns, or health concerns. If the test subject is not able to contact the PI or is not fully satisfied with the response of the PI, he or she should contact the LaRC Safety Office at (757) 864-7233 and/or the LaRC IRB Chairperson.

4.7.3 PIs shall:

a. Immediately report emergencies and/or obtain appropriate medical attention by calling 911 from any LaRC phone or 864-2222 from a cellular phone.

b. Report the event to the LaRC Safety Office at extension 47233.

c. Inform the LaRC IRB Chairperson.

4.7.4 The LaRC Safety Office shall:

a. Provide an initial response and assessment of the situation.

b. Notify LaRC and NASA Headquarters officials in accordance with established policies and protocols.

c. Initiate an investigation or inquiry, if appropriate.

d. Notify the LaRC IRB Chairperson.

e. Notify the Chief Health and Medical Officer at NASA Headquarters as specified in NPR 7100.1.

4.7.5 The LaRC IRB Chairperson shall:

a. Determine whether to issue an immediate suspension of the research.

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b. Notify the Chief Health and Medical Officer at NASA Headquarters as specified in NPR 7100.1.

c. Promptly schedule a meeting of the LaRC IRB to review the circumstances surrounding the reported event.

d. Convene the LaRC IRB for a review of the unexpected event and a decision on whether the research should be suspended or terminated.

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5. Reviewing Research Involving Human Subjects: LaRC IRB

5.1 LaRC IRB Charter

The LaRC IRB Charter is defined in LAPD 1150.2, “Councils, Boards, Panels, Committees, Teams, and Groups.”

5.2 LaRC IRB Authority

5.2.1 The LaRC IRB will have the full authority prescribed by 14 CFR 1230, NPD 7100.8, and NPR 7100.1.

5.2.1.1 The LaRC IRB shall have the authority to approve, disapprove, or require changes in proposed experiments involving human subjects, and to suspend or cancel the approval of research activities that do not comply with previous approvals, have not been approved, or have exhibited the potential to harm anyone.

5.2.2 As conditions warrant, the LaRC IRB shall submit reports or relevant recommendations to LaRC line management, the LaRC Executive Safety Council, and the Chief Medical and Health Officer at NASA Headquarters.

5.3 LaRC IRB Membership

5.3.1 The composition of the LaRC IRB shall comply with the requirements stated in 14 CFR 1230.107 and NPR 7100.1.

5.3.2 The LaRC IRB shall consist of at least seven members with consecutive 3-year terms optional for renewal based on approval by the Executive Safety Counsel.

5.3.3 In addition to the requirements of 14 CFR 1230.107 and NPR 7100.1, the LaRC IRB shall have members with the following skills, expertise, or affiliation:

a. A Medical Doctor.

b. A Lawyer.

c. A Scientist or Engineer.

d. A pilot with formal test pilot school training or a current NASA research pilot.

e. An Industrial Hygienist or Safety Engineer.

f. The LaRC Occupational Health Officer or an employee of the Office of Human Capital Management.

g. An employee of the Office of Chief Counsel.

h. An employee of the Safety and Mission Assurance Office.

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i. A member with no other affiliation with NASA.

j. A member representing the population from which research test subjects are chosen.

5.3.3.1 A single member may fulfill more than one of these requirements.

5.3.3.2 If suitable members are not available from within the LaRC civil service staff, then non-NASA personnel shall fill the membership.

5.3.4 The members of the LaRC IRB are listed in LAPD 1150.2.

5.3.5 The LaRC IRB may enlist input and advice from technical experts to supplement the knowledge of its members.

5.3.5.1 LaRC line management shall support the LaRC IRB in obtaining any needed expertise.

5.3.5.2 Technical experts may participate in LaRC IRB discussions, but shall not vote as a member of the LaRC IRB.

5.4 LaRC IRB Reviews

5.4.1 This document places research involving human subjects into one of four categories. LaRC IRB review of these four categories of research is described below.

5.4.1.1 <u>Category 1 - Research that is conducted using LaRC personnel, facilities, or equipment.</u>

5.4.1.1.1 The LaRC IRB shall review this research.

5.4.1.2 <u>Category 2 - Research that is funded by LaRC, but conducted solely using personnel, facilities, or equipment of another institution.</u>

5.4.1.2.1 For research involving human test subjects that is conducted solely by another institution and does not involve any NASA personnel, equipment, or facilities, the general practice shall be to accept the governance of the local Institutional Review Board (the IRB of the institution conducting the research).

