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January 30, 1979

Director, Supply Service (134C)

Deputy ACMD for Research and Development (15A)

Request for Contract Negotiation with Dr. Michael L. Gross for Dioxin Assays in Human Fat

1. Please negotiate a contract with Michael L. Gross, Ph.D., Professor of Chemistry, Department of Chemistry, University of Nebraska, Lincoln, Nebraska, 68588. This is to cover 20 assays for dioxin content of human fat samples to be submitted to him by the Veterans Administration. Dr. Gross has agreed to conduct these assays for $525 per sample for a total of $10,500.

2. The assay in question is a highly sensitive one detecting parts per trillion of dioxin and as such it requires specialized techniques and equipment. Dr. Gross is able to conduct the assays for so low a sum because he is already engaged in a series of determinations for the EPA. This means that he does not have to assemble equipment, standardize the method, and so on.

3. Attached are the answers to the required 20 questions and the briefing slip. There is also included a Protocol for submission with answers to the questions.

LAWRENCE B. HOBSON, M.D., Ph.D.

Attachments

cc: Mr. Bapel

15A/LBHobson:daz

BRIEFING DOCUMENT

Contractor: Michael L. Gross, Ph.D.
Department of Chemistry
University of Nebraska
Lincoln, Nebraska 68588

Contract: Dioxin in Human Tissue; new contract.

R&D Contact: Dr. Lawrence B. Hobson
Deputy ACMD for Research & Development (15A)

Purpose: This is a contract with an analytical chemist to perform a series of scout assays comparing the dioxin content, if any is detectible, in the abdominal wall fat of veterans exposed to Agent Orange in Vietnam with the dioxin content, if detectible, in the fat of veterans who were not in Vietnam and had no known military exposure to Agent Orange.

History: Public pressure to detect dioxin and compensate veterans for damage supposedly produced by defoliant agents containing small amounts of the chemical has culminated in claims that the material is retained indefinitely in human fat. The quantities, if any material is retained, would be extremely minute and the first question is whether they can be detected. To answer this, the most sensitive available assay will be used to examine fat from 20 veteran volunteers. Ten (10) will have been exposed and usually will claim continuing or late effects from the agent. Ten (10) volunteer control patients who were not in Vietnam but are matched by age, sex, and place of residence will have fat removed at an operation done for medical reasons, e.g., appendectomy. The necessary operations will be performed in VA medical centers.

Justification:

(1) Public pressure is the primary impetus for the study. If dioxin can be detected only in veterans exposed in Vietnam routine assays could be used as proof of exposure. If somewhat more dioxin is found in exposed veterans a larger series would be necessary to establish a significant difference.

(2) Suspicion that the VA is biased against finding dioxin only in veterans exposed to it in Vietnam led to a

decision to use a non-Federal analytical laboratory. Very few chemists are now conducting dioxin assays by the specialized chromatography-mass spectrography method arranged to detect dioxin in parts per trillion.

(3) Dr. Michael L. Gross is currently assaying for dioxin for the EPA and is recommended by that agency as the best qualified analist. As a research contract, this one does not require an RFP. The figure of $525 per assay is low since Dr. Gross already is performing the assays for EPA and does not have to make separate standardizations, etc.

Costs and Schedules:

This is a new contract.

	Current	Future	Total
FY	1979	1980	1 year
Costs	$10,500	0	$10,500

Comments: Should the results suggest a significant difference between veterans exposed to defoliants and the controls, more cases will have to be studied. This would require an extension of the contract with additional funding.

Problem on Project

1. Dioxin in Human Tissue. The contract is for highly sensitive assays of the dioxin content in abdominal wall fat of veterans exposed to Agent Orange, a defoliant, in Vietnam and, for comparison, in fat from veterans who were not in Vietnam and had no known military exposure to Agent Orange.

2. It is not known whether dioxin persists in human fat over a decade or more. Nor is it known whether it causes a problem if it does.

3. Lack of knowledge as to the persistence of dioxin can encourage continuing claims of damage from the chemical.

4. Not relevant.

5. The dioxin assays are to be done on biopsy specimens from veteran volunteers, 10 with exposure to Agent Orange and 10 without known exposure. The biopsies will be performed in VA medical centers to obtain the fat for assay. The assay results are critical as the only data to be obtained.

6. The VA could probably conduct the assays. Veterans groups charge, however, that the VA might bias the results and so a non-Federal assay laboratory was sought. Dr. Michael L. Gross, chemist at the University of Nebraska, was chosen over other analists on recommendation of the EPA as having the most sensitive, precise, and dependable assay.

7. Not relevant.

8. Results of the assays should disclose whether dioxin can be detected in the fat of men exposed to Agent Orange and whether it can also be detected in matched veterans who were not. If the chemical is present only in the exposed veterans, the test can be used to prove exposure. If there seems to be more dioxin in exposed veterans but it occurs in both groups, this scout experiment would have to be extended to determine whether the difference is continuous and significant. If no dioxin is detected (in parts per trillion) it would suggest that current claims for its persistence are unfounded.

