

OAK RIDGE INSTITUTE OF SCIENCE AND EDUCATION

OAK RIDGE ASSOCIATED UNIVERSITIES/
OAK RIDGE NATIONAL LABORATORY
COMMITTEE ON HUMAN STUDIES
ACTIVE PROTOCOLS AND RELATED DOCUMENTS
FILE 3

APPLICATION FOR THE USE OF HUMANS AS EXPERIMENTAL SUBJECTS

To: COMMITTEE ON HUMAN STUDIES
Oak Ridge Associated Universities and
Oak Ridge National Laboratory

Date October 24, 1980

Principal Investigator: C. C. Lushbaugh, M.C.

Co-Investigators: Shirley A. Fry, M.B., Ch.B.

Title of Project: The DTPA Registry Follow-Up Program

I. Objectives of Experiment

The program objective is to study the long-term or delayed human health effects of the calcium and zinc salts of diethylenetriaminepentaacetic acid (DTPA) in order to increase our knowledge of the actions of these pharmaceuticals and to identify any long-term or delayed adverse or side effects associated with their use in the treatment of persons with internally deposited or incorporated radionuclides.

II. Methods of Procedures

Individuals treated with calcium and/or zinc DTPA by co-investigator physicians at remote sites are identified to the DTPA Registry maintained at REAC/TS, Oak Ridge, TN, by individual co-investigators on the FDA-IND for DTPA managed by ORAU, (C. C. Lushbaugh, M.D., Principal Investigator), under the terms of that IND. With the informed consent of recipients of DTPA therapy, their health status will be reviewed at regular intervals through the current plant physician for persons still employed at the site at which DTPA was administered or, if employers will permit us to contact their former employees, by contact with terminated employees directly or indirectly through their personal physician. Consent to the release of pertinent medical, employment and/or exposure records may be requested (copy to be attached). It is intended that the follow-up program should continue throughout the life time of individual participants.

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III. Possible Hazards and Their Evaluation

It is not anticipated that there will be any clinical or psychological hazards associated with this study. Participants will have consented to their inclusion in the follow-up program at the time they are treated with DTPA.

REPOSITORY Oak Ridge Inst. for Science & Education
COLLECTION Medical Sciences Division
BOX No. _____

IV. Radioisotopes and New Drugs

Treatment with DTPA is a prerequisite for inclusion in the follow-up program and not a part of that program. However, DTPA is approved for human use under the terms of the FDA/IND managed by ORAU; a consent form previously approved by the ORAU/ORNL Committee on Human Studies is used. No radioisotopes or new drugs will be used by REAC/TS physicians in the course of obtaining medical follow-up information on persons treated with DTPA.

V. Responsibility of Principal Investigator

An individual's consent to participate in the follow-up medical program of the DTPA Registry is sought by the co-investigator physician at the time of the initial DTPA treatment (copies attached). The co-investigator physician will explain and discuss the follow-up program with a potential participant. All data collected for the Registry follow-up program will be encoded and entered into the password-protected computerized data bank maintained at ORAU as part of the DOE Record System as described in the Federal Register, August 30, 1979. Hard copy data, including medical records, will be stored, protected, and used at REAC/TS according to the rules and regulations of the DOE Record System, of the Privacy Act (1974), the Privacy of Medical Information Act (1979), and of the Freedom of Information Act (1966). Participants will not be identified in any reports, presentations, or publications associated with the program.

The principal investigator will follow the procedures of the Committee on Human Studies in obtaining "informed consent" from the subjects under study. The investigator recognizes that he retains the primary responsibility for safeguarding the interests of the participants under study. Any significant changes in methods of procedure or of the development of unexpected risks will be brought to the attention of the Committee on Human Studies.

Starting Date: 10/30/80

Signatures: C. C. Lambhough, 47 Principal Investigator

[Signature] Co-Investigator

_____ "

_____ "

_____ "

_____ "

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DIVISION REVIEW:

The application described above has been reviewed and approved for submission to the ORAU/ORNL Committee on Human Studies.

Official signing for the institution:

Signature C. C. Lusk / A7

Title Chairman, Medical & Health Sciences Division

Institution Oak Ridge Associated Universities

Date October 24, 1980

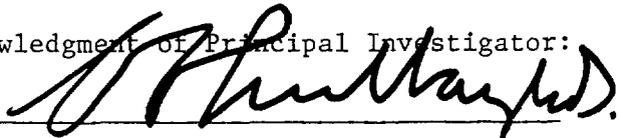
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ORAU/ORNL COMMITTEE ON HUMAN STUDIES

Title of Proposal: THE DTPA REGISTRY FOLLOW-UP PROGRAM

Proposal No.: 61 Principal Investigator: C. C. Lushbaugh, M.D.

Date of Approval: 10/30/80 Date of Disapproval: _____

Acknowledgment of Principal Investigator:


Signature

Date

(This form has been approved for use of noninstitutional physicians by the ORAU/ORNL Committee on Human Studies, Oak Ridge, Tennessee and DOE Biomedical Research Division of Safety, Standards, and Compliance.)

INFORMED CONSENT FORM
FOR USE OF CA-DTPA, AN INVESTIGATIONAL DRUG

NAME: _____ AGE: _____ DATE: _____ TIME _____ AM/PM

I _____, hereby request and authorize
_____ M.D. to give to _____
(myself)

the drug trisodium calcium diethylenetriaminepentaacetate (CA-DTPA) in an attempt to enhance the removal of _____ from my body. I understand that I have been involved in an incident where I was exposed to radioactive _____ and may have been contaminated, to some degree, by this exposure. The above named physician has consulted with me concerning this condition and has advised me that one method of treatment is the use of the drug CA-DTPA. I understand that I may require repeated doses of this drug several times a week and may need to get additional treatments with a drug called Zn-DTPA, depending on the level of contamination that I have experienced, should I decide to accept this method of treatment.