5.4.1.2.2 For cases that pose exceptional risk or where there is no local Institutional Review Board, the LaRC IRB will review the proposed experiment.

5.4.1.2.3 When a Technical Monitor initiates procurement action for a grant/contract, he/she will also forward a copy of the procurement documentation to the LaRC IRB Secretary for appropriate IRB screening and/or review.

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5.4.1.2.4 The IRB Chairperson, Vice-Chairperson or designated member of the IRB shall screen each new NASA funded procurement proposal contract or grant that includes the use of human research subjects prior to its award.

5.4.1.2.4.1 The screening shall determine whether the research experiment will be referred to the LaRC IRB for review and approval.

5.4.1.2.4.2 The screening shall also assure that the contract/grant language contains the following provisions that are required in the procurement documentation by the assigned procurement specialist:

a. Requires adherence to 14 CFR 1230 and the applicable elements of NPD 7100.8D, NPR 7100.1, and this LPR.

b. Requires that Minutes of local IRB meetings related to this research experiment be forwarded to the LaRC Technical Monitor and the LaRC IRB Secretary.

c. Explicitly states an IRB must review and approve the research experiment prior to the recruitment or involvement of any human test subjects.

5.4.1.2.5 The IRB screening official shall document the results of the screening.

5.4.1.2.5.1 This may be in the form of an e-mail sent to and retained by the IRB Secretary and the assigned Procurement official.

5.4.1.2.6 The Contracting Officer or Procurement Official shall not award the contract or grant until they have received IRB documentation affirming that an IRB screening or an IRB review has been completed.

5.4.1.2.7 A summary of all screening activities shall be presented at the next meeting of the LaRC IRB and included with annual management reporting documentation.

5.4.1.3 <u>Category 3 - Cooperative research that is conducted using both LaRC personnel, facilities, or equipment and personnel, facilities, or equipment from another institution.</u>

5.4.1.3.1 Both the LaRC IRB and the IRB of the other institution involved with the research shall review cooperative research tests.

5.4.1.4 <u>Category 4 NASA Research involving human subjects conducted aboard in-flight aircraft. This research includes activities funded by LaRC or activities involving LaRC personnel, aircraft, or equipment.</u>

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5.4.1.4.1 The Johnson Space Center IRB shall review this category of research. (The Johnson Space Center IRB serves as the NASA Flight IRB that is specified in NPR 7100.1, Chapter 6.)

5.4.1.4.2 The PI shall contact the Johnson Space Center IRB to arrange for this review.

5.4.1.4.3 Contact information for the Johnson Space Center IRB can be obtained from the Chairperson or Secretary of the LaRC IRB. (See LAPD 1150.2 for the names of these LaRC IRB members.).

5.4.1.5.4 The LaRC IRB shall support or assist the Johnson Space Center IRB upon request.

5.5 Exempt Status

5.5.1 For reviews that meet the criteria for “exempt” status, the LaRC IRB shall make this determination.

5.5.1.1 The LaRC IRB shall review all requests proposing the use of surveys or interviews except those surveys designated for purposes of customer feedback for products or services rendered by a facility or organization that uses them for the purpose of continuous customer and process improvement.

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5.6 LaRC IRB Meetings

5.6.1 Meetings shall be called by the LaRC IRB Chairperson.

5.6.1.1 The LaRC IRB Secretary or Chairperson shall provide notification to all LaRC IRB members and other invited participants.

5.6.1.2 A copy of the application for LaRC IRB approval and the proposed Informed Consent Statement shall be distributed to LaRC IRB members prior to a meeting, whenever practical.

5.6.2 The PI (and other cognizant personnel) shall be encouraged to attend the LaRC IRB meeting to describe the research and answer questions.

5.6.2.1 If the PI's physical presence is not practical, the use of videoconference or teleconference shall be explored to gain their participation.

