

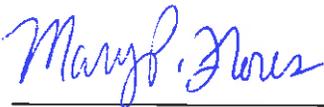
**FULL COMMITTEE REVIEW STANDARD OPERATING PROCEDURE**

**For NASA Johnson Space Center Institutional Review Board Committee for the Protection of Human Subjects**

CPHS/SOP 002/2009

June 29, 2009

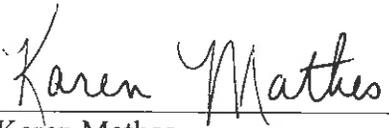
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**FULL COMMITTEE REVIEW STANDARD OPERATING PROCEDURES**

REVISION LOG

CPHS/POL 002/2009

<b>REVISION NO</b>	<b>DATE</b>	<b>DESCRIPTION OF REVISION</b>	<b>PREPARED/REVISED BY</b>
0	June 29, 2009	Original Document	Karen Mathes/Administrator, JSC IRB CPHS

## Full Committee Review Standard Operating Procedures

### I. General Information

This Standard Operating Procedure (SOP) document must remain current and in compliance with all applicable regulations. To remain current, this SOP is reviewed at least annually and the review process will update to comply with the most recent federal regulations. This review will be documented. Notifications of changes and an updated procedure will be distributed to IRB Committee members and posted on the IRB CPHS website.

The fundamental responsibility of the NASA Johnson Space Center (JSC) Institutional Review Board (IRB) Committee for the Protection of Human Subjects (CPHS) is to ensure the health, safety, and well-being of human research subjects while ensuring the ethical conduct of experimental operations. All Principal Investigators (PIs) bear responsibility for implementation of the NASA JSC IRB CPHS guidelines. The Committee approves only those investigations involving “minimal” or “reasonable” risk to the human subject. Animal research is of interest to the NASA JSC CPHS particularly in the context of human health and safety.

The IRB has the authority to disapprove, require modifications to secure approval and approve research based on its consideration of the risks and potential benefits of the research, and whether or not the rights and welfare of human subjects are adequately protected.

The NASA JSC IRB CPHS meets on the third Thursday of every month. Meeting dates and deadline information are posted at <http://irb.nasa.gov> or <http://cphs.nasa.gov>. Principal Investigators (PIs) are required to submit a complete application including all required supporting documentation to the CPHS office by close of business (4:30 p.m.) on the published deadline date for the submission to be considered for review at the subsequent scheduled IRB meeting. Deadlines for submission are two weeks prior to the date of each meeting.

### II. Review Process

The CPHS reviews both ground-based and spaceflight related human research protocols, including analog environments such as NASA Extreme Environment Mission Operations (NEEMO) and reduced gravity aircraft. *All protocols using human test subjects must be approved by the CPHS when research is conducted in spacecraft, JSC facilities, JSC aircraft, or at other centers or institutions when JSC civil service or contractor personnel are directly involved in the research activities.* The application points must be addressed for the CPHS to conduct an adequate review and to comply with federal requirements.

Human-in-the-loop testing refers to hardware tests and evaluations where human test subjects are required to interface in some manner with the hardware and equipment being tested. These tests have the potential of exposing test subjects to some measure of risk to their safety and well-being. These hardware and device evaluations are also reviewed by the CPHS to comply with federal requirements for human subject protection.

The CPHS Office will screen (quality check) the Full Committee Review Application Form for completeness and accuracy using the Submission Checklist (<http://irb.nasa.gov>) to determine if criteria are satisfied and appropriate documents have been provided.

If incomplete, the CPHS Office will contact the PI to request the deficiencies be rectified. For applications not providing appropriate documents, the CPHS Office will notify the PI of any deficiencies prior to submitting the application for consideration by a convened IRB.

If complete, the CPHS Office will add the application to the next meeting agenda, and forward to CPHS Board Members and alternates for review. The CPHS Office will ask the PI to submit 20 copies of the Application. The CPHS office will assign a protocol number and log the protocol into the CPHS database.

An initial submission of human research protocol is defined as the first occasion for a science investigator to submit their study for review by the CPHS. The purpose of the initial review is to ensure protection of the safety, rights and welfare of research participants and compliance with Federal laws and institutional regulations for the protection of human subjects.