I understand that CA-DTPA is an investigational drug and not available for general use. The term "investigational drug" means that the drug is undergoing investigation, under FDA control, to determine its effect on humans. It has been explained to me that this compound has the ability to bind with some heavy metals, including iron, lead, plutonium, and americium, and help the body to excrete them. I have been told that CA-DTPA especially when given in high doses for prolonged periods of time tends to remove zinc from the body. For this reason treatment is switched from CA-DTPA to Zn-DTPA if prolonged treatment is necessary. I understand that all risks may not be known and that unforeseen results may occur. On the other hand, it has been explained to me that the risk of developing adverse late effects from actinide incorporation is decreased with CA-DTPA followed by Zn-DTPA therapy, and I realize that this treatment is offered to me only after careful deliberation by Dr. _____ and colleagues.

I am consenting to its use for the study and treatment of my condition with the understanding that the results of this treatment may not necessarily be of benefit to me. The use of CA-DTPA in the treatment of internal radionuclide contamination is part of a national research program. I do not object if any information relating to my case is used in professional journals or medical books, or for any other purpose in the interest of medical education, knowledge, or research; provided, however, that it is specifically understood that in any such publication or use I shall not be identified in any way. I further agree that I will participate in whatever follow-up studies are deemed appropriate by my physician at whatever intervals are found suitable by the

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investigators. I am reserving the right to withdraw my permission at any time without prejudicing my further medical care. Dr. _____ has also offered to answer any additional questions.

Signed: _____
(patient)

Witness: _____

The foregoing consent was read, discussed, and signed in my presence, and in my opinion the person signing did so freely and with full knowledge and understanding.

Witness: _____

Date: _____

Addendum:

Dr. _____ has also explained to me the possible effects on a fetus that may occur from prolonged treatment with Ca-DTPA.

Signed: _____
(patient)

Witness: _____

(This form has been approved for use of noninstitutional physicians by the ORAU/ORNL Committee on Human Studies, Oak Ridge, Tennessee, and DOE Biomedical Research Division of Safety, Standards, and Compliance.)

INFORMED CONSENT FORM
FOR USE OF ZN-DTPA, AN INVESTIGATIONAL DRUG

NAME: _____ AGE: _____ DATE: _____ TIME: _____ AM/PM

I _____, hereby request and authorize
_____ M.D. to give to _____
(myself)

the drug trisodium zinc diethylenetriaminepentaacetate (Zn-DTPA) in an attempt to enhance the removal of _____ from my body. I understand that I have been involved in an incident where I was exposed to radioactive _____ and may have been contaminated, to some degree, by this exposure. The above named physician has consulted with me concerning this condition and has advised me that one method of treatment is the use of the drug Zn-DTPA. I understand that I may require repeated doses of this drug several times a week for up to several months depending on the level of contamination that I have experienced, should I decide to accept this method of treatment.

I understand that Zn-DTPA is an investigational drug and not available for general use. The term "investigational drug" means that the drug is undergoing investigation, under FDA control, to determine its effect on humans. It has been explained to me that this compound has the ability to bind with some heavy metals, including iron, lead, plutonium, and americium, and help the body to excrete them. There are no known immediate risks at this time in taking Zn-DTPA with daily doses of up to 2 grams. However, I understand that all risks may not be known and that unforeseen results may occur. On the other hand, it has been explained to me that the risk of developing adverse late effects from actinide incorporation is decreased with Zn-DTPA therapy, and I realize that this drug is offered to me only after careful deliberation by Dr. _____ and colleagues. Dr. _____ has indicated to me that the first or the first few doses of DTPA are in some cases given as Ca-DTPA followed by switching to Zn-DTPA for extended therapy.

I am consenting to its use for the study and treatment of my condition with the understanding that the results of this treatment may not necessarily be of benefit to me. The use of Zn-DTPA in the treatment of internal radionuclide contamination is part of a national research program. I do not object if any information relating to my case is used in professional journals or medical books, or for any other purpose in the interest of medical education, knowledge, or research; provided, however, that it is specifically understood that in any such publication or use I shall not be

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identified in any way. I further agree that I will participate in whatever follow-up studies are deemed appropriate by my physician at whatever intervals are found suitable by the investigators. I am reserving the right to withdraw my permission at any time without prejudicing my further medical care. Dr. _____ has also offered to answer any additional questions about this drug.

Signed: _____
(patient)

Witness: _____

The foregoing consent was read, discussed, and signed in my presence, and in my opinion the person signing did so freely and with full knowledge and understanding.

Witness: _____

Date: _____

ORAU-ORNL COMMITTEE ON HUMAN STUDIES VOTING RECORD

Proposal Number and Title #61 - The DTPA Registry Follow-Up Program

Principal Investigator Dr. C. C. Lushbaugh

VOTE OF COMMITTEE

	Signature	Approve	Disapprove	Comment	Date
1.	<i>Donald Woodman</i>	yes			10-30-80
2.	<i>John R. Horen</i>	✓			10/30/80
3.	<i>Cullen M. Beck</i>	✓			10/30/80
4.	<i>W. E. Horen</i>	✓			"
5.	<i>R. Clifford Mink</i>		-		"
6.	<i>Paul D. Miller</i>	✓			10/30/80
7.	<i>Robert W. Taylor</i>				10/30/80
8.	<i>Howard F. ...</i>	✓			10/30/80
9.					
10.					
11.					
12.					
13.					
14.					

Chairman's statement of Committee consensus:

_____ 10/30/80 _____
DATE

RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE

Medical and Health Sciences Division
Oak Ridge Associated Universities
Oak Ridge, TN

REAC/TS STUDIES AND FOLLOW-UP PROGRAM

CONSENT TO RELEASE INFORMATION PROTECTED BY THE PRIVACY ACT OF 1974

(5 USC 522 et. seq.)