5.6.3 Formal reviews shall be conducted at a meeting where a majority of the LaRC IRB members are present.

5.6.3.1 At least one member whose primary role/expertise is in a nonscientific area shall also be present.

5.7 Decisions and Criteria For Approval

5.7.1 A formal action or decision of the LaRC IRB requires a positive vote by a majority of the members present.

5.7.2 A quorum shall consist of a majority of the IRB members and include at least one member whose primary interest or concerns are in nonscientific areas.

5.7.3 Members who have involvement with or conflict of interest with research being reviewed by the LaRC IRB shall declare and explain their situation at the beginning of the LaRC IRB meeting.

5.7.3.1 These members are encouraged to participate in the review by providing relevant information to the Board to ensure it has a complete understanding of the research being reviewed.

5.7.3.2 Members with a conflict of interest shall not participate in the Board's deliberations nor vote on the matter at hand.

5.7.4 The criteria for LaRC IRB approval of human subject research are contained in CFR 1230.111 and NPR 7100.1 - Chapter 10.

5.7.5 The LaRC IRB shall decide whether:

a. Projects require monitoring or review more often than annually

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b. Projects require verification from sources other than the PIs that no material changes have occurred.

5.7.6 The LaRC IRB shall use the checklist provided in LF 193 to guide their review and decision process.

5.7.7 If the LaRC IRB decides to disapprove a proposed research activity, the reasons for the decision shall be included in the minutes of the LaRC IRB meeting.

a. The PI shall be given a subsequent opportunity to respond to the LaRC IRB either in person or in writing.

5.8 Informed consent

5.8.1 The LaRC IRB shall review proposed Informed Consent Statements to verify the content conforms to the requirements of 14 CFR 1230.116 and NPR 7100.1 and the document uses language and terminology that can be clearly understood by the test subjects.

5.8.1.1 The proposed research and the associated Informed Consent Statement shall not be approved until the LaRC IRB's legal advisor has reviewed and concurred with the content of the Informed Consent Statement.

5.8.2 If the LaRC IRB’s legal advisor is not available and a decision is needed prior to the anticipated availability, the LaRC IRB Chairperson shall have another member of the LaRC Office of Chief Counsel provide the required review and concurrence for Informed Consent Statements.

5.9 Expedited Review

5.9.1 Expedited reviews may be used for the situations involving minimal risk to human subjects as specified in 14 CFR 1230 and NPR 7100.1. (See Appendix C of NPR 7100.1 for a list of types of research activities that may be reviewed by an expedited review.)

5.9.1.1 Expedited reviews may also be used to review minor changes in previously approved research during the period for which approval was authorized.

5.9.1.2 The LaRC IRB Chairperson may elect to convene a LaRC IRB meeting to review a proposal that meets the criteria for an expedited review.

5.9.2 Before initiating an expedited review, the LaRC IRB Chairperson shall determine that the proposal meets the allowable conditions specified in 14 CFR 1230 and NPR 7100.1.

5.9.2.1 The LaRC IRB Chairperson shall select one or more LaRC IRB members to conduct the expedited review.

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5.9.2.2 The LaRC IRB legal advisor shall also review and concur with the Informed Consent Statement.

5.9.2.3 The IRB Chairperson may also elect to implement review via electronic medium where assigned board members provide email commentary.

5.9.2.4 A minimum of two board members plus the board member representing the Office of Chief Counsel shall review expedited reviews.

5.9.2.5 The review and approval shall be documented similar to regular meetings.

5.9.2.5.1 Copies shall be distributed to all LaRC IRB members, the PI, and the Chair and Secretary of the Executive Safety Council.

5.9.2.6 If the LaRC IRB's designated reviewer determines that the proposal should be disapproved, a LaRC IRB meeting shall be held to review and determine the disposition.

5.10 Review of Simulators

5.10.1 The LaRC IRB shall review new or modified LaRC facilities such as ground-based simulators and acoustic facilities used for human occupancy prior to system checkout where human subject research testing is conducted and approved by the LaRC IRB and determine the potential risks of the simulator operations to the human research subjects.

5.10.1.1 The LaRC IRB shall make one of the following determinations:

a. Some or all of the simulator operations will be exempt from further LaRC IRB review and approval.

b. Some or all of the simulator operations will be handled by an expedited review.

c. Some or all of the simulator operations will require a full LaRC IRB review.

d. The simulator shall not be used for human subject research.

e. Changes to the simulator are required before it can be used for human subject research.

