

IX. Quality Assurance and Management Considerations

A. Quality Control

(1) Overview

As in any major scientific effort the quality of the data and the comparability of the data over time are key factors in achieving valid results. Quality assurance in both scientific and management aspects of this study are planned, and will be fully integrated into each phase of the study.

(2) Scientific Aspects

(a) Protocol Development

The Air Force scientific protocol has been under development for more than one year. It has been subjected to an unprecedented five stage independent peer review process to insure the highest quality and validity of its science.

(b) Blind Assessment Protocols

The exposed or non-exposed status of each individual will not be revealed to any of the Health Examiners. Each aspect of the physical examination will be conducted by rigid adherence to the examination protocol. Past medical history and review of systems will be obtained by individuals not associated with the examining process.

(c) Population Ascertainment Quality Control

The study/control populations for this effort were ascertained through extensive computer, and hard copy record searches. The matching variables for each individual were entered and verified with a computer program to minimize transcription errors. Data collection for both exposed and control populations was conducted using identical techniques, thus avoiding systematic bias in population ascertainment.

(d) Precision Matching

Computer techniques will permit extremely close matching of the control participants to the RANCH HAND participants for three distinct variables. This will substantially enhance the analytic flexibility and validity of the study.

(e) Questionnaire Techniques

Detailed questionnaire methods are under development to provide comprehensive crosschecks between objective and subjective health information. Particular emphasis will be placed upon techniques to ascertain false positive information which might impact the validity of the study.

(f) Laboratory Quality Control

The contractor for acquisition of health data mandatorily must have a detailed in-house laboratory quality control program coupled with enrollment into the "CLIA" or "CAP" laboratory survey. In addition, randomly selected duplicate specimens will be sent to a central Air Force reference laboratory for verification.

(g) Single Physical Examination Site

All physical examinations conducted by the contractor will be performed at a single site by dedicated teams of health professionals to insure that data variability is at an absolute minimum. The contractor will be a fully accredited medical institution, and must provide organizational evidence of national/international preeminence.

(h) Personnel Qualifications

All examining physicians will be certified and accredited by a Medical Specialty Board. Paramedics, medical students and interns will not participate as examiners in this study.

(3) Management Aspects

(a) Informed Consent

All participants will be fully informed as to the nature and purpose of all medical diagnostic tests and examinations, and will certify their complete understanding by signing specially designed informed consent forms. Release of medical data will be in strict accordance with Privacy Act determinations, and Air Force policies. Total confidentiality will be granted to subjects who are not on active duty. Active duty subjects will be given limited confidentiality with release of medical information to the DOD only in instances in which there is a risk to public safety or national defense.

(b) Monitoring Group

A monitoring group of scientists and personnel outside the USAF will regularly review and assess the conduct of the RANCH HAND study. This group will interact closely with the Air Force principal investigators, and will provide written commentary and recommendations directly to the White House Office of Science and Technology Policy. Approximately equal representation will be maintained between government scientists, academic scientists, and scientific personnel nominated by veterans advocacy groups.

(c) Consultants

In addition to the structured Air Force management system, outside management and scientific consultants will be utilized to provide assistance to the principal investigators upon request.

(d) Contract Performance

All data acquisition contracts will contain highly detailed schedule performance requirements. All statements of work will be coordinated with two procurement levels, appropriate Air Force program coordinators, and the outside monitoring group.

(e) On-Site Contract Monitor

An Air Force Medical Service officer will be assigned to the physical examination site to:

(1) provide visible Air Force representation to all participants,

(2) conduct detailed entry and exit briefings with all participants, particularly ensuring that the health assessment was conducted on a "blind basis",

(3) review all medical data for completeness and accuracy prior to computer entry, and

(4) examine all relevant features of the data acquisition process, and insure absolute compliance to the contract specifications.

(f) Data Security

- All medical information obtained on each participant will be entered into a computer data repository. Access to these data will be limited to key scientific investigators by master code numbers.

B. Management Structure

(1) General Organization

Standard Air Force Systems Command research and development concepts and organization will be used to manage this study and assure effective control of all phases of the investigation. The organizational structure is outlined in Figure 16.

