National Aeronautics and
Space Administration

Office of Inspector General
Headquarters
Washington, D.C. 20546-0001

Reply to Attn of: W

October 9, 2001

TO: A/Administrator

FROM: W/Inspector General

SUBJECT: Assessment of the Institutional Review Board for Human Subject Protection at the Johnson Space Center, G-01-002

The NASA Office of Inspector General initiated a review of the Johnson Space Center (Johnson) Institutional Review Board (IRB) to ascertain whether NASA's IRB's were experiencing problems similar to IRB's at medical and research facilities funded by the Departments of Health and Human Services and Veterans Affairs.[1] Research was suspended at these institutions as a result of a lack of obtaining informed consent, lack of sufficient, designated workspace for IRB activities, insufficient monitoring of research activities, inadequate agency or institutional guidance, insufficient documentation, and research involving humans as research subjects being conducted without the approval of the local IRB.

We found that, in general, the Johnson IRB was timely, well-organized, and staffed with qualified, hardworking, and dedicated individuals. However, the IRB function could be improved with updates of Agency policy, timely education and training opportunities for IRB members, and periodic reviews of the IRB process relating to research involving human subjects sponsored by Johnson. In addition, we are concerned that with heavy workloads and competing priorities IRB member oversight could be weakened. Usually, IRB proposal review occurred before or after the official workday. As a result, we recommend that the Chief Health and Medical Officer and Johnson Space and Life Sciences Directorate management should re-evaluate the time commitment associated with proposal review in order to ensure that IRB decisions are made by individuals who are well informed and have had appropriate time to review proposals and associated documents. This evaluation of the review process should consider if there are procedural requirements that absorb the time and attention of IRB members, if proposal distribution prior to meetings allows for appropriate member review, or determine what other factors may impinge on IRB members duties and how to best address these issues. Johnson management should also consider the importance

[1] In the late 1990's, several research institutions had their human research studies suspended temporarily. Although the infractions varied, the majority of the cases involved a laxity in implementing and providing sufficient processes designed to protect human subjects. These infractions, potentially, placed subjects in danger.

of participation of their employees in the IRB process and allot appropriate duty time to perform this function.

The Office of the Chief Health and Medical Officer and the Office of Space Flight concurred with all the recommendations contained in the report and have taken or planned appropriate corrective actions to address the recommendations.

Roberta L. Gross

Enclosure
Assessment of the Institutional Review Board for Human Subject Protection at the Johnson Space Center, G-01-002

National Aeronautics and
Space Administration

Headquarters
Washington, D.C. 20546-0001

Reply to Attn of: W

October 9, 2001

TO: AM/Chief Health and Medical Officer
M/Associate Administrator for Space Flight

Johnson Space Center
Attn: AA/Acting Director

FROM: W/Assistant Inspector General for Assessments, Administrative Investigations, and Inspections

SUBJECT: Assessment of the Institutional Review Board for Human Subject Protection at the Johnson Space Center, G-01-002

The NASA Office of Inspector General (OIG) examined the policies and procedures of the Institutional Review Board (IRB) for Human Subject Protection at the Johnson Space Center (Johnson). IRB's ensure that research protocols[1] provide for informed consent to participating individuals and do not expose the research subjects to unreasonable risks. The IRB's also conduct continuing reviews of approved research to verify that subject protections remain intact. Johnson's IRB is responsible for:

- Review of all NASA ground-based or aeronautical flight and all space-flight proposed human research protocols submitted to the authorized JSC official prior to funding approval, or execution.
- Review of all flight payload experiments or procedures involving humans as test subjects, ensuring that protocols and safety procedures conform to NASA policy.
- Issuance of guidelines for the conduct of all human research measurements and experimental procedures, flight and ground-based.[2]

We initiated this assessment of NASA's IRB's to determine whether NASA's IRB's were experiencing problems similar to those at medical and research facilities funded by the

[1] A research protocol is a detailed plan of a scientific or medical experiment, treatment, or procedure.

[2] Johnson Procedures and Guidelines (JPG) 1107.1, Sec 4-8.