Requirements must be satisfied in order for the IRB to approve proposed research. This is true of projects reviewed through the full IRB or expedited review, and during both initial approval and annual continuing reviews. The required criteria include the following to approve proposed research:

- a. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
- b. Risks to subjects are "minimal" or "reasonable".
- c. Selection of subjects is equitable from various populations, as applicable. Inclusion and exclusion criteria will be evaluated, and the IRB will be particularly cognizant of special problems of research involving vulnerable populations.
- d. Informed consent will be sought from each prospective subject.
- e. Informed consent will be appropriately documented.
- f. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- g. There are adequate provisions to protect the privacy of subjects, and to maintain the confidentiality of data.

The IRB will consider the following additional criteria when appropriate:

- a. The IRB will consider participant's privacy interests in reviewing the recruitment, consenting, and procedures described in the research plan. Research plans must include a description of how participant privacy will be protected. Some examples of the types of questions the IRB should ask about the research when determining the adequacy of managing participant's privacy concerns include the following:
  - i. Where will participants be recruited?
  - ii. Where will the participant be consented? Will the informed consent process take place in a private room, where participant can ask questions without feelings of embarrassment or discomfort?
  - iii. If the research involves a physical exam, where will the exam be conducted?
- b. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards are included in the study to protect rights and welfare of the subjects.
- c. The IRB will review the design and the scientific basis for the proposed research as it relates to the risks to subjects.
- d. The IRB will also consider the following criteria during initial review, as appropriate to the type of study being proposed. These criteria are assessed for each protocol:
  - i. Whether the purpose of study is clear.
  - ii. Results of any related studies.
  - iii. The number of subjects and duration of participation is stated and appropriate.
  - iv. Duration of the study and frequency of activities are clear and appropriate.
  - v. The setting in which research occurs is appropriate.
  - vi. Plan for recruiting subjects including recruitment and reenrollment procedures and appropriateness of claims made in advertising.
  - vii. The nature or amount of the compensation offered to subjects for participation in research does not create undue influence.
  - viii. The risks of research activities are clearly distinguished.
  - ix. Physical, psychological, social and economic risks, including risks to privacy and the probability of occurrence posed by research design, interventions, and procedures.
  - x. When reviewing a research proposal with elements warranting special attention (e.g., placebo, challenge studies, radiation exposure, deviations from standards of care), the IRB will consider the appropriateness of, and rationale for, such elements and document such considerations.
  - xi. Process for monitoring and reporting adverse events.
  - xii. Information to be used for recruitment or to inform subjects or potential subjects about the nature of the research.
  - xiii. The investigator and research staff has appropriate scientific and human subject protection training to conduct the study

- xiv. Investigator potential financial conflicts.
- e. A statement that a copy of the signed and dated consent document would be given to the person signing the consent document.

Approval cannot occur unless the IRB has sufficient information to determine that the above criteria are included in the proposal.

Prior to the IRB CPHS monthly meeting date, IRB members will be provided all information relevant to the review approximately two weeks prior to the meeting to allow adequate time for a thorough review.

IRB members must self-disclose potential conflict of interest prior to reviewing protocols for which there may be a conflict of interest. Any member with a conflict of interest must disclose that conflict of interest before the project is discussed, and must abstain from voting and cannot participate in the review of protocols in which they have a conflict of interest, except to provide information requested by the IRB.

The Full IRB Committee will:

- Review and discuss the proposal in detail
- Assess risks, benefits and adequacy of subject protection
- Determine whether approval criteria have been met
- Make recommendations for protocol and informed consent revisions
- Submit written review comments
- Vote regarding approval
- Document in minutes that approval criteria have been met
- Communicate with PI in writing of Board recommendations and/or actions (through IRB Administrator)

The PI may attend the meeting to answer questions or provide additional clarification. An absent Committee member can submit their written comments to be read at the meeting.

For each protocol, the IRB will determine the frequency of continuing review of the research, designating an interval appropriate to the degree of risk, but not less than once per year from the meeting date. More frequent review may be appropriate if the IRB believes that previous studies indicate high incidence of adverse events, or if the IRB believes that close monitoring is indicated. The reasons for such a determination will be included in the minutes. In addition, the IRB may limit accrual and require reporting back to the IRB prior to continuing research activities. The determination will be documented in approval correspondence and minutes.

