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Report/Article Title Memorandum: from George D. Lathrop to AMD/SG, with subject Key Questions, Project Ranch Hand II, October 25, 1979.

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Description Notes Item includes 5 attachments, all background papers. 1) Non-DOD Agency Monitoring of the Epidemiologic Investigation of Health Effects Due to Exposure to Herbicide Orange (Project RANCH HAND II), October 24, 1979 2) Partial Contracts Vs In-house Efforts in the Carrying Out of Project RANCH HAND II, October 24, 1979 3) Selection of an Air Force Site for Physical Examinations Conducted as Part of Project RANCH HAND II 4) Payments to Study Participants In Epidemiologic Investigation of Health Effects Due to Exposure to Herbicide Orange (Project RANCH HAND II) 5) Disposition of RANCH HAND II Participants Who Are on Flying Status and Identified as Having a Disqualifying or Potentially Disqualifying Medical Condition

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

25 October 1979



REPLY TO
ATTN OF: EK

SUBJECT: Key Questions, Project RANCH HAND II

10- AMD/SG

1. The attached Background Papers raise several key questions regarding Project RANCH HAND II. Each of the decisions outlined must be made by higher headquarters, and it is essential that each be made quickly. The direction of the RANCH HAND II study, the resources required for its execution, indeed even its success or failure, depend in large part on a speedy resolution of these controversies.

2. Request your assistance in obtaining decisions on these key questions as soon as possible.

FOR THE COMMANDER

George D. Lathrop
GEORGE D. LATHROP, Col, USAF, MC
Chief, Epidemiology Division

5 Atch
1-5 Background Papers

Cy to: SAM/CC

File 8-10-79
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BACKGROUND PAPER

TITLE: Non-DOD Agency Monitoring of the Epidemiologic Investigation of Health Effects Due to Exposure to Herbicide Orange (Project RANCH HAND II)

BACKGROUND:

1. At every occasion when the protocol has been presented for review, the concern has been raised by the reviewers that the credibility of an Air Force sponsored study of this nature will inevitably be questioned. The speculations of inadequate disclosure, cover-up and bias by the lay public and the scientific community is a real concern.
2. The Air Force Epidemiological Board and the Scientific Advisory Board peer review recommendations were for the creation of a group of outside (non-Department of Defense) experts who can provide close, impartial and frequent monitoring of the implementation, analysis, and reporting of this study. Such an advisory group has been recommended to oversee matters regarding civil rights and ethical considerations, the aggressiveness of efforts to identify and follow up subjects, release of information, consent forms, etc.
3. The Scientific Advisory Board has specifically recommended that this committee or group be chosen by and responsible to the National Academy of Sciences or a similar agency.
4. Both Boards feel that the credibility of the study by the public and the scientific community would be greatly enhanced by such an advisory committee or group. Such groups have been very useful in similar large-scale studies carried out by the Department of Health, Education and Welfare.

SUMMARY: Credibility in Project RANCH HAND II is expected to be considerably enhanced as a result of monitoring by a group of outside (non-DOD) experts.

RECOMMENDATION: Recommend that authority for such a monitoring scheme be sought from higher headquarters prior to the 17 November 1979 National Academy of Sciences peer review.

ACTION OFFICE: USAFSAM/EKSO/Capt Sauri/2127

AUTHENTICATION: 
GEORGE D. LATHROP, Col, USAF, MC
Chief, Epidemiology Division

DATE: 24 October 1979

BACKGROUND PAPER

TITLE: Partial Contracts Vs In-house Efforts in the Carrying Out of Project RANCH HAND II

BACKGROUND:

1. Several components of the Project RANCH HAND II epidemiological investigation could be broken off from the main effort, and contracts could be awarded for these discrete parts. These components, while they are of vital importance to the overall study, are relatively self-contained tasks:

a. Physical Examinations. So long as the study protocol were followed exactly, any large medical institution could conduct the approximately 926 physical exams over a 12-month period.

b. Mortality Analysis. Approximately 7200 individuals must be located, and cause of death determined, if appropriate.

c. Medical Records Review. Active duty, retired and/or civilian medical records must be screened for approximately 2400 individuals.

d. Telephone Interviews. Approximately 2400 lengthy interviews must be conducted by telephone.