Departments of Health and Human Services (DHHS) and Veterans Affairs.[3] Research was suspended at these institutions for diverse reasons, including failure to obtain informed consent; lack of sufficient, designated workspace for IRB activities; insufficient monitoring of research activities; inadequate agency or institutional guidance; insufficient documentation, and research involving humans as research subjects being conducted without the approval of the local IRB. Further, in 1998 and 2000, the DHHS OIG released a series of reports that outlined the deficiencies of DHHS' IRB's.[4]

Our review focuses primarily on the Johnson IRB because it receives the most proposals for NASA funded biological research and reviews all experimental protocols involving humans that are to be performed on the Agency's air and space platforms. We found that, in general, the Johnson IRB was timely, well-organized, and staffed with qualified, hardworking, and dedicated individuals. However, the IRB function can be improved by revising Agency policy,[5] increasing diversity of its membership, allowing sufficient time to the members to perform their IRB responsibilities, and conducting periodic reviews of the IRB process relating to research involving human subjects sponsored by Johnson.

BACKGROUND

Research is a systematic investigation (including research development, testing and evaluation) designed to contribute to generalizable knowledge.[6] Research using human subjects is conducted to provide important medical and scientific benefits to individuals and to society. In addition to traditional biomedical and clinical studies, such research includes, but is not limited to, studies that accomplish:[7]

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[3] In the late 1990's, several research institutions had their human research studies suspended temporarily, including six separate universities in the University of Colorado system, West Los Angeles Veterans Affairs Hospital, Duke University Medical Center, Virginia Commonwealth University, the University of Alabama at Birmingham, Rush Presbyterian St. Luke's Medical Center in Chicago, and the University of Illinois-Chicago. Although the infractions varied, the majority of the cases involved a laxity in implementing and providing sufficient processes designed to protect human subjects. These infractions, at least theoretically, placed subjects in danger.

[4] The 1998 reports were titled, *Institutional Review Boards: A Time for Reform*, *Institutional Review Boards: Their Role in Reviewing Approved Research*, and *Institutional Review Boards: Promising Approaches*. The 2000 DHHS OIG report was titled, *Protecting Human Research Subjects: Status of Recommendations*. The major theme to this series of reports was that the effectiveness of the IRB's is in jeopardy. Specifically, IRB's faced major changes in the research environment; they reviewed too much, too quickly, with too little expertise; they conducted minimal continuing review of approved research; they faced conflicts that threaten their independence; they provided little training for investigators and board members; and, the IRB's were not evaluated for effectiveness.

[5] NASA is currently developing a revision of NPD 7100.8. The Johnson IRB document, JPG 107.1, has been revised, but Johnson Space and Life Sciences Directorate management are waiting for the Agency document to be formalized to start the concurrence cycle on their document.

[6] *Research* as defined in 45 Code of Federal Regulations (CFR) part 46, and 14 CFR part 1230.

[7] As explained in 45 CFR part 46 and 14 CFR part 1230.

- Use of humans to examine devices, products, or materials with the express purpose of investigating human-machine interfaces or evaluating environmental alterations when humans are the subjects being tested.
- Use of personally identifiable bodily materials, such as cells, blood, tissues, urine, or hair, even if the materials were collected previously for a purpose other than the current research.
- Collection and use of personally identifiable information, such as genetic information or medical and exposure records, even if the information was collected previously for a purpose other than the current research.
- Collection of personally identifiable data, including surveys or questionnaires, through direct intervention or interaction with individuals.
- The search for generalizable knowledge about categories or classes of subjects (e.g., linking job conditions of worker populations to hazardous of adverse health outcomes).

NASA depends on research that involves humans as research subjects to develop and provide technologies and research data essential to the design and operation of space-based systems, and to maximize the health, well being and productivity of humans in the exploration and utilization of space. Typically, NASA sponsors research to develop therapeutics,[8] procedures, techniques, and equipment needed to address flight medical, safety, and performance issues. Also, research involving humans as research subjects integrates science and medical research to generate the knowledge required to enable flight crews to leave low-Earth orbit, perform their assigned tasks, and return to Earth with their health intact.[9] Human research requires measures to protect the health and safety of participating subjects.