When the convened IRB requests substantive clarifications or modifications that were directly relevant to the determinations required by the IRB, the protocol cannot be approved without a review of the responsive information by a convened Full Committee.

The IRB will vote according to the categories of action described below. The IRB will document in the meeting minutes that the criteria for approval of the project and of the informed consent documents have been discussed at the meeting and that the criteria have been met. The results of IRB review and actions taken by the IRB will be communicated to the PI in writing and in a timely manner. Documentation will include the basis for requiring revision to the application or the reason for disapproval of the research.

### **III. IRB CPHS Categories and Communication Regarding Actions**

The Committee will inform the PI in writing of one of the four decisions following review:

- **Approval:** The research protocol is approved, and no changes to the submission are required or recommended
- **Contingent Approval:** The Committee approves the study in principle. However, the investigator must provide a written response regarding items of concern, usually minor items such as clarifications or revisions in the protocol or consent form. The PI must address the action items using the CPHS Protocol Action Item Response sheet and submit them to the CPHS for review. The study cannot begin until the concerns of the Committee have been satisfactorily addressed and the response is approved.
- **Tabled:** The CPHS is not prepared to approve the study without additional information and review. This decision may occur when serious concerns are raised about issues of human subject protection or when other major changes are required to reconsider the protocol. The PI must respond to the request in writing and this is reviewed by the Committee at a subsequent CPHS meeting. Usually, the revised protocol is granted approval or contingent approval at the time of the second review. However, the study may be returned again if the committee requests it.
- **Disapproval:** The Committee finds that the protocol is not acceptable in principle. A denial of approval cannot be overturned without substantial modifications to the risk-benefit aspect of the protocol. The revised protocol must be resubmitted for all required approvals.

Research cannot commence until fully approved by the IRB and the approval letter is released containing the approval date.

The IRB communicates concerns and suggestions regarding human subject protection issues to the PI following each step of its review. In accordance with federal regulations, IRB communications regarding the approval, disapproval or modifications required to secure IRB approval of research activities are in the form of written correspondence.

The CPHS Office is responsible for drafting communications regarding proposed research and any modifications or clarifications required by the IRB as a condition for approval of proposed research. All IRB communications are reviewed and approved by the IRB Chair prior to dissemination to the PI.

Upon receipt of a PI's response to IRB communications, the CPHS Office will prepare a written evaluation of the response to include any regulatory or administrative guidance. Staff will distribute the evaluation, along with applicable regulatory checklists and relevant historical information from the study file for review in accordance with the prior determination of the IRB.

#### **IV. Record Retention**

All JSC IRB records associated with specific research proposals are retained indefinitely. An off site storage facility shall be used to store archived materials. All records shall be accessible and available for inspection by authorized agency personnel at reasonable times in a reasonable manner. Documentation and Record Retention Standard Operating Procedure (CPHS/SOP 001/2009) may be consulted for more information.

The CPHS Office will conduct periodic self-assessment of IRB members and alternates to assure appropriate training. IRB members and alternates are required to complete the on-line Collaborative IRB Training Initiative (CITI) at: <https://www.citiprogram.org/>. A feature of the CITI software program provides a reminder every two years. Alternatively, IRB members may complete the National Institute of Health (NIH) training: Protecting Human Research Participants NIH Office of Extramural Research at: <http://phrp.nihtraining.com/users/login.php>

The CPHS Office provides the CPHS Human Subjects Protections/Safety training course to Government Contractor and Civil Servant personnel who are engaged in human subject research testing. Records are maintained in the CPHS office with a web-based course implemented every two years.

The CPHS Office has the authority to develop, implement, and monitor the CPHS in accordance with federal, state and local law regulations. Policies and procedures will be reviewed annually to assure compliance with all regulations. The CPHS Office will track all changes to policies, procedures and guidance using a computerized system.

**Regulations:**

45 CFR 46.115

21 CFR 56.115

**References:**

OHRP Guidance on Written IRB Procedures – January 15, 2007.

<http://www.hhs.gov/ohrp/humansubjects/guidance/irbqd107.pdf>

FDA Information Sheets: Frequently Asked Questions: IRB Records

<http://www.fda.gov/oc/ohrt/irbs/faqs.html#IRBRecords>

NASA Policy Directives (NPD)

7100.8E

NASA Procedural Requirement (NPR)

7100.1