5.11 Modifications

5.11.1 The LaRC IRB shall review and approve proposed modifications or changes to tests, procedures, and Informed Consent Statements before they can be implemented.

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5.12 Unexpected Events, Safety Concerns, or Non-Compliances

5.12.1 The LaRC IRB shall review reports of unexpected events, safety concerns, and non-compliances.

5.12.2 The IRB will invite the PI and other parties involved with the reported event to participate in the meeting and supply relevant information.

5.12.3 The IRB shall review the circumstances surrounding the reported event and decide whether the research should be suspended or terminated.

5.12.4 The IRB has the authority to require that changes be made to the research protocol or procedures to assure the safety and health of participants.

5.13 Suspension or Termination of Approved Research

5.13.1 If the LaRC IRB decides to suspend or terminate research that was previously approved, then it shall document the decision and the supporting rationale.

5.13.1.1 A copy of the document shall be promptly distributed to the PI, the associated Organizational Unit Manager, the Safety Manager, and the Authorized NASA Official as specified in NPD 7100.8.

5.13.1.2 Copies shall also be sent to the Chair and Secretary of the Executive Safety Council and all members of the LaRC IRB.

5.13.2 Research that has been suspended or terminated by decision of the LaRC IRB shall not be resumed until a subsequent review is performed resulting in approval by the LaRC IRB.

5.14 IRB Meeting Minutes

5.14.1 The LaRC IRB Secretary will generate minutes of all LaRC IRB meetings.

5.14.1.1 The content of meeting minutes shall comply with the requirements of NPR 7100.1, paragraph 5.1.2 including a listing of action items and their status regarding closure or ongoing work being done on the assigned action.

5.14.1.2 Copies of the minutes shall be distributed in accordance with the requirements stated in LAPD 1150.2. It is permissible to distribute minutes electronically.

5.15 IRB Records

5.15.1 LaRC IRB records shall be maintained in accordance with the requirements of 14 CFR 1230.115 and NPR 7100.1.

5.15.1.1 IRB records shall be retained for 3 years beyond the last IRB action on a specific research proposal or specific issue.

Verify the correct version before use by checking the LMS Web site.

5.15.1.2 The LaRC IRB records shall be filed and maintained by the LaRC IRB Secretary. It is permissible to retain records electronically.

5.15.2 The LaRC IRB shall retain the following documents for each proposed research test it reviews:

a. The presentation material used at the LaRC IRB meeting.

b. The approved version of the Informed Consent Statement.

c. The meeting minutes / approval memo.

5.16 Multiple Project Assurance Document and Annual Reports

5.16.1 The LaRC IRB Secretary shall compile updates to the LaRC Multiple Project Assurance Document.

5.16.1.1 After review and concurrence by the LaRC IRB, the LaRC IRB Secretary shall send the document to NASA Headquarters in accordance with NPD 7100.8.

5.16.1.2 The document shall be routed through the LaRC Safety and Mission Assurance Office.

5.16.2 The LaRC IRB Secretary shall compile a LaRC annual report on IRB activities and research involving human subjects as required by NPD 7100.8.

5.16.2.1 The report shall be routed through the LaRC Safety and Mission Assurance Office and sent to NASA Headquarters in accordance with NPD 7100.8.

5.16.2.2A copy of the report shall be sent to all members of the LaRC IRB, the Director of the Safety and Mission Assurance Office, and the Chairperson of the Executive Safety Council.

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6. Compliance Oversight and Audits

6.1 Oversight of the safety and health aspects of human subject research and the operation of the LaRC IRB shall be provided by:

a. Periodic audits conducted by OSHA under the Voluntary Protection Program.

b. Periodic safety and health audits conducted by NASA Headquarters, Office of Safety and Mission Assurance.

c. Ad-hoc reviews or audits conducted by the NASA Headquarters, Chief Health and Medical Officer.

d. Operations of the LaRC Executive Safety Council.

e. The LaRC Safety and Mission Assurance Office.

(1) By routine safety and health audits.

(2) By routine industrial hygiene audits.

(3) By routine fire safety audits.

(4) Through participation of an employee of the Safety and Mission Assurance Office as a member of the LaRC IRB.

Verify the correct version before use by checking the LMS Web site.