United States Regulations and NASA Policy and Guidance

After World War II, national, international, and Federal department and agency policies and codes were developed to ensure that human participation in research programs was voluntary and safe.[10] Paramount to these policies are the basic principles that the health of the human subject should be the primary concern and that the subject's participation should be voluntary, protected by a physician, and the subject should be removed from a research protocol if continuation would be harmful to the subject. The use of humans as research subjects is

[8] Application of scientific knowledge to remedy disease or injury.

[9] Office of Biological and Physical Research website, Bioastronautics Division Goals (http://www.hq.nasa.gov/office/olmsa/org.html#B).

[10] Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known codes of conduct regarding the rights of human research subjects include: The Nuremberg Code (1947), Kefauver-Harris amendments to the Food, Drug, and Cosmetics Act (1962), the Declaration of Helsinki (1964), and the 1971 Guidelines (codified in Federal regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare codes for the conduct of social and behavioral research, and the Belmont Report (1974-1978).

codified in the DHHS regulation 45 CFR Part 46[11] and is accepted as the Common Rule by 16 Federal agencies. 14 CFR Part 1230 outlines how NASA should conduct research involving humans as research subjects.[12] NASA, in turn, gives Agency guidance to its IRB's via NASA Policy Directive (NPD) 7100.8.[13] Currently, NPD 7100.8 is being revised to reflect changes to the Agency's organization. Johnson and the Ames Research Center are the two NASA Centers that maintain active IRB's. Each Center has the responsibility to enact its own policy, in accordance with NPD 7100.8. The Johnson IRB has a revised draft of its current policy document, but is awaiting approval of the new NPD 7100.8C before finalizing its document.

Membership of the Johnson IRB

Johnson's IRB typically meets once a month depending on the number of grants and topics the members will consider. At Johnson, a senior member of the Space and Life Sciences Directorate chairs the IRB. The alternate chair is also a senior member of Space and Life Sciences Directorate. 14 CFR 1230.107 sets the minimum number of IRB members as five; however, NASA (NPD 7100.8C) and JPG 1107.1, Section 4 increase the minimum membership of the IRB to:

- The chair
- An alternate chair
- A life scientist
- A flight surgeon
- A representative of the Legal Office
- A representative of the Safety, Reliability, and Quality Assurance Office
- An astronaut
- A non-life science employee
- A non-NASA, full-time Federal employee

In addition to the required personnel composition of the IRB, there is often additional representation. The JPG further specifies work to be carried out by members of the IRB and the supporting staff.

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[11] 45 CFR 46 defines research and describes what is considered and what is not considered to be human research. 45 CFR 46 calls for the use of IRB's and supplies the criteria for approval, modification, and disapproval of research protocols. Informed consent, documentation, membership, and expedited review requirements are explained.

[12] 14 CFR 1230 reflects the requirements of 45 CFR 46.

[13] The current version, NPD 7100.8C charges NASA not to perform any research involving humans as research subjects that has more than minimal risk. Further specifications of the NPD include: data must be non-attributable to the individuals who participate in research studies (unless specific informed consent has been obtained. Further if the data are not attributable to an individual, the data for an individual cannot be compared with other operational medical parameters for purposes of developing an integrated, clinical assessment of an individual), the Johnson IRB must approve all flight research, and NASA-sponsored research must also follow the guidance of this NPD.

All members of the Johnson IRB participate as a collateral duty except for the two full-time staff (the secretary and the protocol compliance officer) who are not voting members of the IRB. The secretary is responsible for the collection of accurate records and the publication of Johnson IRB activities, including agendas, proceedings, and action items. Also, the secretary coordinates training and maintains files of all proposals and all IRB correspondence.

The protocol compliance officer is a non-voting, contract medical doctor whose primary responsibility is to verify that all experiments are conducted in accordance with Johnson IRB requirements. The protocol compliance officer routinely participates in research protocols as a monitor and representative of the IRB. The protocol compliance officer is present at the signing of informed consents, performs physical examinations for volunteer subjects, and is a medical monitor of research protocols. This position adds an additional layer of IRB oversight that goes above and beyond the Federal regulations and NASA policies.

