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**Description Notes** Trip Report outlines the events of and concerns resulting from the National Academy of Sciences (NAS) peer review of the Ranch Hand II study protocol.

DEPARTMENT OF THE AIR FORCE  
USAF SCHOOL OF AEROSPACE MEDICINE (AFSC)  
BROOKS AIR FORCE BASE, TEXAS 78235

7 January 1980



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SUBJECT Trip Report - National Academy of Sciences (TA-2091, 29 Nov 79)

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1. Place visited: National Academy of Sciences (NAS), Washington DC, 18 December 1979, for the purpose of obtaining peer review of the RANCH HAND II study protocol.

2. Personnel contacted/participants

a. USAF School of Aerospace Medicine

George D. Lathrop, Col, USAF, MC  
William H. Wolfe, Lt Col, USAF, MC  
Patricia M. Moynahan, Lt Col, USAF, NC  
Alvin L. Young, Maj, USAF  
Richard A. Albanese, M.D.

b. Subcommittee of the Toxicology Section, NAS

Dr. Carl M. Shy, Institute for Environmental Studies, University of North Carolina, Chapel Hill, NC 27514

Dr. Leon Gordis, Department of Epidemiology, Johns Hopkins School of Public Health, Baltimore, MD 21205

Dr. William Halperin, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH, 4676 Columbia Parkway, Cincinnati, OH 45226

Dr. Leonard T. Kurland, Department of Medical Statistics, Epidemiology and Genetics, Mayo Clinic, Rochester, MN 55901

Dr. Philip Landrigan, Director, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH

Dr. Gordon W. Newell, NS-356, National Academy of Sciences, 2101 Constitution Avenue, NW, Washington, DC 20418

Dr. Raymond Seltser, Department of Epidemiology, School of Hygiene and Public Health, Baltimore, MD 20014

c. Other attendees

Ronald Burnett, Lt Col, USAF, HQ AFSC/SGP  
Philip Brown, Maj, USAF, HQ USAF/SGES  
Graduate Student, University of North Carolina

3. Events and Topics:

Elements of the RANCH HAND II study design were presented by the USAFSAM team to the NAS toxicology subcommittee, but several factors affected the effectiveness of the USAF presentation and the quality of the peer review process.

a. Thirty minutes prior to the start of the review, the USAFSAM team was informed that it could not present their prepared briefing. Instead, they were to respond to specific questions in the general areas of the Mortality Study, Morbidity Study, and Follow-up Study. This format did not allow the review committee members to view the proposed study design as an integrated effort over time.

b. Initially, the USAFSAM team had been informed that they would have four hours to conduct the briefing, and that additional time in the evening could be made available if needed. Upon arrival, they were informed that only 2-1/2 hours were allowed, so that a final report by the committee could be prepared at 1600 hours. This time limitation did not permit completion of discussion on the Morbidity Study, and the follow-up aspects of the proposed design were not addressed at all. The NAS chairman privately expressed the opinion that two days were needed to properly discuss the protocol. Had the USAFSAM team been permitted to follow the original format, most of the review committee's questions would have been answered.

Difficulties caused by both a and b above could have been avoided by better staffing and coordination between the USAF, NAS staff and the subcommittee chairman.

c. Despite having the protocol in their possession 18-20 days prior to the review meeting, many of the committee members were unfamiliar with even basic and fundamental aspects of the design. Their questions reflected a lack of understanding and knowledge of the design. They repeatedly asked questions which were clearly addressed and answered in the protocol. Two of the seven committee members present failed to ask any questions and only four members participated significantly in the discussion.

d. Two key members of the subcommittee, Dr. Alan Poland, a recognized TCDD expert, and Dr. Ian Higgins, a statistician/epidemiologist, were not in attendance.

e. An epidemiology graduate student/physician from Milan, Italy attended the committee meeting at the request of Dr. Shy, his major professor. While he did not participate in the discussion, his presence at the meeting was inappropriate.

f. The committee chairman did not state the intent and the purpose of the meeting. Rather than a "Dog and Pony Show," as he put it, he stated that the members would ask pertinent questions thereby eliminating the need for a long session. The meeting was conducted in a manner which discouraged the input of the peer review process, and simulated a student/professor relationship. One of the committee members commented later that this meeting was like a doctoral dissertation defense.

g. The subcommittee members from Johns Hopkins asked essentially all of the questions and concentrated almost exclusively on the limited size (and power considerations) of the exposed group for the USAF Mortality Study as contrasted with the US Marine Corps population noted in the Government Accounting Office (GAO) report. They did not perceive the Mortality Study as more than a determination of deaths as of March 1980, and did not integrate the planned 5-year follow-up analysis and analysis of disease patterns.

h. The committee dwelled at some length on how and why the USAF Surgeon General made the decision to conduct this study. They made no substantive comments to improve the study design, and did not discuss/find any element of the study that required extensive improvement.

In short, they presented no scientific debate which indicated that the study should be conducted in any fashion other than stated in the protocol.

#### 4. Recommendations:

a. In view of the political orientation of the NAS subcommittee and the cursory nature of the scientific review, the Air Force should be prepared to respond to any adverse criticism of the protocol leveled by the NAS.

b. A consortium of university experts should be formed by the Air Force or DOD to monitor and review all aspects of the study from design, through data collection, to final analysis.

5. Items of interest to procurement and USAFSAM programming: None

6. This information may be of interest to AMD/SG, HQ AFSC/SGP, and HQ USAF/SG.



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