U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
National Policy

ORDER
AM 9950.3C

Effective Date:
3/15/07

SUBJ: Aerospace Medicine Research Program

1. Purpose of This Order. This order delineates responsibilities and procedures for the review of research performed under the Office of Aerospace Medicine (AAM) Research, Engineering and Development (RE&D) Program.

2. Audience. 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. Where Can I Find This Order. You can find this order on the Directive Management Information System (DMIS) website: http://dmis.faa.gov.

4. What this Order Cancels. Order 9950.3B, Office of Aerospace Medicine Research Program, dated February 6, 2006 is canceled.

5. 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 4 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), and the Wendell H. Ford Aviation Investment and Reform Act (4/6/2000), 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.

(h) This order provides documentation of the procedures for implementing the aforementioned Acts 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.

6. Definitions.

(a) Human Research Subject. A person about or from whom an investigator obtains research data.

(b) Human-Use. Research involving human subjects.

(c) Institutional Review Board (IRB). A group charged with the responsibility for review of research activities involving human research subjects conducted at, or sponsored by, the institution. The composition of the IRB and details of its procedures and responsibilities are specified in 49 CFR Part 11 and FAA Order 9500.25, Protection of Human Research Subjects.

(d) Principal Investigator. The individual who is primarily responsible for the scientific content, conduct, and completion of scientific research projects.

(e) 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.

(f) AAM Research Committee. The group responsible for implementing this order.

7. Goals. The mission of the Office of Aerospace Medicine is to *"Enhance aerospace safety through surveillance, research, education, medical standards, and prevention of illness and injury."* To meet this challenge the research program is dedicated to:

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

(b) Developing advisory circulars, aeromedical standards for aviation personnel based on valid aeromedical and human factors data, technical reports, open scientific literature articles;

(c) Providing research information for science-based decision making processes;

(d) Maintaining an effective FAA workforce; and

(e) Maintaining high professional standards for advancement of aeromedical and human factors research.

8. Scope. This order guides personnel who manage or conduct aeromedical and human factors research under the purview of the Federal Air Surgeon (FAS).

9. Objectives. Biomedical and human factors affect safety in aviation. The Office of Aerospace Medicine Research Program (AAMRP) addresses the conditions and problems encountered in

aviation environments and enhances the health and safety of all who work in or utilize the National Airspace System. Investigators utilize state-of-the-art and innovative methods and techniques, and maintain the highest professional standards. Managers 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 conform to federal regulations and human use guidelines, ensuring that the rights, dignity, safety, and well-being of human participants are maintained. AAM scientists participate in the activities of their respective scientific societies. Procedures utilized in animal investigations will be in full compliance with federal guidelines. The AAMRP will be conducted in accordance with procedures established for the RE&D process of the FAA.

10. AAM Research Committee. The AAM Research Committee shall consist of the following:

(a) Chairperson (CAMI Director Designee)

(b) CAMI Division Managers

(c) AAM Medical Specialties Division Manager

(d) AAM Regional Flight Surgeon representative

Other AAM managers may participate by invitation from the Committee Chairperson. Similarly, FAA personnel, budget representatives, and legal representatives may serve, by invitation through the Committee Chairperson.

11. Responsibilities of Committee and Individuals. Tasks which must be accomplished by the individuals or committees listed in paragraphs 11a through 11d below, can be delegated. However, responsibility for accomplishment of those tasks may not be delegated.

(a) Director, CAMI. The CAMI Director has responsibility for all four of the Institute's missions: Aeromedical Certification, Occupational Health, Education, and Research. 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 AAM Research Committee. The AAM Research Committee will assist the director to accomplish the tasks above.

(b) AAM Research Committee. The AAM Research Committee will take a holistic approach to establishing the direction of the AAM research program by responding to the agency's fundamental mission areas such as capacity, safety, security, and efficiency. The committee will be responsible for reviewing AAM research programs, regardless of funding source. The committee will ensure that human and animal use considerations have been properly addressed. It will review requirements established by Technical Community Representative Groups (TCRG), update AAM research priorities, review research accomplishments, identify gaps and opportunities for collaboration, and make recommendations regarding the direction of AAM's aerospace medical and human factors research to the CAMI

Director and the TCRGs. The committee will meet quarterly unless determined unnecessary by the chairperson.

(c) Chairperson, AAM Research Committee. This individual presides over meetings of the AAM Research Committee, archives and forwards the Committee's meeting minutes and any recommendations to the CAMI Director, and appoints the Regional Flight Surgeon representative to the AAM Research Committee.

(d) Division Managers, AAM. Each Division Manager is responsible for ensuring that any research originating within his/her division has scientific merit and will monitor its execution in terms of financial requirements and organizational resources. Managers oversee the conduct of research in accordance with FAA RE&D policies and procedures, including IRB guidelines when the research involves the use of human subjects and guidelines for the ethical conduct in the care and use of animals.

12. Research Sponsorship. Research projects will be responsive to the Office of Aviation Safety (AVS), Air Traffic Organization (ATO), TCRGs, or other sponsoring organizations' requirements as appropriate. AAM researchers will regularly interact with sponsors and potential sponsors to determine research requirements. Teams of sponsors and research providers will develop coherent programs that can be accomplished within expected budgets.

13. General AAM Research Requirements.

(a) All personnel shall maintain the highest scientific and ethical standards in the conduct of research and activities associated therein.

(b) Research processes will be conducted in accordance with the International Organization for Standardization (ISO) 9001:2000 standard as implemented through the AVS Quality Management System.

(c) 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.

(d) Any agreement outlining research conducted in collaboration with any agency, department, or organization must contain a statement designating at least one AAM staff member as principal investigator, co-investigator, or associate investigator.

(e) Any research study that involves the use of human subjects must be cleared through the IRB.

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Federal Air Surgeon