I. IRB VOTING AND RECORDKEEPING NEEDS IMPROVEMENT

As stated previously, NASA's policy reflects the policies codified in 14 CFR Part 1230 and 45 CFR Part 46. NPD 7100.8C reflects the regulations regarding attaining appropriate informed consent, retaining multiple project assurances,[14] and obtaining IRB approval of research protocols prior to commencement of research studies. In addition, NPD 7100.8C addresses IRB responsibilities for space flight and astronaut participation in research protocols.[15]

A review of two years of Johnson's IRB meeting minutes (1999 and 2000) disclosed one area where more attention is warranted. 14 CFR 1230.114 states that "the vote on these actions [approval, modification, or disapproval of a proposed research protocol] including the number of members voting for, against, and abstaining" should be reflected in the meeting minutes. Vote counts by the Johnson IRB are not reported in the minutes. Tallies of votes for and against a research proposal would provide a record of individual reviewer concerns and may result in increased information being transmitted to the research investigator. Further, without a published tally of votes, there is no record of members abstaining or recusing themselves. A tally of votes may also reinforce the responsibility that each reviewer has to the IRB process.

Recommendation 1: In keeping with the direction of 14 CFR 1230.114, the Johnson IRB should maintain a record of vote counts and publish them in their minutes.

[14] A multiple project assurance is a written document from a federally funded institution showing that institution's commitment to the ethical principles governing research with human beings. 14 CFR 1230.103 requires that an institution engaged in research which is covered by this policy and which is conducted or supported by a Federal Department or Agency will provide written assurance satisfactory to the Department or Agency head that it will comply with the requirements set forth in this policy.

[15] NPD 7100.8C states that "astronaut and other human experimental data derived from or associated with such approved research, must be nonattributable to any individual." The Johnson IRB is also charged with the review of "all research involving human subjects, including flight crews, which is performed in NASA spacecraft. . . ."

II. TIME COMMITMENT OF IRB MEMBERS

Currently, the Johnson IRB reviews protocols that are developed by NASA investigators prior to submission for funding. In addition, the IRB also spends considerable time on approving NASA-funded research at other institutions. These proposals are sent to NASA in response to NASA research announcements from the Office of Biological and Physical Research. Prior to selection and funding by NASA, these proposals are reviewed by the IRB at the Principle Investigator's home institution. Thus, these proposals receive 2 IRB reviews. The Johnson IRB is also responsible for the review of the research complement to be flown on the Space Shuttle or the International Space Station and reviews the integrative research program to assure that the summation of individual protocol risks does not result in unreasonable total risk for the crew subject.

In 1999 and 2000, the Johnson IRB reviewed 152 and 197 research proposals, respectively. In 1999, there were 21 IRB-associated meetings, 7 of which did not review proposals. In 2000, the IRB had 12 regularly scheduled meeting and 1 special topic meeting. For each of the regular meetings, each reviewer is asked to review each proposal. Monthly totals of proposals vary, but there is an increase in proposals to be reviewed preceding NASA Research Announcement deadlines. Because of primary job-related tasks that are performed during duty hours, IRB proposal review usually occurred before or after official work hours. However, none of the present members felt that the time commitment was too much or that there was any compromise of their assessment of proposals. In contrast, a previous IRB member criticized the IRB process stating that there was never enough time to review each proposal. The DHHS OIG, in their 1998 report *Institutional Review Boards: A Time for Reform*, lists time issues as a major concern regarding effectiveness of IRBs. Our concern is that with heavy workloads and competing priorities, IRB member oversight could be weakened.

