



U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

ORDER
9950.3B

2/6/06

SUBJ: MEDICAL RESEARCH PROGRAM GUIDE

1. **PURPOSE.** This order delineates responsibilities and procedures for the approval, conduct, and review of all research projects conducted under the Office of Aerospace Medicine (AAM) Research, Engineering and Development (RE&D) Program.
2. **DISTRIBUTION.** This order is distributed to the director level in Washington headquarters, regions and centers, with a branch level distribution in the Office of Aerospace Medicine, and the Aerospace Medical Divisions in the regions.
3. **CANCELLATION.** Order 9950.3A, Office of Aviation Medicine Research Program, dated December 6, 1974 is canceled.
4. **BACKGROUND.** The Civil Aerospace Medical Institute (CAMI) is a mandated organization with an overall mission of aviation safety. CAMI was established as part of the Federal Aviation Act of 1958 under Section 106 Title 49 United States Code, subsection j. The research component of the mission was specifically authorized as an amendment to the Federal Aviation Act of 1958 (49 U.S.C. App. 1353, section 312e, codified as 49 U.S.C. Section 44507, July 5, 1994). That authorization, further clarified in the Aviation Safety Research Act (Public Law 100-591, 1988), helped to define the aeromedical and human factors research programs that would be conducted by CAMI. Emphasis was placed on: (a) protection and survival of aircraft occupants; (b) medical accident investigation and airman medical certification; (c) toxicology and the effects of drugs on human performance; (d) the impact of disease and disability on human performance; (e) vision and its relationship to human performance and equipment design; (f) human factors of flight crews, air traffic controllers, mechanics, inspectors, airway facility technicians, and other persons involved in the operation and maintenance of aircraft and air traffic control equipment; and (g) agency workforce optimization, including training, equipment redesign, reduction of errors, and identification of candidate tasks for automation. This order provides documentation of the procedures for implementing the Federal Aviation Act and the Aviation Safety Research Act of 1988 (Public Law 100-591) and further defines those steps that ensure optimum benefit-to-cost ratios in the execution of AAM's components of the FAA RE&D program.
5. **DEFINITIONS.**
 - a. **AAM Technical Report.** A scientific report of research results written in technical language, consisting of relevant data and specific recommendations.

b. **Ad Hoc Committees.** Groups appointed to perform specific tasks. Generally, the period of appointment will not exceed six months. Ad hoc committees may be appointed by the Director of CAMI or by the Chairperson of the Research Committee, or there may be subcommittees formed by any standing committee.

c. **Human Subject.** A person about or from whom an investigator obtains research data.

d. **Human Use.** Research involving human subjects.

e. **Institutional Review Board (IRB).** A board or committee charged with the responsibility for review of research activities involving human subjects conducted at, or sponsored by, the institution. The composition of the IRB and details of its procedures and responsibilities are specified in 45 CFR Part 46 and FAA Order 9500.25, Protection of Human Research Subjects.

f. **Principal Investigator.** The individual who is primarily responsible for the scientific content, conduct, and completion of research.

g. **Protocol.** The documented plan for the conduct of a scientific research project.

h. **Quality Assurance.** Monitoring, evaluating, and improving research projects.

i. **Research, Engineering, and Development (RE&D) Funds.** Funds specially appropriated for Research, Engineering and Development projects.

j. **Research.** Scientific investigations and experimentation having as their aim: the discovery of new facts and their correct interpretation; the revision of accepted conclusions, theories, or laws in the light of newly discovered facts; or the practical applications of such new or revised conclusions, theories, or laws.

k. **Research Committee.** The group responsible for reviewing the overall AAM research effort to ensure scientific merit and benefits for research sponsors.

l. **Scientific Member.** A member of a standing committee who possesses an earned graduate degree in one of the sciences or holds an engineering degree and is assigned or employed in the discipline of that degree.

6. **GOALS.** The mission of the Office of Aerospace Medicine is to provide the safest, most efficient and responsive aeromedical system in the world. To meet this challenge the research program is dedicated to:

a. Reduce accidents/incidents due to biomedical and human factors and decrease injuries and loss of life resulting from accidents which do occur;

b. Develop advisory circulars and aeromedical standards for aviation personnel based on valid aeromedical and human factors data;

c. Maintain an effective FAA workforce; and

d. Maintain high professional standards for advancement of aeromedical and human factors research.

7. **SCOPE.** This order guides personnel who manage or conduct research under the immediate purview of the Federal Air Surgeon (FAS).

8. **OBJECTIVES.** Biomedical and human factors affect safety in aviation. The Aerospace Medicine Research Program (AMRP) will address the conditions and problems encountered in aviation environments and enhance the health and safety of all who work in or utilize the National Airspace System. Investigators will utilize state-of-the-art and innovative methods and techniques, and maintain the highest professional standards. Managers will keep to a minimum the reporting requirements placed on investigators so as to conserve investigators' time and energy for their primary function: the conduct of research. Experimental techniques and procedures will conform to federal regulations and human use guidelines, ensuring that the rights, dignity, safety, and well-being of human participants are maintained. AAM scientists will participate in the activities of their respective scientific societies. Procedures utilized in animal investigations will be in full compliance with federal guidelines. The AMRP will be conducted in accordance with procedures established for the RE&D process of the FAA.

