ORDER

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

9500.25

10/16/96

SUBJ: **PROTECTION OF HUMAN RESEARCH SUBJECTS**

1. PURPOSE. This order establishes standardized policies and procedures for conducting research involving human test subjects and promulgates the model Federal policy for protection of human subjects in research conducted or sponsored by the Federal Aviation Administration (FAA). This order establishes the Institutional Review Board (IRB).

2. DISTRIBUTION. This order is distributed to the director level in Washington, regions, and centers, with a branch level distribution in the Office of Aviation Medicine and at the Technical Center.

3. EFFECTIVE DATE. This order shall become effective on October 1, 1996.

4. BACKGROUND. In December 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the Commission) issued a report which included a recommendation that Federal agencies engaged in research involving human subjects adopt the pertinent regulations of the Department of Health and Human Services (DHHS). These regulations, specified in 45 CFR, Part 46, deal with requirements for protection of human research subjects. In response to the Commission's recommendation, in March 1982, the Chairman of the Federal Coordination Council for Science, Engineering and Technology appointed an Ad Hoc Committee for the Protection of Human Research Subjects. The Ad Hoc Committee, composed of representatives of affected departments and agencies, developed a Model Policy which applies to research involving human subjects that is conducted, supported, or regulated by Federal departments and agencies. This policy is based on Subpart A of 45 CFR, Part 46. On January 8, 1984, the Secretary of Transportation agreed to implement the Model Policy without exception. The final form of this Model Policy was promulgated on June 18, 1991. This order specifies procedures that are in accordance with the Model Policy. Subsequent to the promulgation of the Model Policy, the Office of the Secretary of Transportation identified the Office of Aviation Medicine as the Department of Transportation representative on the Interagency Human Subjects Coordinating Committee. This order, dealing with the FAA program for protection of human research subjects, follows from that responsibility.

5. DEFINITIONS.

a. Assurance (Multiple Projects, (or) Single Project) means the written documentation, satisfactory to the Administrator, required from the prospective performing institution that ensures institutional compliance with and implementation of appropriate procedures for the protection of human research subjects.

b. Certification is the official notification to FAA by an institution or internal FAA component, in accordance with the requirements of 49 CFR Part 11, that a research project or activity involving human subjects has been reviewed and approved by an Institutional Review Board in accordance with an approved assurance.

c. Contracting Officer is a person authorized to enter into, administer, or terminate contracts and to make related determinations and findings.

d. Expedited Review is a review procedure carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. Only those research proposals which involve no more than minimal risk may utilize this review process. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited review procedures as set forth in 49 CFR Part 11, and further specified in this order.

e. Human Subject is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

f. Informed Consent is the legally effective consent by the human research subject, or the subject's legally authorized representative, to participate in research covered under this policy. It is obtained after providing to the subject the basic elements of informed consent as set forth in 49 CFR Part 11. Informed consent documents shall include disclosure of all potential risks and related consequences or adverse effects, as well as any benefits that may occur as a result of such participation.

g. Institution is any public or private entity or agency (including Federal, State, and other agencies).

h. Institutional Review Board (IRB) is a board or committee charged with the responsibility for review of research activities involving human subjects conducted at, or sponsored by, the institution and approved by DHHS or FAA. The composition of the IRB and details of its procedures and responsibilities are specified in 49 CFR Part 11 and included in the multiple, single, or other project assurance.

i. IRB Approval is the determination of the IRB that the research has been reviewed and may be conducted at an institution or facility within the constraints set forth by the IRB and by other institutional and Federal requirements.

j. Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

k. Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of this order, whether or not they are conducted under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

6. POLICY. It is the policy of FAA to ensure the safety and well-being of all human subjects taking part in FAA-sponsored or FAA-conducted scientific research, and to adhere strictly to the provisions of the Federal Policy for the Protection of Human Subjects.

7. SCOPE. This order shall apply to all research involving humans as test subjects conducted by FAA, by or under the direct supervision of an FAA employee, or an employee detailed to FAA from industry or a university or from another Government agency and to all contractors and subcontractors performing work for FAA as provided by law and/or contract, and as implemented by the appropriate contracting officer.

8. RESPONSIBILITIES AND AUTHORITIES.

a. The Administrator establishes the FAA policy for the protection of human subjects consistent with 49 CFR Part 11.

b. Federal Air Surgeon (AAM-1) is responsible for the implementation of 49 CFR Part 11 within FAA in accordance with the policy established by the Administrator.

c. Principal Investigators of any research projects involving human subjects are responsible for ensuring that the protections afforded subjects under 49 CFR Part 11 are maintained and that all proposed research falling within the scope of this order is submitted for review as described herein.

d. Contracting Officers are responsible for the inclusion of appropriate language in all research projects falling within the scope of this order which shall ensure that all contracted research activities involving human subjects are conducted in accordance with 49 CFR Part 11. They shall also ensure that performing organizations have completed appropriate Single or Multiple Project Assurances, in accordance with 49 CFR 11.103. The Contracting Officers are assisted by the Contracting Officer's Technical Representative (COTR) who normally is in day-to-day contact with the execution of a research project and is therefore in a position to be aware of deviations from the provisions of this order and 49 CFR Part 11.