Recommendation 2: In order to ensure that IRB decisions are made by individuals who are well informed and have had appropriate time to review proposals and associated documents, the Chief Health and Medical Officer and Johnson Space and Life Sciences Directorate management should re-evaluate proposal review time commitments. This evaluation of the review process should consider if there are procedural requirements that absorb the time and attention of IRB members, if proposal distribution prior to meetings allows for appropriate member review, or determine what other factors may impinge on IRB members duties and how to best address these issues. Johnson management should also consider the importance of participation of their employees in the IRB process and allot appropriate duty time to perform this function.

Recommendation 3: The Chief Health and Medical Officer and Johnson Space and Life Sciences Directorate management should reconsider the decision to review all research funded at NASA, if that research has been previously reviewed by the originating university's IRB. However, when making this assessment these NASA officials should establish criteria such that when a research protocol poses unique or particularly complex hazards that may be beyond the capabilities of a university's IRB, a Johnson IRB review is required. Thus, when selecting research for funding NASA program officials should determine whether to accept only the university's IRB approval or require the review of the Johnson IRB.

III. EDUCATION AND TRAINING OF IRB MEMBERS

The Johnson IRB provides educational seminars to its members and the Johnson scientific community once a year. Training includes lectures on ethics and IRB functions and processes. At the time of our review, several IRB members had not received training and were unaware of any training provided by the IRB. These individuals were new to the IRB within the last 6 months. Most individuals were provided Johnson IRB guidance, included in the handbook *JSC Institutional Review Board: Guidelines for Investigators Proposing Human Research for Space Flight and Related Investigations*. The secretary is trained and is certified as an IRB secretary.[16]

Recommendation 4: The Johnson IRB should make the education and training of new IRB members a priority. The Chief Health and Medical Officer and the IRB Chair should verify that all new members receive a policy handbook and have had some introduction to IRB function and processes before participating in the IRB process.

IV. PERIODIC EVALUATION OF THE IRB

Currently, there is no Federal or NASA requirement of the evaluation of the IRB process. We found no record to indicate any previous evaluation of Johnson IRB function has occurred. Currently, the Johnson Space and Life Sciences Directorate is in the process of developing a contract to provide a single external audit of the IRB. Periodic review of the IRB process should occur as a safety priority. Evaluations would alert the Johnson IRB members to any potential problems or concerns regarding retention of IRB records, collection of informed consent, inadequate review, inadequate monitoring, or any other IRB function deficiencies.[17] Further, these evaluations should consider the IRB's responsibility to represent the interests of the subjects, not only the Agency's goals.

Recommendation 5: NASA should revise its policy, NPD 7100.8, to require periodic evaluation (not less than once every 5 years) of IRB's for their effectiveness, as well as such areas as record retention, time commitment, controversial issues, personnel and expertise issues, appropriateness of continuing reviews, and IRB independence.

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[16] Public Responsibility in Medicine and Research (PRMR), a non-profit education, advocacy, and membership organization sponsors both training for IRB officials and administration of IRB certification exams. At this time, PRMR certification is not required of IRB members. Certification of IRB staff is a recent development in the human research protection field.

[17] In 1998, the DHHS OIG calls for an adequate system of performance-focused evaluations of IRBs. This recommendation is built on a 1995 report by the Advisory Committee on Human Radiation Experiments that concluded that a "system be subjected to regular, periodic evaluations that are based on an examination of outcomes and performance and that include the perspective and experiences of research as well as the research community."

V. COMPREHENSIVE REVIEW OF RESEARCH PROPOSALS

According to the Federal regulations and NASA Policies, all research, including operational research, involving humans as research subjects should also be approved by the IRB. During our inspection, we discovered that the Johnson IRB did not approve a particular NASA research project involving humans as research subjects. This particular research protocol used humans as research was conceived, administered, and funded through Johnson; nevertheless, the Johnson IRB did not review the research. NASA personnel incorrectly believed that because the research was "operational"[18] the IRB did not need to evaluate it.

This non-IRB approved research resulted in an adverse event. Briefly, NASA researchers who initiated the research collaborated with researchers at a university that had appropriate facilities to conduct the research. In this case, the IRB at the participating university approved the research. However, NASA requirements at the time required review of the research by the Johnson IRB. Further, despite review by the IRB at the other institution, the Johnson IRB may have had more appropriate expertise dealing with microgravity conditions to review this research.