Equipment and Skills

9. Equipment lack is no problem.

10. Skills required are those of an organic analytic chemist experienced in the specific assay for dioxin by the specialized gas-liquid-chromatograph-mass-spectrophotometric technique for halogenated polycyclic compounds.

Personnel

11. For this scout experiment, qualified VA personnel would not be suitable if available because of the public fear of bias.

12. The surgeons who will biopsy the abdominal fat of exposed veteran volunteers and the surgeons who remove a small amount of fat from selected volunteers undergoing an abdominal operation for other reasons, e.g., appendicitis, are the only VA personnel directly involved in conducting the trial. Minimal clerical time will be required for mailing the 20 specimens.

13. The chemist is a full-time faculty member at the University of Nebraska and the small number of assays would not justify hiring him.

14. See question 6. Dr. Michael L. Gross, according to the EPA, is best qualified and already is performing assays for that agency. A considerable number of other organic chemists could perform the assays but would require time and money to "tool up" and standardize the procedure.

Firms

15. Not relevant.

Cost of Contract and Funds

16. & 17. Estimated cost is $10,500 to be paid from Medical Research funds.

Attachments

18. "Tentative Protocol for Dioxin Content of Fat in Vietnam and Non-Vietman Veterans."

19. --

Automated Data Processing

20. Not relevant.

TENTATIVE PROTOCOL FOR DIOXIN CONTENT OF FAT
IN VIETNAM AND NON-VIETNAM VETERANS

PURPOSE: To compare the dioxin content in abdominal wall fat of veterans presumed to be exposed to Agent Orange in Vietnam with the dioxin content in the fat of veterans who were not in Vietnam and had no known contact with Agent Orange.

SUBJECTS: Initially, 10 men will be included in each of two groups: (a) the experimental group composed of former servicemen who were in areas of Vietnam within 6 months of defoliation by spraying with Agent Orange and (b) the control group of former servicemen who never served in Vietnam and who never had known contact with Agent Orange during their military service. Each subject in the experimental group will be matched with a control subject who is resident in the same state, and who lives in the urban or rural environment, and who is within 5 years of his age. Each experimental subject will have a biopsy of the abdominal wall to obtain a fat sample or the sample will be obtained at laparotomy for another purpose. Each control subject will have a fat sample taken during laparotomy for a medical indication.

SAMPLING TECHNIQUES: During the biopsy or at the start of laparotomy, the surgeon will obtain a specimen of fat, weighing about 10 grams, from the anterior abdominal wall. This corresponds to a volume of about one cubic inch. The specimen may be obtained using local or general anesthesia and there is no restriction on premedication or agents for induction.

The one substance that will interfere with the analysis for dioxin and is likely to be encountered during surgery is hexachlorophene (contained in Pre-op and Pre-op Plus Scrub Sponge [Davis & Geck], pHisoHex [Winthrop], Presulin Cleanser [Schieffelin], and Soy-Dome Cleanser [Dome]). Hexachlorophene should be avoided in surgical scrubs,

pre-operative preparation, and instrument sterilization prior to obtaining the fat specimen.

The specimen should be placed in a test tube that has been rinsed twice with reagent grade acetone and allowed to dry. The tube should be closed with a cork also twice rinsed with acetone. These rinses remove interfering compounds. Plastics are intrinsically contaminating and should not be allowed to touch the specimen.

Each tube will be labeled with (1) the patient's name and SSN, (2) the hospital name, and (3) the date.

The test tube can be stored in a deep freeze until shipment. It should be sent air freight in a shipping tube filled with dry ice to

Dr. Michael Lawrence Gross
Professor of Chemistry
Department of Chemistry
University of Nebraska
Lincoln, Nebraska 68588

The material should be shipped on a Monday so that delivery will not be attempted on the weekend.

INFORMATION SHEET: A separate Information Sheet will be completed on the day of biopsy for each subject. One copy should be mailed to

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Another copy should be placed in the subject's medical record. The Sheet will contain data for (1) identification of the subject, (2) location of subject's residence, age, and occupation, (3) military exposure to Agent Orange including place, duration, date, and nature of exposure, (4) known exposure to chemical herbicides apart from military experience, including name of herbicide, place, duration or frequency, date, and nature of

exposure, (5) symptoms or conditions (past or present) that patient ascribes to Agent Orange, (6) current diagnosis or diagnoses, (7) operation performed, (8) pre-operative medication, agents for induction, and anesthetic used, (9) date, (10) informant.

INFORMED CONSENT: Each experimental subject and each control patient will have the procedure and its purpose explained to him. He will then be asked to sign the consent documents which will be placed in his medical record prior to the biopsy.

DIOXIN ASSAY: Dr. Gross will analyze an aliquot of each specimen for its dioxin content. Another aliquot will be analyzed if dioxin is found in the first. Standards will be analyzed as necessary to assure accuracy and precision.

L.B.Hobson 8/3/78

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