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INTERAGENCY AGREEMENT BETWEEN THE
VETERANS ADMINISTRATION
AND THE
US ENVIRONMENTAL PROTECTION AGENCY

I. PURPOSE

The Veterans Administration (VA) and the Environmental Protection Agency (EPA) agree that it would be mutually advantageous in fulfilling each agency's mission to cooperate in a study of dioxins and furans in human adipose tissue. The cooperative efforts of both agencies in pooling scientific expertise and resources will enhance the scientific quality of the study.

The purpose of this agreement is to describe and stipulate the responsibilities of each agency to the other in this undertaking.

II. BACKGROUND AND SCOPE OF WORK

The VA has determined that the EPA's National Human Adipose Tissue Survey (NHATS) program constitutes a unique and valuable source of adipose tissue specimens that can be used in a study of dioxin and furan levels in Vietnam era veterans as well as males of that age group in a matched control sample of non-veterans. Under an earlier separate interagency agreement between the VA and EPA [V101(91)-82016], the EPA identified 528 males born between 1937 and 1952 from whom adipose tissue specimens had been collected for NHATS. EPA contacted the hospital or medical

examiner's office which submitted each of the 528 specimens and received identifying information (name with/without social security number) for 494 of the individuals from whom the specimens were obtained. The VA has determined the military service status of most of the individuals and has abstracted appropriate military service information for those who are veterans. Among these are approximately 40 men known to have served in Vietnam.

In addition, the EPA has completed an extensive literature review, has had two meetings with leading U.S. and foreign scientists with recognized expertise in the analysis of polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and has prepared a proposed methodology for the analysis of PCDDs and PCDFs in human adipose tissue (EPA prime contract No. 68-02-3938, MRI Project No. 7901-A(08)).

Under this agreement, the adipose tissue specimens previously identified for the study will be analyzed for their selected dioxin and dibenzofuran content.

III. RESPONSIBILITIES

A. Under the terms of this agreement the EPA will:

1. Provide the VA with a copy of its computer tape containing demographic information on the 528 individuals who have been identified as potential donor subjects for the study. (The tape is called SAS DATA SET CN. EPA DNJ A011.VA RECORD TAPE). Individuals'

names will be deleted from this tape prior to submission to VA.

2. Provide the VA with information on chlorinated pesticide levels already determined on each of the 528 specimens. This information may be provided on the tape cited in Paragraph 1 above.

3. Conduct the necessary methods development work to finalize the analytical protocol. This effort will follow the guidelines provided in the document entitled Proposed Analytical Method for Analysis of PCDDs/PCDFs in Human Adipose Tissue - (Special Report, EPA Prime Contract No. 68-02-3938, MRI Project No. 7901 A(08) March 28, 1984). Details will be provided in accordance with item A.6. below.

4. Locate and retrieve the selected specimens from the NHATS archives and conduct the analysis of the adipose tissue specimens selected for the study in accordance with the protocol to be finalized as noted above.

Within the constraints of funding by the VA as described in Section V below, the number of adipose tissue specimens to be analyzed will be approximately 250, excluding the Quality Assurance/Quality Control (QA/QC) program. The number of samples for QA/QC purposes will not exceed 30% of the individual adipose tissue specimens which form the basis of the study. As a minimum, and consistent with the availability of standards, quantitative determinations will be made for the following analytes:

Chlorinated dibenzo-p-dioxins:

2,3,7,8-tetrachloro-DD

1,2,3,7,8-pentachloro-DD

1,2,3,6,7,8-hexachloro-DD

1,2,3,4,6,7,8-heptachloro-DD

1,2,3,4,6,7,8,9-octochloro-DD

Chlorinated dibenzofurans:

2,3,7,8-tetrachloro-DF

2,3,4,7,8-pentachloro-DF

1,2,3,4,7,8/1,2,3,6,7,8-hexachloro-DF

1,2,3,4,6,7,8-heptachloro-DF

5. Within the constraints of funding for the study, the EPA Office of Toxic Substances (OTS) will have responsibility for administering the QA/QC program for the study. OTS will utilize to the extent possible EPA's laboratories in Las Vegas or Research Triangle Park for this effort. This program will include the following:

a. An appropriate number of tissue samples fortified with known quantities of PCDDs and PCDFs.

b. Analysis of split samples to spot check for consistency of results in cases where adequate tissue is available.

c. A laboratory method blank.

6. Within 45 calendar days of the effective date of this agreement provide the VA with the overall project milestones and within 60 days the details of the QA/QC plan.

7. Assist the VA in the selection of the study specimens, the analysis of data and the preparation of the final report.

8. Beginning 45 calendar days from the effective date of this agreement and on a frequency of every 4 months provide to the VA status reports, including expenditures. The EPA will promptly notify the VA when 80% of the funding, as outlined in Section V below, has been expended.

B. Under the terms of this agreement the VA will:

1. Complete the ascertainment of military service status for as many of the entire 528 individuals as possible, and abstract the military personnel records of those who are veterans.

2. Review, analyze and abstract all available pathology/autopsy reports on these individuals.

3. In consultation with the EPA, complete the study survey design and select which of the 528 specimens will be used for analysis. The selection process, where applicable, will include consideration of the geographic locations of the institutions which submitted the adipose tissue specimens, ages of individuals, consideration of the calendar

years the specimens were obtained and consideration of military service data such as branch of service, rank, time of service, interval between discharge from military and sampling year, etc.

4. Analyze the data and prepare the final joint VA/EPA report. VA will assume the lead in the preparation of the report. The draft final report will be completed no later than four (4) months following final submission of all analytical data by EPA to VA.

IV. DURATION

This agreement shall continue in effect for 18 months from the date of last signature or until the EPA has supplied to the VA all requested data and information obtainable within the constraints of available funding, whichever comes first.

V. FUNDING

The VA will provide the necessary funds, not to exceed $340,000, for the conduct of the work as outlined in this agreement.

Any unused funds and/or equipment purchased with said funds will revert to the VA at the conclusion of the study.

The EPA will provide staff expertise and the use of its contractual mechanisms for the chemical analysis including the QA/QC program. The EPA will not provide additional funding for the conduct of the study.

VI. PROJECT OFFICERS

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VII. OTHER

Any revisions or amendments to this agreement may be made in writing by the signatories hereto or by their successors.

VIII. AUTHORITY

This agreement is made pursuant to Veterans Health Programs Extension and Improvement Act of 1979, Section 307(c), Public Law 96-151, 93 Stat. 1098 (1979), 38. U.S.C. Section 219 Note(c) (Supp. IV, 1980), the Federal Insecticide, Fungicide and Rodenticide Act (the "Insecticide Act") as amended (7 U.S.C. Sections 136, et seq.); Section 10(a) of the Toxic Substances Control Act of 1976 (the "Toxic Substances Act") (Public Law 94-469, 90 Stat. 2003, 2031, (1976)); and the Economy Act of 1932 (the "Economy Act"), as amended by Public Law 97-258, Section 1 at 31 U.S.C. Section 1535, 96 Stat. 877, 933 (1982), as amended by Public Law 97-332 (October 15, 1982).

APPROVED AND ACCEPTED FOR THE VETERANS ADMINISTRATION

BY _____
CLYDE C. COOK
Director, Office of
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APPROVED AND ACCEPTED FOR THE ENVIRONMENTAL PROTECTION AGENCY

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