IRB officials stated that many efforts have been taken to ensure that Johnson researchers, whether in the Space and Life Sciences Directorate or not, are aware of the requirement to have research involving human participation reviewed by the IRB.

Recommendation 6: Johnson management should ensure that all basic or operational research involving humans as research subjects sponsored or initiated by Johnson investigators be reviewed by the Johnson IRB. Further, if this research occurs at non-NASA facilities, this research must be receive IRB approval from the institution's IRB. In addition, if this research protocol poses unique or particularly complex hazards that may be unique to NASA research or beyond the capabilities of a university's IRB, a Johnson IRB review should be required.

SUMMARY AND EVALUATION OF NASA MANAGEMENT'S RESPONSE

We received and evaluated NASA management's response to the draft report (See Appendix A). NASA management concurred with all six recommendations and provided planned actions that are responsive to the recommendations. We consider these six recommendations resolved pending verification of corrective action.

[18] "Operational" research, as defined by NASA, is applied research that is necessary to support crew safety for flight. Program managers or directors often initiate operational research. Regardless of whether research is operational or basic, peer-reviewed science, IRB review is required if human subjects are involved. As 14 CFR 1230 states, IRB review is required for all research that obtains data through intervention or interaction with the individual or identifiable private information. Intervention includes both the physical procedures by which data are gathered and the manipulations of the subject or the subject's environment that are performed in order to collect data.

CONCLUSION

Research involving humans as research subjects is important for NASA to further technological advances, to design and operate space-based systems, and to maximize the health, well-being and productivity of humans in the exploration and utilization of space. The IRB review is essential for the safety and integrity of research involving humans as research subjects. We believe the recommendations we make in this report will increase the efficiency and effectiveness of the Johnson IRB.

[original signed by]
David M. Cushing

3 Enclosures:
Appendix A: NASA Management Response
Appendix B: Report Distribution
NASA Office of Inspector General Reader Survey

MAJOR CONTRIBUTORS TO THIS REPORT

Dana M. Mellerio, Director, Information Technology and Security Assessments
Dr. Holly K. Patton, Aerospace Technologist (team leader)

Appendix A

NASA Management Response

Action Plan
for
Implementation of the OIG Recommendations
on the
Assessment of the Institutional Review Board for Human Subject Protection at the Johnson Space Center

The Office of the Inspector General (OIG) conducted a study of the policies and procedures of the Institutional Review Board (IRB) for Human Subject Protection at the Johnson Space Center (JSC). The Report and Recommendations from the OIG were distributed to NASA internal offices on July 11, 2001. All of the recommendations were addressed to the Chief Health and Medical Officer and the Associate Administrator of the Office of Space Flight. The purpose of this action plan is to lay out the approach to addressing these recommendations and to assign responsibilities and dates for the completion of these actions.

The Office of the Chief Health and Medical Officer (OCHMO) concurs on all the recommendations of the OIG.

Recommendation 1: "In keeping with the direction of 14 CFR 1230.114, the JSC IRB should maintain a record of vote counts and publish them in their minutes."

Action #1: The OCHMO shall direct that the JSC IRB minutes (and all other approved NASA Field Center IRB minutes) will reflect the vote for each proposal. The vote of the IRB committee shall be recorded thusly: "Members for Acceptance of the Proposal," "Members Against Acceptance of the Proposal," and "Members Abstaining from the Vote." It is anticipated that most of IRB decisions will be determined by the principle of consensus. Even if consensus is achieved, votes will be tallied and published in the meeting minutes.

Additionally, the JSC IRB recently decided to explicitly not identify members by name in the meeting minutes because that might inhibit critical comments being freely expressed to the committee.

Assigned: Chairs of the respective Field Centers IRB

Completion: Immediately on receipt of notification from the OCHMO.