9. PROCEDURES

a. FAA Institutional Review Board. A committee composed of at least five persons shall be constituted to evaluate matters within the scope of this order. The committee shall be called the FAA IRB and shall be empowered to review all research conducted in FAA which falls within the scope of this order. This IRB represents the Federal Air Surgeon and shall approve all research having FAA involvement judged to contain above minimal human subject risk. With the approval of the Federal Air Surgeon, other IRB's may be constituted by individual offices within FAA to review research falling within their particular domain. The membership and actions of these other boards shall, however, be subject to the review and approval of the Federal Air Surgeon. Research sponsored by FAA but performed by another organization (for example, a university or the Volpe Transportation Systems Center) shall be reviewed by the IRB of the performing organization in accordance with 49 CFR Part 11.109.

b. Composition of the FAA IRB. The FAA IRB shall consist of at least five members appointed by the Federal Air Surgeon or her/his designee. The chair of the FAA IRB shall be appointed by the Federal Air Surgeon for a 1-year term. Additional members, beyond the minimum, may be appointed by the Federal Air Surgeon. Members shall be appointed for 1-year terms. In order to comply with the requirements of the Federal Advisory Committee Act (Public Law 92-463, Title 5, U.S. Code, Appendix II), all members of the IRB shall be Federal employees or under contract to FAA. This requirement also applies to the ad hoc members described in paragraph 9. The membership of the IRB shall be diverse, with, at a minimum, the following members:

(1) One member who is a physician, with clinical experience or specialization in aerospace medicine.

(2) One member with expertise in the behavioral and social sciences.

(3) One member who is not an employee of FAA, with expertise in ethics. This member, if not a Federal employee, must be under contract to FAA in order to comply with the Federal Advisory Committee Act, as noted above.

(4) One member with expertise in safety or industrial hygiene. In addition to review of research protocols, this member also shall, at the direction of the IRB Chair, conduct on-site inspections to assess overall safety of the proposed research projects.

(5) One member representing the FAA Chief Counsel.

c. Ad hoc members of the FAA IRB. In the event a proposed project utilizes members of groups at special risk (for example, institutionalized, disabled, children) an expert familiar with that particular group shall be included as an ad hoc member of the IRB. Ad hoc members may also be appointed to provide special expertise related to a proposed project under review. Ad hoc members are appointed by the FAA IRB Chair for specific project reviews and do not take part in discussions or vote on projects beyond the specific project for which their expertise was required.

d. Prohibitions against conflicts of interest.

(1) Scientific Conflict of Interest - Members of the IRB whose projects are under review shall recuse themselves from voting, but may, at the discretion of the IRB Chair, participate in discussions. This prohibition shall also apply to supervisors and other managers of scientists whose research projects are under review. Scientists whose research projects are under review are specifically excluded from ad hoc membership.

(2) Financial Conflict of Interest - No member of the IRB shall participate in IRB proceedings concerning a project in which the member, the member's family, employer, or partner, or an organization in which the member serves as officer, director, or trustee, or an organization with whom the member is negotiating or has any arrangement concerning prospective employment, has a financial interest without a written waiver issued by the IRB Chair, with the concurrence of the Chief Counsel's IRB representative.

e. Frequency of Meetings. Meetings will be called annually or more frequently as determined by the IRB Chair to meet review needs. Meetings shall also be called by the IRB Chair as necessary to consider unprogrammed research, changes in approved protocols, or petitions for waivers.

f. Determination of Requirement for IRB Review. Section 101 of the Federal Policy for the Protection of Human Research Subjects (49 CFR Part 11.101) shall be used to determine whether planned research is covered by provisions of this policy. Research determined to be exempt from this policy shall not be subject to further review under this order. The Federal Air Surgeon shall have the authority to approve non-exempt human research and to grant exceptions and waivers. This authority may be further delegated to the Chair of the FAA IRB described in paragraph 9b.

g. Application for Review. The senior task scientist (principal investigator) performing any research as described in this order shall submit a research application to the IRB in a format to be provided by the IRB Chair. Each application shall include an assurance of compliance with Federal regulations for protection of human research subjects utilizing a format designated by the IRB. This or a related document will be utilized to document compliance with the model Federal program policy on human research subjects. In addition to any other information which the IRB deems necessary for the review of a proposed research project, this application shall include information on:

(1) Research protocol.