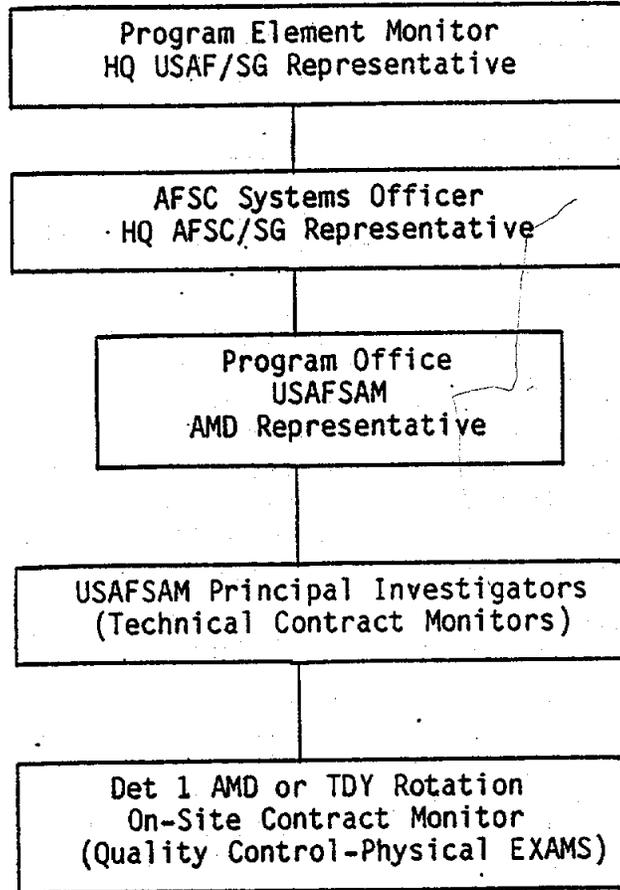
(2) Functions

(a) Program Element Monitor (PEM)

The tasks of the PEM will be performed by a representative of the USAF Surgeon General's staff. The PEM will serve as the Air Staff Program Monitor, and as such, he will represent the needs and interests of the primary investigators to the Surgeon General and the Air Staff. He will support the needs of the study to the Deputy Chiefs of Staff, the Secretary of the Air Force, the Secretary of Defense, and Congress.

Figure 16

MANAGEMENT STRUCTURE



(b) Systems Officer (SYSTO)

The SYSTO will serve as the Program Manager at the Air Force Systems Command level. In this capacity, he will monitor program status, key issues, and problems. He will also serve as coordinator and expediter between the PEM and the primary investigators. Additionally, the SYSTO will prepare program documentation, coordinate all aspects of the program, monitor obligations and expenditures, and initiate reprogramming actions to support unfunded study requirements.

(c) Program Office

The Program Office will be staffed by a representative of the primary investigators and an Aerospace Medical Division (AMD) representative. This office is responsible for implementation of the complete program

management plan on a day-by-day basis. Routine periodic management assessments and program status information will be provided to the SYSTO. The office will assure that all professional and technical aspects meet the stringent quality requirements outlined in the study protocol. It is the responsibility of this office to insure that all schedules, milestones, and financial requirements are met. This office also interfaces with, and provides guidance and support to the onsite contract monitor(s).

(d) USAFSAM Principal Investigators/Scientists

This team is the leading technical resource for this program. Members of this team are responsible for the faithful execution of the protocol, and as such, approve/disapprove all protocol changes, working in concert with the outside monitoring group. The principal investigators are the technical monitors on all contracts under the protocol. They are responsible for the security of all data, for all data analysis, and for all interpretation of analyses subject to review by the outside monitoring group. These investigators provide summary data to Air Force management personnel on request, to enable proper contract billing and program resource analysis. The primary flow of data, data analyses, and analysis interpretation from the principal investigators/scientist directly to the monitoring group is designed to obviate any appearance of Air Force management bias.

(e) Onsite Contract Monitor (Physical Examination Contractor)

The onsite monitor will act as the Air Force representative at the examination site. He will monitor and assess the quality and timeliness of the contractor's performance, and will advise the Program Office of any performance decrements, as well as other problems encountered at the examination site. He will be responsible for the quality control of all aspects of the examination process (physical examination, laboratory procedures, and psychological and physiological testing). He will also welcome each study subject, review the results of the complete evaluation, and debrief each subject at the conclusion of the examination process.