I am asked to consent to and authorize the release of copies of my records from those physician(s) (Attachment 1), hospital(s) (Attachment 2), and diagnostic laboratory(ies) (Attachment 3) identified by me, together with all copies of my medical radiation exposure, and any bioassay records maintained by those employer(s) (Attachment 4) also identified by me, for the exclusive use of the DTPA Registry* (hereinafter referred to as the Registry). The purpose and extent of my involvement with the Registry have been explained to me by _____ of (affiliation) _____. The potential benefits of my release of this information to the Registry have been explained to me also.

I have been advised that:

1. The primary purpose of the DTPA Registry is to compile complete clinical histories of individuals who have been treated with the calcium or zinc salts of diethylenetriamine pentaacetic acid (DTPA), as a basis for long-term epidemiological studies.
2. The information will be used without identification or identifiers by the REAC/TS staff, physicians, and other health care personnel to provide medical care for patients with real or suspected internal deposition or incorporation of radionuclides. The information may be included also, in professional presentations, scientific publications, and other official reports.
3. The information contained in the Registry is retrievable by name or other individual identifier; however, I will not be individually identified unless I give my consent subsequently.
4. I may be contacted on an annual or other more agreeable basis concerning the status of my health and may be requested to release copies of my most recent medical records to the Registry.

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5. All expenses in obtaining copies of my personnel and medical records will be borne by the Registry.
6. I further understand that neither the U. S. Department of Energy (DOE) nor Oak Ridge Associated Universities (ORAU) assumes any financial responsibility for me or for the expense of my health care.
7. The potential benefits of this program, if I choose to enroll, are:
 - a. My physician will have available to him the medical expertise of other physicians who are associated with the Registry.
 - b. The physicians associated with the Registry will, upon my request, provide to my present attending physician or any physician whom I may engage in the future any copies of my medical history in their possession.
8. I may cancel this authorization and/or withdraw from any part or all of the activities of the Registry at any time.

Therefore, based upon my discussions and understanding of the material herein set forth, I do hereby consent to and authorize the release of the aforementioned records from the sources identified by me (see attachments) to _____ of the Medical and Health Sciences Division, Oak Ridge Associated Universities, Oak Ridge, TN.

Signed: _____

Date: _____

Witness: _____ Date: _____

Witness: _____ Date: _____

Attachments

*The DTPA Registry is operated for the Department of Energy by the Radiation Emergency Assistance Center/Training Site (REAC/TS), a subunit of the Medical and Health Sciences Division of ORAU. It is one of the registries in the REAC/TS Registry System established to provide a data bank of the effects of accidental and some occupational exposures of humans to ionizing radiation on a world-wide basis.

ATTACHMENT 1

AUTHORIZATION FOR RELEASE OF INFORMATION

Physicians authorized by me to release copies of my records to _____
of the Medical and Health Sciences Division of Oak Ridge Associated Universities.

1. Name _____
Address _____
Street City State Zip
Approximate period of care 19__ - 19__.

2. Name _____
Address _____
Street City State Zip
Approximate period of care 19__ 19__.

3. Name _____
Address _____
Street City State Zip
Approximate period of care 19__ - 19__.

4. Name _____
Address _____
Street City State Zip
Approximate period of care 19__ - 19__.

Signed: _____

Date: _____

If additional space is required, please attach another sheet.

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ATTACHMENT 2

AUTHORIZATION FOR RELEASE OF INFORMATION

Hospitals authorized by me to release copies of my records including face sheets, discharge summaries, histories, and physicals, x-ray reports, reports of operations and/or procedures, pathology reports, all laboratory data, physicians' progress notes, physicians' orders, nurses' notes, and results of any special tests to _____ of the Medical and Health Sciences Division of Oak Ridge Associated Universities. If applicable, I also authorize the loan of any x-ray films, microscopic slides, paraffin blocks or other special materials relating to the above hospitalization to ~~the~~ above mentioned individual.

1. Hospital _____
Address _____
Street City State Zip
Approximate period(s) of care: _____ inpatient ()
outpatient ()

2. Hospital _____
Address _____
Street City State Zip
Approximate period(s) of care: _____ inpatient ()
outpatient ()

3. Hospital _____
Address _____
Street City State Zip
Approximate period(s) of care: _____ inpatient ()
outpatient ()

Signed: _____

Date: _____

If additional space is required, please attach another sheet.

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ATTACHMENT 3

AUTHORIZATION FOR RELEASE OF INFORMATION

Diagnostic Laboratory(ies) authorized by me to release copies of the results of investigations performed on me to _____ of the Medical and Health Sciences Division of Oak Ridge Associated Universities.

1. Name (Laboratory) _____

Address _____

Street City State Zip

Approximate dates of investigations: _____

2. Name (Laboratory) _____

Address _____

Street City State Zip

Approximate dates of investigations: _____

3. Name (Laboratory) _____

Address _____

Street City State Zip

Approximate dates of investigations: _____

4. Name (Laboratory) _____

Address _____

Street City State Zip

Approximate dates of investigations: _____

Signed: _____

Date: _____

If additional space is needed, please attach another sheet.

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ATTACHMENT 4

AUTHORIZATION FOR RELEASE OF INFORMATION

Employers or contractors authorized by me to release copies of my medical, radiation exposure or any bioassay records to _____ of the Medical and Health Sciences Division of Oak Ridge Associated Universities.

1. Name of Company/Employer _____

Address _____

Street City State Zip

Approximate period of employment _____

month/year - month/year

2. Name of Company/Employer _____

Address _____

State City State Zip

Approximate period of employment _____

month/year - month/year

3. Name of Company/Employer _____

Address _____

State City State Zip

Approximate period of employment _____

month/year - month/year

Signed: _____

Date: _____

If additional space is needed, please attach another page.