Recommendation 2: "In order to ensure that IRB decisions are made by individuals who are well informed and have had appropriate time to review proposals and associated documents, the Chief Health and Medical Officer and Space and Life Sciences management should re-evaluate proposal review time commitments. This evaluation of the review process should consider if there are procedural requirements that absorb the time and attention of IRB members, if proposal distribution prior to meetings allows for appropriate member review, or determine what other factors may impinge on IRB members duties and how to best address these issues. JSC management should also consider the importance of participation of their employees in the IRB process and allot appropriate duty time to perform this function."

Action #2: The OCHMO shall request that an internal review be performed by each NASA Field Center to evaluate whether IRB members have appropriate work time set aside to adequately review proposals and associated documents. The Center Director shall notify the Chief Health and Medical Officer of the reviews findings, and recommendations, and what changes were instituted by the Center Director.

Assigned: Directors, Field Center having approved IRB committees.

Completion: March 30, 2002

Recommendation 3: "The Chief Health and Medical Officer and the Space and Life Sciences management should reconsider the decision to review all research funded at NASA, if that research has been previously reviewed by the originating university's IRB. However, when making this assessment these NASA officials should establish criteria such that, when a research protocol poses unique or particularly complex hazards that may be beyond the capabilities of a university's IRB, a JSC IRB review is required. Thus, when selecting research for funding NASA program officials should determine whether to accept only the university's IRB approval or require the review of the JSC IRB."

Action #3. NASA Policy Directive (NPD) 7100.8x, "Protection of Human Research Subjects," allows each individual Field Center the discretion to determine the level of IRB review of extramural research requiring human subjects that has been submitted to NASA for funding that does not have a NASA co-investigator or use NASA facilities or equipment. (Research requiring human subjects that use NASA personnel, facilities or equipment is required to undergo a NASA IRB review.)

Recommendation 4: "The JSC IRB should make the education and training of new IRB members a priority. The Chief Health and Medical Officer and the IRB Chair should verify that all new members receive a policy handbook and have had some introduction to IRB function and processes before participating in the IRB process."

Action #4. Currently a revised NPD 7100.8x "Protection of Human Research Subjects" is undergoing NASA review with its companion document NPG 7100.xx. The revised NPD and new NPG requires that IRB members receive appropriate and continuing education for their IRB duties for both new and continuing IRB members. Completion of this requirement will be documented by the IRB and this information forwarded on a timely basis to the OCHMO.

Assigned: Chief Health and Medical Officer and the appropriate Field Centers.

Completion: NPD 7100.8x approval is pending and NPG 7100.xx is currently in the NASA review cycle (annually, beginning 2002).

Recommendation 5: "NASA should revise its policy, NPD 7100.8x, to require periodic evaluation (not less than once every five years) of IRB's for their effectiveness, as well as such areas as record retention, time commitment, controversial issues, personnel and expertise issues, appropriateness of continuing reviews, and IRB independence."

Action #5. NASA Procedures and Guidelines (NPG) 7100.8x, pending final approval, outlines the implementing procedures and guidelines for the Agency to conduct, or support research involving human subjects. Information addressing IRB evaluation, record retention, time commitment, controversial issues, personnel and expertise issues, appropriateness of continuing reviews, and IRB independence are covered in the compendium NPG 7100.xx (currently in the NASA review cycle).

Since the OIG audit, Theradex Corporation completed an audit of the JSC IRB and its records (April 30, 2001). Their recommendations have been incorporated into JSC IRB procedures. Further, the chairman of the JSC IRB sent informational letters to each principal investigator performing human research funded by NASA JSC programs. Each principal investigator was asked to review these procedural recommendations and then respond to the contracting officer's technical representative (COTR) with a statement documenting their intent to implement these recommendations as appropriate for their research.

An audit of the IRB at the Ames Research Center has also already been completed and the recommendations are being evaluated.

Assigned: OCHMO

Completion: See Action #4 regarding approval of NPD 7100.8x & NPG 7100.xx. Review of IRB activities is required annually and the evaluation for renewal of the IRB charter (Multiple Project Assurance) by the OCHMO is required at least every 5 years.

