



Dr Kehoe

University of Cincinnati Medical Center

3223 Eden Avenue
Cincinnati, Ohio 45267

DEPARTMENT OF ENVIRONMENTAL HEALTH
KETTERING LABORATORY
(513) 872-5700

October 15, 1974

Mitchell R. Zavon, M.D.
Medical Director
Ethyl Corporation
451 Florida
Baton Rouge, Louisiana 70801

RE: Kehoe Lead Balance Studies in Humans

Dear Mitch:

Please find a draft of the scientific proposal and contract agreement along with Dr. Kehoe's letter of confirmation for the proposed analysis of the Kehoe data. Perhaps I can negotiate any changes directly with your Ethyl Corporation lawyer while you are out of the country. The final instruments can then be approved either by mail or when you return in November.

Have a safe trip..

Sincerely,

Stanley B. Gross, Ph.D.
Assistant Professor of Environmental
Health (Toxicology)

SBG/hk
Enclosure

KE 0006149

N 7501



University of Cincinnati

Cincinnati, Ohio 45267

COLLEGE OF MEDICINE, EDEN AND BETHESDA AVENUES
NETTERING LABORATORY
DEPARTMENT OF ENVIRONMENTAL HEALTH

October 15, 1974

Stanley B. Gross, Ph.D.
Assistant Professor
Department of Environmental Health
University of Cincinnati
Cincinnati, Ohio 45267

Dear Doctor Gross:

I fully approve of the agreement proposed for submission to Ethyl Corporation for the completion of the work to be done with the data of my experiments on the behavior of lead in the human subject.

Sincerely yours,

A handwritten signature in cursive script, reading "Robert A. Kehoe".

Robert A. Kehoe, M.D.
Professor Emeritus of
Occupational Medicine

RAK:wb

KE 0006150

N 7501.01

CONTRACT PROPOSAL

KEHOE LEAD BALANCE STUDIES IN HUMANS

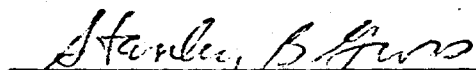
Submitted by

University of Cincinnati, Department of Environmental Health

Eden & Bethesda Avenues, Cincinnati, Ohio 45267

To

Ethyl Corporation
Medical Department
451 Florida
Baton Rouge, Louisiana
70801



Stanley B. Gross, Ph.D., Project Director
Department of Environmental Health



Raymond R. Suskind, M.D., Director
Department of Environmental Health

Robert S. Daniels, M.D.
Interim Dean, College of Medicine

Date: 10/15/74

KE 0006151

N 7501.02

Kehoe Lead Balance Studies in Humans

Scope of Effort

The lead balance studies carried out by Dr. Robert A. Kehoe, of this Department, date back to the late 1930's and involve twenty different subjects. Six of these have been oral ingestion studies only and the remainder both oral and inhalation uptake studies. Four oral studies including E.B., I.F., M.R. and S.W. as subjects have been reported in the Harben lectures and in several other papers. The data reported, by comparison to the amount of information available from the studies, were very limited. Data on eleven of 14 subjects used in inhalation studies have been published also in a very limited way.

The data obtained from the balance studies are currently stored in several different locations in the Department. This project proposes to assemble all the data from these balance studies for the purpose of analysis and publication as described below.

Three types of analyses are anticipated. These are:

1. The statistical variations of the many measurements made in these studies including variations within an individual and variations among the different individuals;
2. changes in the health parameters measured during the different oral and inhalation exposures; and,
3. changes in the body burden of lead due to these exposures.

From these analyses, we shall develop mathematical models to express the rates of change in such parameters as blood and urinary lead from measurements made at the beginning of exposure, during week-end periods of no exposure and at the terminations of the exposures. Models will also be developed, if possible, to predict changes during intermediate exposure rates.

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A tentative schedule of activities will be as follows:

- Phase 1. Detailed review of the data by Drs. Gross and Tsay leading to development of protocols.
- Phase 2. Discussion with Drs. Kehoe, Suskind, Zavon, Sobel and Ter Haar leading to approval of protocols and of a priority listing of activities. The beginning of data processing.
- Phase 3. Continue data processing. Quarterly reports.
- Phase 4. Continued data processing. Draft of final reports and publication manuscripts.
- Phase 5. Final report and manuscripts.