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REVIEW AND ACTION

ORAU/ORNL Committee on Human Studies

Principal Investigator C. C. Lushbaugh, M.D. Ident. No. 61

Project Title The DTPA Registry Follow-Up Program

1. In the opinion of this committee the rights and welfare of the subjects in this project or activity will be protected. The committee states that adequate safeguards against any untoward effects have been provided.

2. In the opinion of the committee the informed consent procedures to be used in this project will be both appropriate and adequate. The committee also finds that no inappropriate psychological or sociological risks will exist for the subjects involved in this project.

3. The committee seeks continuing communication with the investigator(s) on this project along the following lines:

4. Other committee comments:

Approve X

Disapprove

Robert D. Long, M.D.
Chairman of Committee

10/30/80

Date

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3. Are there any planned changes? No

4. Do you wish the project to be continued? Yes

5. Comments. Comments to be made under this in following up

by attending to various particular
New system of ... directly
from ...

Federal Register

Tuesday
May 12, 1981

Part II

Department of
Energy

Privacy Act of 1974; Proposal of New
Systems

DEPARTMENT OF ENERGY

Privacy Act of 1974; Proposal of New Systems

AGENCY: Department of Energy.

ACTION: Proposal of three new systems of records.

SUMMARY: The Department of Energy is proposing three new systems of records subject to the Privacy Act of 1974 (Pub. L. 93-579; 5 U.S.C. 552a(o)).

DATES: Written comments on or before June 8, 1981.

ADDRESSES: Written comments should be directed to the following address: U.S. Department of Energy, Phillip M. Kannan, Attorney, Office of Chief Counsel, P.O. Box E, Oak Ridge, Tennessee 37830 (615) 576-1204.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Energy, Milton Jordan, Director, Division of FOI and Privacy Acts Activities, Forrestal Building, Room 1G-051, Washington, DC 20585, (202) 252-5922.

A. Supplementary Information

I. Report on three New Systems of Records.

1. Comments Procedure.

II. System Notice DOE—The Radiation Accident Registry.

VI. System Notice DOE—The Department of Energy Radiation Study Registry.

V. System Notice DOE—The US-DTPA Registry.

1. *Background:* This Report of New Systems, consisting of three separate parts, is submitted by the Department of Energy as required by the Privacy Act of 1974, 5 U.S.C. 552a(o). The Office of Management and Budget requires a Report on New Systems by a Government agency whenever a new system of records is proposed or certain significant changes occur to previously established systems. The Department of Energy is submitting the Reports on New System required by OMB Circular A-108 concurrently with the publication of this Federal Register notice. At this time, the Department of Energy is proposing to establish three systems of records for which no notice has yet been published. Their proposed designations are as follows:

- (a) The Radiation Accident Registry
 - (b) The Department of Energy Radiation Study Registry
 - (c) The US-DTPA Registry
2. DOE-71, the Radiation Accident Registry: (a) *Purpose:* This system will serve primarily to provide complete clinical and accident histories as basis

for clinical and epidemiological studies of the life-time morbidity of individuals accidentally exposed to acute dose of ionizing radiation, to provide data for comparative studies of the efficacies of the methods and regimens used in the diagnosis and therapy of acute radiation-induced injuries, and to serve as a resource of technical and medical data for the education of physicians, health physicists and allied health care personnel.

(b) *Authority:* This system is established under the authority vested in the Secretary contained in 5 U.S.C. 301 and Section 644 of the Department of Energy Organization Act, Pub. L. 95-91, to prescribe such procedural and administrative rules as he may deem necessary or appropriate to manage functions vested in him.

(c) Potential consequence on individual privacy, and;

(d) Safeguards against unauthorized access.

The data in the system of records will be available only to scientists and supporting staff. Any reports generated will not identify the individuals to whom the data pertains. Thus, there will be a minimal effect on the privacy of the individuals. There will be no other effect on any other personal or property right of the individuals. Thus, it is the evaluation of the Department that the proposed system will have no detrimental effect on federalism or separation of power.

The records will be maintained in locked file cabinets or on computer storage devices in locked security areas. These areas are not accessible to members of the public. Only scientists approved by the Department of Energy will have access to this information. Reports published based on this information will not identify the individuals. It is the Department's evaluation that the risk of unauthorized disclosure is minimal.

3. DOE-72, The Department of Energy Radiation Study Registry:

(a) *Purpose:* This system will provide complete clinical histories as a basis for life-time morbidity studies of civilians in a defined population whose exposure to ionizing radiation at one of DOE's (or its predecessor's) plant sites, laboratories, test stations, or nuclear naval bases was at least 5 REM in any calendar year.

(b) *Authority:* This system is established under the authority vested in the Secretary contained in 5 U.S.C. 301 and Section 644 of the Department of Energy Organization Act, Pub. L. 95-91, to prescribe such procedural and administrative rules as he may deem necessary or appropriate to manage functions vested in him.

(c) Potential consequences on individual privacy.

4. DOE-73, The US-DTPA Registry:

(a) *Purpose:* This system will provide complete clinical histories of individuals treated with diethylenetriaminepentaacetic acid (DTPA) in either the calcium or zinc form and administered intravenously, intramuscularly, orally, or by inhalation of the aerosol preparation of the drug. Such histories will be the basis of studies by epidemiological methods to identify any long-term, adverse or side effects of DTPA.

(b) *Authority:* This system is established under the authority vested in the Secretary contained in 5 U.S.C. 301 and Section 644 of the Department of Energy Organization Act, Pub. L. 95-91, to prescribe such procedural and administrative rules as he may deem necessary or appropriate to manage functions vested in him.

B. Comments Procedure

As provided by Section 3(e)(11) of the Privacy Act of 1974 (5 U.S.C. 552a(e)(11)), interested persons are invited to submit written data, views or arguments related to these proposal to: Phillip M. Kannan, Attorney, U.S. Department of Energy, Office of Chief Counsel, P.O. Box E, Oak Ridge, Tennessee 37830, (615) 576-1204.