Recommendation 6: "JSC management should ensure that all basic or operational research involving humans as research subjects sponsored or initiated by JSC investigators be reviewed by the JSC IRB. Further, if this research occurs at non-NASA facilities, this research must be receive IRB approval from the institution's IRB. In addition, if this research protocol poses unique or particularly complex hazards that may be unique to NASA research or beyond the capabilities of a university's IRB, a Johnson IRB review should be required. "

Action #6: The OCHMO shall develop an educational program and require that each Field Center initiate appropriate activities to instruct NASA employees and on-site contractors who potentially could become or currently are investigators using human subjects on IRB requirements on a regular basis. The OCHMO is working with the Director, Office for Human Research Protections, a new office in the Department of Health and Human Services, for research educational instruction.

The Space and Life Sciences Directorate memorandum, dated August 17, 1998 (see Attachment 5), has instituted a vigorous program to prevent such occurrences. All human research conducted under a cooperative or reimbursable arrangement or agreement entered into by JSC and another Government agency, private entity, non-Federal public entity, or foreign entity must comply with the terms and conditions of Johnson Procedures Guidelines (JPG) 1107.1 (see Attachment 9) and NPD 7100.8C.

Completion: Ongoing

Concurrence:

Joseph H. Rothenberg
Associate Administrator for Space Flight

Approved:

Richard S. Williams, MD, FACS
Chief Health and Medical Officer

Appendix B

Report Distribution

Distribution

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Q/Associate Administrator for Safety & Mission Assurance
U/Acting Associate Administrator for Biological & Physical Research
Director/Lyndon B. Johnson Space Center
Chief Health & Medical Officer/Lyndon B. Johnson Space Center
Chair, Johnson Institutional Review Board/Lyndon B. Johnson Space Center

NASA Advisory Officials:

Chairman, NASA Aerospace Safety Advisory Panel
Chairman, Space Flight Advisory Committee
Chairman, Life & Microgravity Sciences and Applications Advisory Committee

Non-NASA Federal Organizations and Individuals:

Assistant to the President for Science and Technology Policy
Deputy Associate Director, Energy and Science Division, Office of Management and Budget
Budget Examiner, Energy Science Division, Office of Management and Budget
Associate Director, National Security and International Affairs Division, General Accounting Office
Professional Assistant, Senate Subcommittee on Science, Technology, and Space

Chairman and Ranking Minority Member of Each of the Following Congressional Committees and Subcommittees:

Senate Committee on Appropriations
Senate Subcommittee on VA-HUD-Independent Agencies
Senate Committee on Commerce, Science and Transportation
Senate Subcommittee on Science, Technology and Space
Senate Committee on Governmental Affairs
House Committee on Appropriations
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Report: Assessment of the Institutional Review Board for Human Subject Protection at the Johnson Space Center, G-01-002

Please circle the appropriate rating for the following statements.

		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
1.	The report was clear and readable	5	4	3	2	1	N/A
2.	The report was logically organized	5	4	3	2	1	N/A
3.	The report was concise and to the point	5	4	3	2	1	N/A
4.	The facts were presented fairly and accurately	5	4	3	2	1	N/A
5.	The report contained sufficient information to support the finding(s) in a balanced and objective manner	5	4	3	2	1	N/A
6.	The recommendation(s) made sense and were relevant	5	4	3	2	1	N/A
7.	The recommendation(s) were timely	5	4	3	2	1	N/A

Overall, how would you rate the report?

Excellent Fair
Very Good Poor
Good

How could we improve the report? _____

_____

_____

Are there steps we should have taken, but didn't? _____

_____

_____

Is there anything else we should have done differently?_____

_____

_____

How did you use the report? _____

_____

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Can you suggest any additional (related or unrelated) issues that the NASA Office of Inspector General should review? (You can also call our anonymous 24-hour Hotline at 1-800-424-9183) _____

_____

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Additional comments _____

_____

_____

_____

Your occupation

Congressional Staff
NASA Employee
Private Citizen
Government: Federal: _____ State: _____ Local: _____
Media
Public Interest
Other: _____

May we contact you about your comments?

Yes: _____ **No: _____**
Name: _____
Telephone: _____

Thank you for completing this survey.