2. Statements of work could be very specific for these efforts; nevertheless, a certain measure of control is lost when tasks of this sort are done by an agency other than the agency conducting the analysis of the study's results.

3. In any case, a considerable time lag will be encountered if these efforts are contracted. Additionally, it is felt that contractual efforts will be more costly than those done in-house.

SUMMARY: Some parts of Project RANCH HAND II could be done by contract. Some control would be lost, and such contracts would be costly. An early decision is required to prevent delays in the overall investigation.

RECOMMENDATION: Recommend that the entire epidemiologic investigation be done in-house.

ACTION OFFICE: USAFSAM/EKSO/Capt Daves/2127

AUTHENTICATION:

George D. Lathrop
GEORGE D. LATHROP, CoT, USAF, MC
Chief, Epidemiology Division

DATE: 24 October 1979

BACKGROUND PAPER

TITLE: Selection of an Air Force Site for Physical Examinations
Conducted as Part of Project RANCH HAND II

BACKGROUND:

1. Approximately 926 extensive physical examinations will be conducted over a 12-month period. The selection of a medical facility in which to conduct these examinations must take into account the following:

a. Support Requirements. The physical examinations will be very comprehensive, with procedures similar to an expanded Class II flying physical. Therefore, the diagnostic facilities of an Area Medical Center will be required.

b. Single Site. It is essential to the success of the investigation that all of the physical examinations be done at a single site, by a single staff, in order to achieve continuity and reproducibility of results. The study protocol must be followed exactly.

c. Proposed Locations. At least four suggested locations have been proposed:

(1) USAFSAM Clinical Sciences Division. SAM could accommodate a workload of this magnitude only if some portion of their present mission were at least temporarily curtailed. Additionally, USAFSAM is perceived by flying personnel to be the agency which identifies disqualifying defects in flyers, and therefore voluntary participation by those on flying status would decrease.

(2) USAF Medical Center Scott. Scott has been put forward as the medical center most centrally located in CONUS. Doing physical exams at Scott AFB, therefore, would decrease travel time, cost and inconvenience.

(3) USAF Medical Center Keesler. Keesler's unique capabilities in clinical research lend themselves to a study of this sort.

(4) Wilford Hall USAF Medical Center. The advantages inherent in conducting physical examinations at this largest, most highly specialized Air Force medical facility are obvious. Not only is the extensive diagnostic capability immediately available, but also epidemiologic consultations is at hand from the USAFSAM Epidemiology Division.

2. Undoubtedly, manpower augmentation would be required at whichever facility these physical examinations are conducted.

SUMMARY: Physical examinations for Project RANCH HAND II must be accomplished at one Air Force medical center. Manpower augmentation will be

required to accomplish this workload.

RECOMMENDATION: Recommend that Wilford Hall USAF Medical Center be designated as the site of RANCH HAND II physical exams. Further recommend that USAFSAM/EK furnish the physical examination protocol to Wilford Hall USAF Medical Center; Wilford Hall USAF Medical Center should then provide an estimate of resources required to accomplish this workload.

ACTION OFFICE: USAFSAM/EKSO/Lt Col Moynahan/2127

AUTHENTICATION: 
GEORGE D. LATHROP, Col, USAF, MC
Chief, Epidemiology Division

DATE: 24 October 1979

BACKGROUND PAPER

TITLE: Payments to Study Participants in Epidemiologic Investigation of Health Effects Due to Exposure to Herbicide Orange (Project RANCH HAND II)

BACKGROUND:

1. It will be necessary for study participants (both from former Ranch Hands and members of the control group) to spend several days undergoing an extensive physical examination at an Air Force medical facility somewhere in CONUS. Although their travel expenses will be reimbursed IAW JTR, we can anticipate reluctance on the part of many retired or separated Air Force members to lose several days' wages as a result of their voluntary participation in this study.

a. Number of Physical Exams. Approximately 926 physical exams will be scheduled over a 12-month period. Of these, approximately 232 (25%) will be done on active duty Air Force members, and 694 (75%) on separated or retired members.

b. Scheduling. Some flexibility is available to conform with participants' vacation schedules, holidays, etc. Nevertheless, some participants may still encounter resistance from employers and be forced to use vacation time or leave without pay in order to perform the necessary travel.

c. Voluntary Participation. All participants, whether active duty, retired, or separated, will be included in the investigation only on a voluntary basis. Every effort will be made to encourage participation, but in the last analysis, the choice must remain with the individual. In order for the investigation to be successful, voluntary participation on the part of former Ranch Hands must approach 100%; in the control group, participation can be somewhat less.