Comments should be identified on the outside of the envelope and on the documents submitted to the Department of Energy with the designation "Department of Energy Privacy Act Systems Proposals." These comments and all other relevant information will be considered by the Department of Energy before the various proposals are adopted in their final form.

Any information or data considered by the person furnishing it to be confidential must be so identified and submitted in writing, one copy only. The Department of Energy reserves the right to determine the confidential status of the information or data and to treat it according to that determination.

If no comments to the contrary are received with respect to a particular proposed system, it is the intent of the Department of Energy to operate any such system as proposed at the expiration of the 60-day advance notice period for informing Congress and the Office of Management and Budget of proposed new systems, as defined in OMB Circular A-108.

The Department of Energy has determined that this document does not contain a proposal requiring preparation of a regulatory analysis under Executive Order 12044.

(Privacy Act of 1974, Pub. L. 93-579; Department of Energy Organization Act, Pub. L. 95-91; Executive Order 12009, 42 FR 46287; and those authorities vested in the Department's predecessor agencies which are incorporated by reference in Title III of the Department of Energy Organization Act)

In consideration of the foregoing, the measures described above are proposed. Set forth below as Sections III-V of SUPPLEMENTARY INFORMATION, respectively, is a listing of the three Department of Energy Systems as proposed.

Issued in Washington, D.C., April 23, 1981.
William S. Haffelfinger,
Director of Administration.

DOE 71

System name: The Radiation Accident Registry.

Security classification: Unclassified.

System location: Oak Ridge Operations Office, P.O. Box E, Oak Ridge, Tennessee 37830.

Categories of Individuals Covered by the System:

1. Those persons accidentally exposed to acute doses of ionizing radiation as defined by exposure dose criteria agreed to by the Department of Energy and the Nuclear Regulatory Commission by an interagency agreement. The dose criteria established by this agreement include one or more of the following: (a) Greater than or equal to 25 REM (Roentgen Equivalent Man) to the whole body, active blood-forming organs or gonads; (b) greater than or equal to 800 REM to skin of whole body or extremities; (c) greater than or equal to 75 REM to other tissues or organs from an external source; (d) greater than or equal to 1/2 NCRP maximum permissible organ burden internally; all those medical misadministrations of radioisotopes that result in a dose or organ burden equal to or greater than those given above.

2. Those individuals known to have been involved in an event in which one or more other persons received a dose equal to or in excess of the DOE/NRC criteria but whose personal dose was less than these criteria. The histories of these individuals contribute control population data.

Categories of Records in the System:

1. Official accident reports including reports of those accidents that have occurred within the jurisdiction of the Nuclear Regulatory Commission and which have been transferred to the Department of Energy for the Accident Registry according to the Department of Energy/Nuclear Regulatory Commission agreement.

2. Names, addresses, social security numbers or other identifiers, and vital status information such as age, sex, race, etc.

3. Original or copied medical records compiled at the time of the accident. Such records include physician and hospital records, diagnostic and laboratory test reports, radiographs, EKGs, etc., and radiation exposure reports.

4. Original or copies of medical records of illnesses, examinations, including routine follow-up exams, investigations, etc., that have occurred since the radiation exposure.

5. Photographs or facsimiles of radiation-induced injuries.

6. Search and contact information for registrants as yet not identified and/or located.

7. Consent to release information forms completed by registrants.

8. Death certificates (copies).

9. Anecdotal information.

10. Correspondence relating to the accident and/or the individuals involved; originals and copies.

Authority for Maintenance of the System:

5 U.S.C. 301; Department of Energy Organization Act, including authorities incorporated by reference in Title III of the Department of Energy Organization Act; Executive Order 12009.

Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of Such Uses:

1. To provide a current record of radiation accidents for use by the Department of Energy, and its contractors and consultants.

2. To identify specific populations for use in epidemiological and clinical studies.

3. To conduct medical surveillance during the lifetime of the registrants.

4. Additional uses 4, 8, 9, 10, as listed in Appendix B to the Department of Energy publication of systems of records, 45 FR 51125, 8/30/79.¹

Policies and Practices for Storing, Retrieving, Accessing, Retaining, and Disposing of Records in the System:

Storage: Paper records, computer tapes, computer printouts, punched cards, discs, magnetic tape and microfilm.

Retrievability: By name and social security number.

Safeguards: Records are maintained in locked security areas in locked file cabinets. Access is limited to

individuals whose official duties require access.

Retention and Disposal:

Records retention and disposal authorities are contained in the DOE Order 1324.1, "Records Disposition." Records within the Department of Energy are destroyed by shredding, burning, or burial in a sanitary landfill, as appropriate.

System Manager(s) and Address:

The Manager of the Oak Ridge Operations Office is the System Manager.

Notification Procedure:

a. Requests by an individual to determine if a system of records contains information about him or her should be directed to the Privacy Act Officer, Department of Energy, P.O. Box E, Oak Ridge, Tennessee 37830 in accordance with the Department of Energy's Privacy Act regulations (10 CFR Part 1008, 45 FR 61576, September 16, 1980).

b. Required identifying information: Name, social security number, and time period.

Record Access Procedures:

a. Requests by an individual for access to a system of records that contains information about him or her should be directed to the Privacy Act Officer, Department of Energy, P.O. Box E, Oak Ridge, Tennessee 37830 in accordance with the Department of Energy's Privacy Act regulations (10 CFR Part 1008, 45 FR 61576, September 16, 1980).

b. Required identifying information: Name, social security number, and time period.

Record Source Categories:

The individual, medical records, physicians, medical institutions, and reports of incident/accident investigations from private and public sources, radiation dosimetry records, security clearance records and employment records.

Systems Exempted from Certain Provisions of the Act: None.

DOE 72

System name: The Department of Energy Radiation Study Registry.

Security classification: Unclassified.

