

## U.S. DEPARTMENT OF TRANSPORTATION FEDERAL AVIATION ADMINISTRATION

Aerospace Medicine Policy



Effective Date: 9/15/2010

## SUBJ: Aerospace Medicine Research Order

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 MyFAA Employee website: https://employees.faa.gov/tools\_resources/orders\_notices/.

**4. What this Order Cancels.** Order AM 9950.3C Chg 1, Office of Aerospace Medicine Research Program, dated February 19, 2007 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.

6. Purpose. 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.

## 7. 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) Aerospace Medicine Technical Committee Research Group (TCRG). The group responsible for setting priorities for Aeromedical Research for the Aviation Safety (AVS) Research and Development Requirements Portfolio.

(g) AAM Research Committee (AAMRC). The group called together as needed to recommend policy to the Federal Air Surgeon concerning research processes and products.

**8.** 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.

**9.** Scope. This order provides guidance to personnel who manage or conduct aeromedical and human factors research under the purview of the Federal Air Surgeon (FAS).

**10. 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 wellbeing of human participants are maintained. AAM scientists participate in the activities of their respective scientific societies. Procedures utilized in animal investigations (if any) are in full compliance with federal guidelines. The AAMRP is conducted in accordance with procedures established for the RE&D process of the FAA.

11. Aerospace Medicine Technical Committee Research Group (TCRG). The TCRG shall consist of the following:

- (a) AAM-600 Division Manager (Chairperson);
- (b) CAMI Division Managers;
- (c) AAM Medical Specialties Division Manager; and
- (d) AAM Regional Flight Surgeon representative.
- 12. AAM Research Committee (AAMRC). The AAMRC shall consist of the following:
  - (a) CAMI Deputy Director (Chairperson);
  - (b) CAMI Division Managers;
  - (c) IRB Chairman;
  - (d) AAM Medical Specialties Division representative; and

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

**13. Responsibilities of the Aerospace the Aerospace Medicine TCRG, AAMRC and Individuals.** Tasks which must be accomplished by the members of the Aerospace Medicine TCRG and AAMRC can be delegated. However, responsibility for accomplishment of those tasks may not be delegated.

(a) CAMI Director. The CAMI Director has responsibility for the executive oversight of the Institute's programs in Aerospace Medical Certification, Medical Education, Medical Research, Human Factors Research, and Occupational Health. 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 appoints the Regional Flight Surgeon representative to the Aerospace Medicine TCRG, and reviews the task prioritization developed annually by the Aerospace Medicine TCRG for the AVS Research and Development Portfolio.

(b) Aerospace Medicine TCRG. Committee members develop, review, and prioritize requirements for Aeromedical Research for the Aviation Safety (AVS) Research and Development Requirements Portfolio. The TCRG shall meet at least annually. The Chairperson presides over meetings, archives and forwards prioritized requirements to the AVS R&D Manager, Office of Aviation Safety Analytical Services (ASA-100)

(c) AAMRC. This committee advises the CAMI Director and takes a holistic approach to establishing the direction of the AAM research program by responding to the agency's fundamental mission areas such as safety, capacity, security, and efficiency. The committee is responsible for reviewing AAM research programs, regardless of funding source. The committee ensures that human and animal use considerations are properly addressed. The committee reviews (as needed) requirements established by Technical Community Representative Groups (TCRG), updates AAM research priorities, reviews research accomplishments, identifies gaps and opportunities for collaboration, and makes recommendations regarding the direction of AAM's aerospace medical and human factors research programs to the FAS and the CAMI Director.

(d) AAMRC Committee Members. Committee members shall meet annually and as called by the Chair to conduct a high level assessment of aeromedical and human factors research needs and the degree to which the current research programs and tasks address those needs. This includes independent discussion of long-term research directions expected for these research programs, assessment of how research findings should be incorporated into future research plans, and specific research topics needing broader focus. The CAMI Director or the Federal Air Surgeon may call upon the Committee members to review AAM policies, procedures and regulations, and recommend changes or actions based upon research data. The CAMI Deputy Director presides over meetings of the Committee, and archives and forwards the committee's meeting minutes and any recommendations to the CAMI Director and the Federal Air Surgeon.

(e) Research Division Managers. Managers are responsible for ensuring that any research originating within their divisions have scientific merit and will monitor their execution in terms of financial requirement 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.

14. Research Sponsorship. Research tasks 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.

## 15. General AAM Research Requirements.

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

(b) AAM research processes will be conducted in accordance with the International Organization for Standardization (ISO) 9001:2008 standard as implemented through the AVS Quality Management System.

(c) AAM research 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-investigators or associate investigator.

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

Frederick E. Tilton, M.D. Federal Air Surgeon

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