2. In order to encourage participation, some monetary consideration is often paid to participants in research studies in the civilian sector. In Project RANCH HAND II, such a compensation would be in partial remuneration for loss of wages, or the opportunity cost associated with the use of vacation time for this purpose rather than for recreation, etc.

SUMMARY: Voluntary participation in Project RANCH HAND II must be encouraged if the investigation is to be successful. Payment of a monetary consideration to volunteers undergoing physical exams would increase participation. A suggested rate might be \$100 per day.

RECOMMENDATION: Recommend that authority to pay monetary compensation to Project RANCH HAND II participants be sought from higher headquarters.

ACTION OFFICE: USAFSAM/EKSO/Capt Daves/2127

AUTHENTICATION: *George D. Lathrop*
GEORGE D. LATHROP, CoT, USAF, MC
Chief, Epidemiology Division

DATE: 24 October 1979

BACKGROUND PAPER

TITLE: Disposition of RANCH HAND II Participants Who Are on Flying Status and Identified as Having a Disqualifying or Potentially Disqualifying Medical Condition

BACKGROUND:

1. It is estimated that many study participants will be associated, either vocationally or avocationally, with the aerospace industry. As a consequence, it is suspected that a large proportion of these individuals will be actively flying. The proportion of RANCH HAND II participants, 25% of whom will be on active duty, who are actively engaged in flying, on or off-duty, is unknown.

2. The medico-legal considerations with respect to informed consent require that these participants be made aware of the fact that the identification of a disqualifying medical condition must be evaluated and/or reported to the FAA. In other words, the individual before volunteering for this study must be informed that he could lose his job and livelihood as a result of his participation.

3. Currently, it is felt that the rate of identification of disqualifying defects or medical conditions will be low. An estimate cannot be accurately obtained since published statistics of this nature deal with a younger population and a less comprehensive physical examination. Further, any adverse effect due to Herbicide Orange exposure could affect this rate. In addition, it is felt that any disqualifying medical condition will probably not be detected much earlier than on the flyer's routine periodic physical examination. Nevertheless, due to the comprehensiveness of the proposed physical examination, the question arises as to the proper management of abnormal results in the more detailed tests.

4. All medical history, physical examination and laboratory data for each study participant will be consolidated at USAFSAM, and diagnostic impressions will be formed. The presence of a laboratory or physical examination abnormality of undetermined significance unassociated with a disease process should not generate difficulties in releasing information to the FAA. The FAA and the USAF regulations are quite specific as to which medical diagnoses or conditions are disqualifying for each category of flying status. Our responsibility should be to inform the USAF and/or FAA only of those individuals found to have obviously disqualifying conditions. Those individuals found to have abnormalities of laboratory or examination in the absence of a disqualifying condition should not be reported.

5. Specifically addressing the question of Informed Consent, it is our feeling that the best compromise must be developed between full disclosure and maximal participation. This compromise can be achieved by reflecting the positive effect of undergoing a medical evaluation at the same time as stating the obvious "danger" that such an evaluation would

have on the individual's job and livelihood or recreational pastime. Enclosed is an example of the Informed Consent form that we are recommending for use.