System location: Oak Ridge Operations Office, P.O. Box E, Oak Ridge, Tennessee 37830

¹These routine uses are reprinted below.

Categories of Individuals Covered by System:

Registrants are those present and former employees of contractors of the Department of Energy and its predecessor organizations including the Manhattan District, USAEC, and ERDA, and present and former civilian employees in the Department of Energy Naval Reactor Program who received a whole body exposure of ionizing radiation equal to or in excess of 5 REM in any one calendar year.

Categories of Records in the System:

1. Rosters of names of individuals meeting the above criteria for inclusion in the Registry submitted through the Department of Energy field operation offices from Department of Energy-owned and operated facilities and sites. In addition to names of such individuals, these rosters include social security number or other identifying information, sex, race, date of birth, date and/or place of death, first date of hire, last date of termination, continuity of hire, year in which they received first dose, greater than or equal to 5 REM, actual radiation dose in excess of 5 REM, total career radiation exposure dose.

2. Original or copied lifetime medical records from plant and private physicians and hospitals including routing physical examinations, reports of diagnostic and laboratory tests, radiographs, EKGS, etc., or abstracted portions of such records as are required for the purposes of the study.

3. Search and contact information for registrants who are no longer employed at qualified sites or who are deceased.

4. Death Certificates.

Authority for Maintenance of the System:

5 U.S.C. 301: Department of Energy Organization Act, including authorities incorporated by reference in Title III of the Department of Energy Organization Act; Executive Order 12009.

Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of Such Uses:

1. To provide a current record of registrants for use by Department of Energy, and its contractors and consultants.

2. To identify specific populations for use in epidemiological and clinical studies.

3. To conduct medical surveillance during the lifetime of the registrants.

4. Additional uses 4, 8, 9, 10, as listed in Appendix B to the Department of

Energy publication of systems of records, 45 FR 61123, 6/30/79.¹

Policies and Practices for Storing, Retrieving, Accessing, Retaining, and Disposing of Records in the System:

Storage: Paper records, computer tapes, computer printouts, punched cards, discs, magnetic tape and microfilm.

Retrievability: By name and social security number.

Safeguards: Records are maintained in locked security areas in locked file cabinets. Access is limited to individuals whose official duties require access.

Retention and Disposal: Records retention and disposal authorities are contained in the DOE Order 1324.1, "Records Disposition." Records within the Department of Energy are destroyed by shredding, burning, or burial in a sanitary landfill, as appropriate.

System Manager(s) and Address: The Manager of the Oak Ridge Operations Office is the System Manager.

Notification Procedure:

a. Requests by an individual to determine if a system of records contains information about him or her should be directed to the Privacy Act Officer, Department of Energy, P.O. Box E, Oak Ridge, Tennessee 37830 in accordance with the Department of Energy's Privacy Act regulations (10 CFR Part 1008, 45 FR 61576, September 16, 1980).

b. Required identifying information: Name, social security number, and time period.

Record Access Procedures:

a. Requests by an individual for access to a system of records that contains information about him or her should be directed to the Privacy Act Officer, Department of Energy, P.O. Box E, Oak Ridge, Tennessee 37830 in accordance with the Department of Energy's Privacy Act regulations (10 CFR Part 1008, 45 FR 61576, September 16, 1980).

b. Required identifying information: Name, social security number, and time period.

Record Source Categories:

The individual, medical records, physicians, medical institutions, and reports of incident/accident investigations from private and public sources, radiation dosimetry records, security clearance records and employment records.¹

¹ These routine uses are reprinted below.

Systems Exempted from Certain Provisions of the Act: None.

DOE 73

System name: The US-DTPA Registry.

Security classification: Unclassified.

System location: Oak Ridge Operations Office, P.O. Box E, Oak Ridge, Tennessee 37830.

Categories of Individuals Covered by the System:

Registrants are those individuals who, because of real or suspected internal contamination with transuranic elements, have received diethylenetriaminepentaacetic acid (DTPA), in the calcium or zinc form during the course of chelation therapy. Administration of the agent DTPA is limited to physicians who are co-investigators with the Department of Energy contractor staff on the Investigative New Drug License of the Food and Drug Administration.

Categories of Records in the System:

1. The records compiled by the physician administering DTPA in the event of an exposure that was known to have or was suspected of having caused transuranic contamination internally requiring chelation therapy with DTPA. These records include a description of the exposure, the results of serial bioassays and investigations conducted to evaluate the level of internal contamination and the efficacy of subsequent chelation by DTPA. The form of DTPA and the route and frequency of administration are recorded together with an untoward effects of the therapy.

2. Names, social security numbers or other identifiers and vital status of treated persons. The last known addresses and the names of the private physicians of individuals who have relocated or who are no longer within the practice of the administering physician(s) are included in the DTPA Registry to facilitate the search and contact of these individuals.

3. Original or copies of medical records of illnesses, examinations, including routine followup examinations, investigations, etc., that have occurred since the initial administration of DTPA.

4. Death certification.

Authority for Maintenance of the System:

5 U.S.C. 301: Department of Energy Organization Act, including authorities incorporated by reference in Title III of the Department of Energy Organization Act; Executive Order 12009.

Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of Such Uses:

1. To provide a current record of individuals treated with DTPA for use by the Department of Energy and its contractors and consultants.
2. To identify by epidemiological methods any long-term untoward effects associated with DTPA therapy.
3. To provide information to FDA in accord with the L.N.D. license and issuances.
4. Additional uses 4, 8, 9, 10, as listed in Appendix B.¹

Policies and Practices for Storing, Retrieving Accessing, Retaining, and Disposing of Records in the System:

Storage: Paper records, computer tapes, computer printouts, punched cards, discs, magnetic tape and microfilm.

Retrievability: By name and social security number.

Safeguards: Records are maintained in locked security areas in locked file cabinets. Access is limited to individuals whose official duties require access.

