U.S. Department of Transportation
Federal Aviation Administration

Aeromedical Research Resume
Research Project Initiative Subtask for FY01

1. Title:	2. Sponsoring Organization/Focal Point:	3. Originator Name, Organization
Toxicology and Radiobiology Research in Support of Aircraft Accident Analyses and Aircraft Occupant Health	AAI-1: Steven B. Wallace AAM-1: Jon L. Jordan M.D.	Dennis V. Canfield, Ph.D. AAM-610, FAA, CAMI (405) 954-6252
		4. Origination Date: August 2000 Start Date: Oct. 1, 2000
5. Parent RPI Number: 532	6. Subtask Number: AM-B-00-TOX-202	7. Completion Date: September 30, 2003
8. Parent MNS: Aeromedical Research (159)	9. RPI Manager Name, Organization, Phone: James E. Whinnery Ph.D., M.D. AAM-600, FAA, CAMI (405) 954-4808	

10. Research Objective(s):

1. Reduce transportation accidents and major incidents due to drugs, alcohol, and other substances by ascertaining their impact on human performance; by determining their association with accidents and major incidents; and by state of the art chemical/biochemical analysis of their presence in body fluids and tissues of individuals involved in accidents and incidents.

1. 2. Reduce pilot incapacitation causing fatal aviation accidents by continuous evaluation of the medical condition of pilots involved in such accidents and reassessment of existing medical certification standards.

2. 3. Provide regulatory authorities and the public information concerning the effects of drugs, alcohol, and other substances on pilot and crew performance.

4. Determine the impact of ionizing radiation on flight crews and aircraft occupants. Assist in establishing federal regulations to reduce the risk of ionizing radiation to flight crews. Provide an inexpensive means of monitoring exposure and determining the risk of ionizing radiation.

11. Technical Summary: In compliance with PUBLIC LAW 100-591 [H.R. 4686] (November 3, 1988) and NTSB safety recommendation A-84-93, specimens will be collected at aviation accidents/incidents; those specimens will be identified and analyzed for drugs and alcohol. Reliable toxicology data from these tests will be stored in a computerized, searchable form and provided to investigative and regulatory authorities for use in determining the cause of aviation accidents, evaluation of regulatory statues, and to determine trends in the use of alcohol and drugs for the annual report to congress. Information collected will be reported to regulatory authorities and the public. This information will identify drugs and medical conditions that need additional study of their effects on human performance. New procedures will be developed to assist in the identification of commonly prescribed drugs at therapeutic and sub-therapeutic levels. State-of-the-art DNA technology will be applied to identify specimen source and possible confounding components. Information gathered in this research will be used to monitor compliance of pilots with the FAA medical certification regulations. These data will help determine the extent to which drugs and medical conditions are contributing to fatal aviation accidents.

Data derived from collaborative research on ionizing radiation involving people in an enclosed aircraft environment will help determine the risks associated with this environment. This data will provide regulatory authorities the necessary information to establish safety standards and to educate those working and traveling in the National Airspace System.

12. Resources Requirements:	FY01	FY02	FY03
FAA Staff Years	15-18	15-18	18-20

13. Description of Work:

(1) Brief Background

The Toxicology, Biochemistry, and Accident Research Laboratory (TBARL) has collected and archived extensive data on drug and alcohol use. The TBARL will continue to collect data on drugs, alcohol, and other substances in fatal aircraft accidents. Software developments by the TBARL have made it possible to rapidly analyze the available data for requesters. Testing capability permits direct in-house assessment of chemical presence, permitting a wide spectrum of qualitative and quantitative toxicological data collection. The laboratory has a fully functional DNA testing capability for identifying victims of aircraft accidents and identifying infectious diseases present in blood samples. The FAA also has an agreement with the NTSB to conduct drug testing on surface accidents. The Radiobiology Research Team has developed a program to determine exposure to ionizing radiation and the risk to flight crews. That program has been adopted by many European countries to meet the international requirement for monitoring radiation dose to flight crews. This topic is a major issue in the public media because of the expected increase in solar flares.

(2) Statement of Work

The following operational hypotheses will be evaluated:

I. The most prevalent therapeutic and abused drugs in the USA will be routinely detectable by TBARL procedures.

II. The prevalence of drug abuse in pilots of fatal aircraft accidents is at least three times that of the pilots in nonfatal aircraft accidents.

Specimens received from nearly all fatal aviation accidents will be tested for the presence of drugs and alcohol. Analyses and interpretations will be channeled through the FAA's Office of Accident Investigation to the NTSB. Selected evaluations of the impact of drug effects on performance will be investigated in response to research sponsors. New procedures will be developed to assist in the identification of commonly prescribed drugs. To better understand how aircraft occupants become incapacitated or die in fires, new sensitive methods must be developed to analyze cyanide and carbon monoxide in whole blood, as well as in any other available postmortem tissue sample. New DNA procedures will be developed and adopted to assist in the identification of pilot remains and infectious diseases. Additional DNA research will be conducted to differentiate the origin (antemortem ingestion or postmortem production) of alcohol found in aviation accident fatalities. Furthermore, the applicability of the gene expression endpoint in conjunction with other biological endpoints will be explored as an additional tool for aeromedical research. Special quality control programs [external: CAP; internal: CAMI's Postmortem Forensic Toxicology Proficiency-Testing by the Biochemistry Research Team] are maintained to assure data accuracy and integrity. Research into the interaction of hypoxia and the distribution of drugs in biological specimens will be evaluated. The existing program for determining ionizing radiation dose will continue to be improved and evaluated against empirical data collected by researchers.