6. There are several options that we can take in the disposition of those flying participants found to have disqualifying conditions:

a. Do nothing and let the individual notify his flight surgeon or AME of the condition or wait until the next periodic physical examination to perhaps pick up the defect as "significant." This option obviously denies any responsibility of the evaluators to report any medical condition. Such an option may require FAA approval or consultation.

b. Report any or all results to the participant's designated physician and/or flight surgeon (or AME). This option ethically satisfies any reporting requirement but leaves it to the participant whether or not he wants his flight surgeon (or AME) to know of the results.

c. Directly notify the flight surgeon or AME of the results of the evaluation. This option allows for reporting of potentially disqualifying defects for further evaluation and allows the flight surgeon or AME to decide as to the significance of the condition. On the other hand, this option requires that we determine the flying status of the participant and request from him his designated flight surgeon or AME of choice. The Informed Consent would probably require a more indepth discussion of this requirement than is present in the attached example.

d. Submit the results of any or all of the physical examination (and history) to the FAA for review and disposition. This option is felt to be unreasonable from several points of view. Though it satisfies all medico-legal requirements, it would not apply to active duty rated participants on flying status, would require FAA approval, and would adversely affect the participation rate of the study since such a fact would have to be succinctly stated in the Informed Consent form.

e. Respond to a request from the FAA to provide them a listing of all examinees who have disqualifying conditions/diseases IAW applicable FAA regulations. This procedure was found to be an appropriate release of medical information by HQ USAF/JACL in an 8 October 1976 letter to HQ USAF/SGPA.

f. Compensate all individuals so identified with full flying pay and promotion advantages. Though theoretically this would encourage individuals in participation, it is felt that many will not feel that even this is adequate compensation. Furthermore, such an option would be an unprecedented move by the Government. This last option is unrealistic from our standpoint and is included simply for completeness sake.

SUMMARY: Voluntary participation in Project RANCH HAND II must be encouraged if the investigation is to be successful. To accomplish this, the disposition of the participants who are on flying status (both active

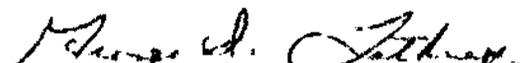
duty and civilian) and identified as having a disqualifying or potentially disqualifying medical condition must be such that it does not discourage participation in the study to a significant degree. A compromise is necessary between full disclosure and maximal participation schemes.

RECOMMENDATIONS:

1. Recommend that clarification be sought from higher headquarters as to the Air Force's responsibility to report disqualifying medical conditions to the FAA and/or Surgeon General.
2. Recommend that the enclosed Informed Consent Form be evaluated from the medico-legal standpoint.

ACTION OFFICE: USAFSAM/EKSO/Capt Sauri/2127

AUTHENTICATION:


GEORGE D. LATHROP, Col, USAF/MC
Chief, Epidemiology Division

DATE: 24 October 1979

STATEMENT OF INFORMED CONSENT

You have been identified as having served in Vietnam during the period of time in which United States Air Force personnel were exposed to potentially hazardous environmental contaminants. Your selection as part of the Air Force evaluation was based on your organization of assignment in Southeast Asia.

The six-year study will involve your participation in three telephone questionnaires, as well as three comprehensive, periodic medical evaluations at a major medical facility. Transportation and per diem will be provided. Schedules for these evaluations will be made to conform with your time schedule as much as possible.

For those of you who already undergo periodic occupational medical evaluations, it is unlikely that any serious disabling medical disorder so identified would be detected much earlier than your routine physical examination. However, for the rest of the participants, there is a definite benefit of discovering any serious medical condition at a much earlier stage of the disease allowing for timely, perhaps more effective, treatment.

It cannot be presumed, on an individual basis, that any specific medical condition so identified was the result of exposure to these toxic contaminants. Only by analysis of the results of the entire study can such a cause and effect statement be made.

Though emergency treatment will be delivered for any identified life-threatening medical conditions, the investigators will simply report all results to your designated physician and/or occupational physician so as

to insure the appropriate evaluation of the medical condition.

If the above explanation is to your satisfaction, we request your consent below to enter you into this study.

I, _____, authorize the United States Air Force to obtain and furnish complete information to my designated physician and/or occupational physician, (name/ mailing address) _____

_____ concerning the results of medical evaluation of the undersigned to be made as a result of my participation into this study. The United States Air Force will be allowed to give emergency treatment of any serious, life-threatening disorder identified in the undersigned as a result of these medical evaluations.

Date _____

Signature _____

Witness _____