Retention and Disposal: Records retention and disposal authorities are contained in the DOE Order 1324.1, "Records Disposition." Records within the Department of Energy are destroyed by shredding, burning, or burial in a sanitary landfill, as appropriate.

System Manager(s) and Address:

The Manager of the Oak Ridge Operations Office is the System Manager.

Notification Procedure:

- a. Requests by an individual to determine if a system of records contains information about him or her should be directed to the Privacy Act Officer, Department of Energy, P.O. Box E, Oak Ridge, Tennessee 37830 in accordance with the Department of Energy's Privacy Act regulations (10 CFR Part 1008, 45 FR 61576, September 16, 1980).
- b. Required identifying information: Name, social security number, and time period.

Record Access Procedures:

- a. Requests by an individual for access to a system of records that

contains information about him or her should be directed to the Privacy Act Officer, Department of Energy, P.O. Box E, Oak Ridge, Tennessee 37830 in accordance with the Department of Energy's Privacy Act regulations (10 CFR Part 1008, 45 FR 61576, September 16, 1980).

b. Required identifying information: Name, social security number, and time period.

Contesting Record Procedures:

a. Requests by an individual to correct or amend the content of a record containing information about him or her should be directed to the Privacy Act Officer, Department of Energy, P.O. Box E, Oak Ridge, Tennessee 37830 in accordance with the Department of Energy's Privacy Act regulations (10 CFR Part 1008, 45 FR 61576, September 16, 1980).

Record source Categories:

The individual, medical records, physicians, medical institutions, and reports of incident/accident investigations from private and public sources, radiation dosimetry records, security clearance records and employment records.

Systems Exempted from Certain Provisions of the Act: None.

Appendix B—Additional Routine Uses

The following routine uses apply to and are incorporated by reference into each system of records as stated therein:

1. In the event that a record within this system of records maintained by this agency indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program pursuant thereto, the relevant records in the system of records may be referred as a routine use to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.
2. A record from this system of records may be disclosed as a routine use to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary, to obtain information relevant to an agency

decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

3. A record from this system of records may be disclosed, as a routine use, to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

4. A record from this system of records may be disclosed, as a routine use (a) to appropriate parties engaged in litigation or in preparation of possible litigation, such as potential witnesses, for the purpose of securing their testimony when necessary; (b) to courts, magistrates or administrative tribunals; (c) to parties and their attorneys for the purpose of proceeding with litigation or settlement of disputes; and (d) to individuals seeking information by using established discovery procedures, whether in connection with civil, criminal, or regulatory proceedings.

5. A record maintained by this agency to carry out its functions which relates to civil and criminal proceedings may be disclosed to the news media in accordance with guidelines contained in Department of Justice regulations 28 CFR 50.2.

6. A record maintained by this agency to carry out its functions may be disclosed to foreign governments in accordance with treaty obligations.

7. A record from this system of records may be disclosed to the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular No. A-19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

8. A record from this system of records may be disclosed, as a routine use, to DOE contractors in performance of their contracts, and their officers and employees who have a need for the record in the performance of their duties subject to the same limitations applicable to DOE officers and employees under the Privacy Act.

¹ These routine uses are reprinted below.

9. A record in this system of records may be disclosed, as a routine use, to a member of Congress submitting a request involving the individual when the individual is a constituent of the member and has requested assistance from the member with respect to the subject matter of the record.

10. A record in this system of records which contains medical and/or psychological information may be disclosed, as a routine use, to the physician or mental health professional of any individual submitting a request for access to the record under the Privacy Act of 1974 and DOE's Privacy Act regulations if, in its sole judgment and good faith, DOE believes that disclosure of the medical and/or psychological information directly to the individual who is the subject of the record could have an adverse effect upon that individual, in accordance with the provisions of 5 U.S.C. 552a(f)(3) and applicable DOE regulations.

[FR Doc. 81-14227 Filed 5-11-81; 9:46 am]
BILLING CODE 6450-01-M

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. C. C. Lushbaugh
FROM: Dianne Gresham, Secretary - Committee on Human Studies
RE: Progress Reports
DATE: February 18, 1982

The guidelines for the ORAU/ORNL Committee on Human Studies require that yearly all principal investigators of ongoing proposals present a progress report to the Committee on the status of their proposals. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions below and add any other information you feel pertinent and return by March 8, 1982. (If additional space is needed, please use the back of this form or attach extra sheets.)

Title of Project: The DTPA Registry Follow-Up Program

Proposal No.: 61 Date Approved: 10/30/80



Signature of Principal Investigator

Date Signed

1. Report progress made in past year.

At ORAU's request co-investigators initiated the follow-up of 385 individuals treated with DTPA prior to FY 80. To date, the 12 co-investigators involved have provided information on 186 treated individuals, the majority of whom are still employed at the facility at which they were treated.

2. Report any complications.
None.

1144690

3. Are there any planned changes?

Follow-up will be expanded to include persons treated in FY 80 and FY 81.

4. Do you wish the project to be continued? Yes.

The DTPA Registry will continue to be maintained and operated to meet the requirements of the INDs and the programmatic needs of DOE and the Medical and Health Sciences Division.

5. Comments.

Active follow-up of terminated individuals will be conducted as part of a single-contact interview designed to provide follow-up data for the DTPA Registry and other registries at ORAU and for the plutonium workers study being conducted by the Epidemiology Group at Los Alamos National Laboratory. In preparation for interviewing terminated employees, efforts continued to determine the vital status and current location of these persons. To accomplish this, searchers utilize records of the Social Security Administration and the motor vehicle and driver's license departments of the appropriate states, as well as telephone directories.

Draft Original attached.