9. **COMPOSITION OF RESEARCH COMMITTEE.** The Research Committee shall consist of the following: Chairperson (CAMI Director Designee), CAMI Division Managers, Medical Specialties Division Manager, a Regional Flight Surgeon representative, and the AAM senior representative to the FAA RE&D process. Other AAM managers may participate as non-voting members. During review of research proposals, a peer review specialist from outside the agency will be added to the Committee as a non-voting member to provide an external review and to provide recommendations. FAA personnel and budget representatives, and legal representatives from the Assistant Chief Counsel's Office at the Aeronautical Center will serve as resource persons but will not actively participate in the decisions. A quorum will consist of five voting members. A committee member will not vote on a proposal when that person is the principal investigator or co-investigator. Voting will ordinarily be by hand count, although it may be by written ballot if so specified by the chairperson. Findings of the meetings will be recorded.

10. **RESPONSIBILITIES OF COMMITTEES AND INDIVIDUALS.** Tasks which must be accomplished by the individuals or committees listed in paragraphs 10a through 10f., below, can be delegated. However, responsibility for accomplishment of those tasks may not be delegated.

a. **Director, CAMI.** The CAMI Director has the responsibility for all four of the Institute's missions: aeromedical certification, occupational health, education, and research. Additionally, the Director is delegated by the FAS the responsibility to review, approve, modify, and close-out research proposals and programs, in coordination with the appropriate sponsor(s). The Director will appoint the chairperson of the Research Committee.

b. **Chairperson, Research Committee.** This individual presides over meetings of the Research Committee, forwards the recommendations of that committee to the CAMI Director for

approval/disapproval, appoints the regional flight surgeon representative to the Research Committee, and appoints ad hoc committees, as appropriate, to function in the area of research.

c. **Research Committee.** This committee is responsible for oversight of all AAM research programs, regardless of funding source. The committee will ensure that all human and animal use considerations have been properly reviewed. The committee will meet quarterly unless determined unnecessary by the chairperson. The committee may also meet at the special call of the chairperson. At regular meetings, the committee will evaluate proposals for research, review research accomplishments, update priorities, and make recommendations to the Director of CAMI.

d. **Division Managers, AAM.** Each manager is responsible for ensuring that any research proposal originating within his/her division has scientific merit. Managers conduct their research in accordance with FAA RE&D policies and procedures and will be responsible for the periodic review of the scientific credentials of every principal investigator. Division managers ensure that any proposal submitted to the IRB or Research Committee is complete and in the proper format.

e. **CAMI Program Management Specialist.** Or designee appointed by the CAMI Director:

(1) Is responsible for:

(a) Maintaining a file of all current research tasks and all research tasks completed or otherwise closed in accordance with appropriate guidelines;

(b) Assisting investigators or responsible individuals in coordinating, organizing and developing cost data and budget estimates by research task for inclusion in proposals;

(c) Monitoring and providing the current budget status; and

(d) Maintaining financial records on tasks and maintaining records necessary to secure reimbursable costs of tasks.

(2) Is the point of contact to assess availability of resources to support projects and will coordinate those resources.

(3) Maintains currency with respect to continuing regulatory and statutory constraints and communicates them appropriately.

(4) Ensures that all research is administratively consistent with FAA RE&D policies and procedures.

f. **Legal Counsel.** The Assistant Chief Counsel's Office at the Aeronautical Center provides legal advice to the research committee.

11. RESEARCH SPONSORSHIP. The AMRP is conducted as a component of the Agency's RE&D program. All research projects must be authorized by AAM, and by another agency sponsoring organization as appropriate. AAM researchers will regularly interact with sponsors and potential sponsors to determine their research requirements. Teams of sponsors and research providers develop coherent programs that can be accomplished within expected budgets.

12. RESEARCH GUIDELINES. AAM conducts an internal program to assure the quality of its research. The AMRP consists of a core program of planned research and of research activity which responds to urgent, unforecasted requirements. All components support the agency's fundamental mission areas such as capacity, safety, security, and efficiency.

a. **Consideration of Research Ideas.** The submission of research needs and ideas is encouraged from all sources, e.g., individual FAA scientists, the operational FAA field and headquarters personnel, the civil aviation community and other interested industries, universities, and governmental groups. Research ideas (solicited and unsolicited) developed separate of official FAA research sponsorship will be submitted to the Research Committee chairperson and presented to the Committee for evaluation. Ideas consistent with the FAA research program will be forwarded for coordination with the research sponsor.

b. **Consideration of Proposals.** Proposals to be considered by the Research Committee must be completed in the format specified by the Research Committee.

c. **Required Reviews.** All planned research within AAM whether for in-house, grants, or contractual execution will be reviewed by: the branch and division concerned; an IRB, if human subjects are involved; and the Research Committee. The principal investigator performing research as described in this order shall submit a research proposal to the Research Committee in a format provided by the committee. The Research Committee will review the research proposal and project plans to assure their technical merit and benefits for the research sponsor. Committee recommendations will be forwarded to the CAMI Director for appropriate action.

d. **General Requirements.**

(1) All procurements will follow FAA policies and procedures, in accordance with the FAA Acquisition Management System and DOT Regulations on Employee Responsibilities and Conduct required in FAA Order 3750.3C, Orientation to Government-Wide Standards of Conduct.

(2) Projects conducted in collaboration with any agency, department, or organization must state in an agreement that at least one AAM staff member is designated as principal investigator, co-investigator, or associate investigator.


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