14. Intended End Products / Deliverables:

Reduce accidents and major incidents due to medical incapacitation of crew by 15% relative to baseline levels noted in the Office of Aviation Medicine Medical Incapacitation Database. Approximately 600 forensic toxicology reports from fatal aviation accidents will be provided annually to the research sponsors. Knowledge gained from this research will yield OAM Technical Reports and scientific research manuscripts. Valuable knowledge gained through this research will help determine the causes of aviation accidents, the interpretation of toxicology reports, the incidence of drug and alcohol use in aviation accidents, and new methods of analysis for the identification and quantitation of drugs. New DNA procedures that prevent misidentification and misinterpretation of specimen analyses will be shared with all federal/state forensic toxicology and law enforcement officials. An annual report to Congress regarding the use of drugs and alcohol in fatal aviation accidents will be provided. A computerized program that will accurately determine the ionizing radiation dose of flight crews and the risk associated with the dose will be developed. This program and information will be made user friendly and provided in an easily accessible internet based format for public utilization.

15. Schedule/Milestones:	***FY01***	***FY02***	***FY03***
1. Accept all post-fatality and select non-fatality specimens for analysis as requested by sponsor.	Continuous	Continuous	Continuous
2. Collaborative study to determine risk factors associated with ionizing radiation to crew members in aviation.	Continuous	Continuous	Continuous
3. Perform need-based DNA analysis of tissues using state-of-the-art techniques.	Continuous	Continuous	Continuous
4. Toxicological/analytical aspects of cyanide and carbon monoxide in aviation accidents.	Q4		
5. Collaborative study on the effects of new antihistamines and hypoxia.	Q3		
6. Publish a manuscript on abused drug RIA screening optimization.	Q3		
7. DNA-based feasibility study for determining the incidence of infectious disease.			Q1
8. Collect DNA data on the incidence of infectious diseases.			Q4
9. Explore application of gene expression for its incorporation into existing biochemical endpoints, and use them in aeromedical research, including postmortem ethanol production.	Continuous	Continuous	Continuous
10. Evaluate alternative chemical methods for determining postmortem ethanol production.		Q4	
11. Develop chemical methods for the determination of postmortem ethanol production.		Q1	
12. Implement new chemical method for determination of postmortem ethanol production.			Q4
13. Develop method for the identification of pilots who use crack cocaine.		Q2	
14. Implement method for the identification of pilots who use crack cocaine.			Q1
15. Develop analytical procedure to differentiate between true opiate ingestion and artifactual morphine production (i.e., develop markers for "Poppy Seed Ingestion").			Q3
16. The distribution of Butabital in biological fluids and tissues	Q1		
17. Case study of sulfide poisoning	Q1		

16. Procurement Strategy/Acquisition Approach/Technology Transfer:

Procurements anticipated in FY-01 follow standard acquisition strategies.

Analytical Equipment Upgrades: 150K
Data Automation Upgrades: 50K

17. Justification/History:

Medical certification of pilots restricts or prohibits the use of most pharmaceuticals and compliance must be assessed. The NTSB Safety Recommendation A-84-93, requested that the FAA establish at CAMI the capability to perform state-of-the-art toxicological tests on the blood, urine, and tissue of pilots involved in fatal accidents to determine the levels of both licit and illicit drugs at both therapeutic and abnormal levels. This project is in compliance with PUBLIC LAW 100-591 [H.R. 4686]; November 3, 1988. This project is consistent with the FAA Research, Engineering, and Development (RE&D) Plan, and directly supports the Bioaeronautics portion of the National Plan for Civil Aviation Human Factors.

18. Issues:

Performance testing of human subjects will be described in separate protocols reviewed by the CAMI Institutional Review Board (IRB).

19. Transition Strategy:

Not applicable.

20. Impact of Funding Deferral:

Identifying drugs and alcohol that have caused or contributed to an aviation accident would not be accomplished. Testing of specimens for the FAA's Office of Accident Investigation and the NTSB would not occur. Those deficiencies would cause an increase in multimillion-dollar liability claims against the government, which could not be defended; currently, the research data generated by this project results in an annual saving to the FAA of millions of dollars per year. The annual report to congress regarding drug and alcohol use found in fatal aviation accidents would be impossible. It would be impossible to comply with PUBLIC LAW 100-591 [H.R. 4686]; November 3, 1988, and the FAA would not be able to support the intent of NTSB Safety Recommendation A-894-93. Failure to monitor cosmic and other sources of radiation would prevent assurance of a safe environment for those entering the National Airspace system.

21. R&D Teaming Arrangements:

Coordination will be carried out with the Office of Accident Investigation (AAI), the Office of the Chief Counsel (AGC), and the National Transportation Safety Board (NTSB). AAI represents the primary sponsor, and the AGC, AAM, and the NTSB, primary users, for this research. The toxicology laboratory has been asked by the National Safety Council to help in the development of safety standards, which will reduce transportation accidents.

22. Special Facility Requirements:

A state-of-the-art forensic toxicology laboratory and nucleic acid analytical capability at CAMI must be maintained to ensure technically correct and legally defensible toxicological assessments. Attention to chain-of-custody requirements further necessitates that the facilities have special locks and passwords, photo surveillance, and motion detectors.

23. Approvals (Signature Authority):			***Performing Organization***
Steven B. Wallace, AAI-1	***Date***	***Name:***	William E. Collins, Ph.D.
Nancy C. Lane, AIR-3	***Date***	***Title:***	Director, FAA Civil Aeromedical Institute, AAM-3
Jon L. Jordan, M.D., AAM-1	***Date***	***Date:***	