(2) Subjects to be used, including both numbers and types of subjects.

(3) Use of any additionally protected groups, such as children.

(4) Provisions to ensure privacy and confidentiality of subject data.

(5) Ethical considerations, including assessment of physical risk, safety precautions, and provisions for medical assistance.

(6) Informed consent, including a copy of the consent document to be used.

(7) An explanation of why this project qualifies for exempted or expedited review, if appropriate.

h. IRB Review Process and Criteria:

(1) Members of the IRB will be provided copies of experiment protocols requiring evaluation no later than 1 month prior to the IRB meeting dates set by the Chair. Changes to an approved protocol must also be resubmitted to the IRB Chair, who will retain the prerogative of recommending exceptions, expeditious reviews, and interim approval pending either routine notification of IRB members or the reconvening of the full IRB.

(2) Any waiver request to previously approved protocols must be submitted to the IRB within a reasonable time before the planned initiation of the human research. However, failure of the IRB to respond to a request does not constitute approval of the request.

(3) The IRB has a responsibility to provide timely responses, if an experiment protocol change or a waiver request is necessitated by analyses or data becoming available after an experiment has already begun. The IRB Chair retains the prerogative of recommending exceptions, expeditious reviews (as defined in this order), or interim approval or disapproval of such requests, pending either routine notification of IRB members or the reconvening of the IRB.

i. Review of FAA IRB Findings. The Federal Air Surgeon or his designee will be provided with minutes of IRB deliberations and decisions. While expressed review and concurrence is desirable, if the Federal Air Surgeon does not indicate any objections prior to indicated experiment startup dates, this will be considered concurrence with the IRB recommendation.

j. Review of Local IRB Findings. If a local FAA IRB (for example, an IRB approved by the Federal Air Surgeon to review research at the Technical Center) determines the risks associated with a proposed research project to be above minimal, then the minutes of the local FAA IRB deliberations shall be provided to the FAA IRB for review. At a minimum, the information provided shall include that specified in paragraphs 9g(1) through 9g(7). Research shall not commence until the FAA IRB representing the Federal Air Surgeon provides approval.

k. Contracts, Grants, and other Agreements Review. In those contracts, grants, and other agreements referenced above where human research is contemplated, the Contracting Officer shall ensure that an appropriate standard clause is incorporated that requires compliance with the procedures of this order. Because FAA retains ultimate responsibility for the safety of all subjects participating in FAA-sponsored or conducted research, all research involving human subjects for which the performing institution's IRB has determined the risk to be more than minimal shall be reviewed by the FAA IRB. Research shall not commence until the FAA IRB representing the Federal Air Surgeon provides approval.

10.SPECIAL CLASSES OF SUBJECTS. Research which involves members of special classes of subjects shall receive special attention by the IRB. Particular attention must be applied in these cases to assess the risks involved and the degree to which informed, voluntary consent to participate has been obtained. At a minimum, when considering research involving members of these or similar groups, the IRB shall incorporate members possessing special expertise with the subject group and shall require evidence from the investigator that due consideration has been given to the use of other classes of subjects. These groups include:

a. Pregnant and lactating women.

b. Children.

c. Mentally Disabled.

d. Prisoners.

11. INTERNATIONAL STUDIES. For all studies conducted outside the United States, FAA requires that a review and approval process functionally equivalent to the IRB be conducted, and that the studies be conducted in conformance with the ethical principles outlined in the Declaration of Helsinki or with the laws and regulations of the country in which the research is conducted, whichever provides the greater subject protection.

12. RECORDKEEPING FOR SUBJECT IDENTIFICATION. For all studies not falling under the exempted or expedited review provisions as specified in paragraph 13, a record shall be maintained of all subjects who participate. At a minimum that record shall include the subject's name, mailing address, and, if available, telephone number. This record shall be maintained for a minimum of 5 years after termination of the subject's involvement in the study and shall be utilized to contact subjects in the event post hoc analyses or later scientific findings indicate that the subject has been exposed to greater risk during the study than was described in the informed consent.

13. EXEMPTED REVIEW. Research which meets the specifications of 49 CFR Part 11.101 is exempt from IRB review and is not subject to further review under this order.

14. EXPEDITED REVIEW. If the Chair of the IRB and at least one other member judge a research proposal to meet the specifications of 49 CFR Part 11.110, involving no more than minimal risk or review of minor changes in previously approved research, an expedited review process may be used. Review of research found to qualify for expedited review may be carried out by the IRB Chair.

15. REQUESTS FOR INFORMATION. Additional information on the requirements of this order may be obtained from the Biomedical and Behavioral Sciences Branch (AAM-240), the Human Resources Research Division (AAM-500), or the Aeromedical Research Division (AAM-600) .

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Administrator