It is expected that phases 1 and 2 will be completed within 2-3 months.

The time table for the remaining phases will be derived jointly by the 3rd month.

Personnel

Dr. Stanley B. Gross, of the Department, will serve as the Project Director and will be under the general supervision of Dr. Kehoe. Dr. Gross will be assisted by Ms. Susan Rasche, research technician and Dr. Jia-yeong Tsay, postdoctoral fellow in biostatistics. Dr. Peter Gartside, Statistician in the Division of Epidemiology and Biostatistics, will serve as a consultant to Dr. Gross and Dr. Tsay.

Dr. Mitchell Zavon, Medical Director of Ethyl Corporation, will serve as Project Monitor. Dr. Raymond Suskind, Director of the Department and Drs. Bernard Sobel and Gary Ter Haar, of Ethyl Corporation, will serve in advisory capacities to Drs. Gross and Zavon.

In the event that mathematic models will be developed to describe the kinetics of lead distributions, Drs. Stanley Day and Carl Evert of the University's Electrical Engineering Department, will provide guidance for an engineering assistant who will develop the mathematical models from data provided by Dr. Gross using the E.E. Department's hybrid computers.

Reports

Quarterly reports will be due within 15 days after the end of the quarterly period. Several informal oral reports and/or consultations (at least one per month)

between the Department and the Corporation will be made during the 1st three months of the project. A final report will be due within 15 days after the termination of the study as planned or 30 days after an unscheduled termination.

Termination of Project

Because of the variable nature of this study, this project may be terminated when (1) the project greatly exceeds the scope of the original plans, (2) there is a lack of agreement concerning the protocols to be defined in the first 3 months of the project, (3) or by mutual consent or (4) there develops unacceptable delays in performance (30 days).

BUDGET

Personnel:

Dr. Stanley Gross	Project Director	50%	\$ 8,508
Dr. Jia-yeong Tsay	Postdoctoral Fellow	25%	2,500
Mrs. Susan Rasche	Research Technician	50%	4,248
	Secretarial Assistance	10%	720
			<u>\$ 15,976</u>

Fringe Benefits:

15.2% of Applicable Salaries (13,476)	\$ 2,048
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Other Direct Costs:

Computer Services	1,000
Misc. Supplies (computer draws, folders, etc.)	400
	<u>\$ 1,400</u>

Overhead:

60.00% of Salaries (15,976)	\$ 9,586
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TOTAL	\$ 29,010
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Quarterly Amount	\$ 7,252.50
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Any trips in connection with this study would be borne by Ethyl Corporation.

A G R E E M E N T

THIS AGREEMENT, made this _____ day of _____ 1974,
between Ethyl Corporation, Medical Department, 451 Florida, Baton Rouge,
Louisiana, hereinafter called "the Donor", and the University of Cincinnati,
hereinafter called "the University".

W I T N E S S E T H

WHEREAS, the Donor wishes The Department of Environmental Health
(hereinafter called "the Department") to conduct a study described in
the attached Scope of Effort of the Kehoe Balance Studies in Humans;

WHEREAS, the University has approved of this study by said Department;

NOW, THEREFORE, in consideration of the mutual promises hereinafter
specified,

IT IS AGREED:

1. The Department shall carry out such investigations within the limits
of its available facilities and scientific interests.

2. The Donor shall pay the University therefore the sum of Twenty-
Nine Thousand, Ten Dollars (\$29,010) for the conduct of this study in four
installments of Seven Thousand Two Hundred Fifty-Two Dollars and fifty cents
(\$7,252.50) at the end of each three month period of the project.

3. The name of the University or of the Department or of any member,
officer or employee of the University or the Department, shall not be used
in any advertising matter at any time during the progress of the work or
thereafter. A written report shall be made of the findings and such a report
or photostatic copy thereof may be used by the Donor as evidence of the facts
established. If the findings are published in a scientific journal, the Donor
shall be free to quote such findings subsequent to publication.

4. The investigative work shall be planned and carried out by the University, and the University shall have the right to disseminate for the public good any information obtained. However, before the issuance of public reports or scientific publications, the manuscripts therefore will be submitted to the Donor for criticism and suggestion.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement by their proper officer, respectively, who are hereby certified to have been duly authorized to execute the same.

ETHYL CORPORATION

BY _____

UNIVERSITY OF CINCINNATI

BY _____

KE 0006156