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

July 82

TO: Dr. C. C. Lushbaugh, ORAU, M&HSD
FROM: Dianne Gresham, Secretary - Committee on Human Studies
RE: Progress Reports
DATE: March 23, 1983

The guidelines for the ORAU/ORNL Committee on Human Studies require that yearly all principal investigators of ongoing proposals present a progress report to the Committee on the status of their proposals. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions below and add any other information you feel pertinent and return by April 6, 1983. (If additional space is needed, please use the back of this form or attach extra sheets.)

Title of Project: The DTPA Registry Follow-Up Program

Proposal No.: 67 Date Approved: 10/30/80

[Signature]
Signature of Principal Investigator

[Date]
Date Signed

1. Report progress made in past year.

This program continued to manage for DOE the IND's for both Ca-DTPA and Zn-DTPA, experimental chelation drugs for decorporation of internal transuranic contaminants. A total of 18 persons were treated with DTPA drugs during FY 82 by five of the 44 authorized physician co-investigators. * The desirability of obtaining NDA status for Ca-DTPA and/or Zn-DTPA was evaluated, and it was determined that such a move would not be advantageous at this time.

Active follow-up of 199 persons previously treated with DTPA awaited OMB approval of the questionnaire developed in conjunction with the Epidemiology Group at Los Alamos National Laboratory for use in follow-up of plutonium workers.

include

2. Report any complications.

None.

1144692

No adverse effects were reported as a result of the ^{by any of the approved routes} these therapeutic administrations of either Ca- or Zn-DTPA

3. Are there any planned changes? *no*

4. Do you wish the project to be continued?

Yes.

5. Comments.

Chelation therapy with DTPA drugs remains the method of choice for decorporation of internally deposited actinide contaminants. ~~The~~

Reports of new developments in chelation therapy will be monitored. When clinical trials of new agents or amended protocols for the existing agents are indicated, the appropriate IND applications or amendments will be submitted through DOE to FDA.

To Dr. C. C. Lushbaugh From Dianne Gresham
June 22, 1983 Copies to Dr. Fry,
Dr. Lange, File

Subject APPROVAL OF CONTINUATION OF PROPOSALS REVIEWED BY COMMITTEE ON HUMAN STUDIES

The Committee on Human Studies approved for continued study Proposals 52, 55, and 60-64. Your request to name Dr. Shirley Fry as principal investigator on Proposals 60, 62, and 63 was approved by the Committee; Dr. Fry is aware of the change in responsibility and will be requested to submit a progress report next year and to notify the Committee Chairman immediately of any changes or problems should they occur.

Thank you for your assistance and cooperation.

dg

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

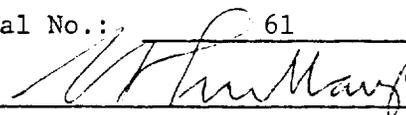
TO: Dr. C. C. Lushbaugh
FROM: Blanche Carden, Secretary - Committee on Human Studies
RE: Progress Reports
DATE: April 23, 1984

The guidelines for the ORAU/ORNL Committee on Human Studies require that yearly all principal investigators of ongoing proposals present a progress report to the Committee on the status of their proposals. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions below and add any other information you feel pertinent and return by May 7, 1984. (If additional space is needed, please use the back of this form or attach extra sheets.)

Title of Project: The DTPA Registry Follow-Up Program

Proposal No.: 61

Date Approved: 10/30/80



May 9, 1984

Signature of Principal Investigator

Date Signed

1. Report progress made in past year.

This program continued to manage for DOE, the INDs for both Ca-DTPA and Zn-DTPA, experimental chelation drugs for the decorporation of internal transuranic contaminants. Seven of 47 co-investigators on the IND, administered Ca-DTPA (56 doses) and Zn-DTPA (55 doses) to a total of 24 persons; 17 persons received Ca-DTPA only, one person received Zn-DTPA only and six persons received Ca-DTPA followed by Zn-DTPA.

Active follow-up of all persons previously treated with DTPA is being initiated using the questionnaire developed in conjunction with the Epidemiology Group at Los Alamos National Laboratory for use in follow-up of plutonium workers and approved by OMB in 1983. This follow-up will be conducted in conjunction with the follow-up of DOE ≥ 5 Rem Study participants as many persons are on both rosters.

2. Report any complications.

No serious adverse effects were reported in persons treated with either Ca- or Zn-DTPA alone or in sequence. One patient developed faintness and syncope during treatment with Ca-DTPA (IV) for a contaminated wound. One patient complained of a sore shoulder following treatment with Zn-DTPA (IV) and of subsequent deminished urinary output. IM injection of Ca-DTPA resulted in considerable local pain for 6-8 hours in one patient.

1144695

3. Are there any planned changes?

No.

4. Do you wish the project to be continued?

Yes.

5. Comments.

Chelation therapy with DTPA drugs remains the method of choice for decorporation of internally deposited actinide contaminants.

Reports of new developments in chelation therapy will be monitored. When clinical trials of new agents or amended protocols for the existing agents are indicated, the appropriate IND applications or amendments will be submitted through DOE to FDA.

Current literature reports indicate that DTPA continues to be the chelating agent of choice for the treatment of persons contaminated with transuranic elements.



To Dr. C. C. Lushbaugh From Blanche Carden *B. Carden*
Date June 12, 1984 Copies to File, Committee on Human Studies
Subject PROPOSALS REVIEWED BY COMMITTEE ON HUMAN STUDIES

Proposals 55, 61 and 64 were approved for continuation by the Committee on Human Studies on May 25, 1984. If there should be any changes or problems with these proposals, please report them to the Committee Chairman.

bbc



Oak Ridge
 Associated Universities Post Office Box 117
 Oak Ridge, Tennessee 37831-0117

Medical and
 Health Sciences
 Division

March 20, 1985

M E M O R A N D U M

To: Dr. Lushbaugh

From: Lynn Reeves, Secretary *Lynn Reeves*
 ORAU/ORNL Committee on Human Studies

Subject: PROGRESS REPORTS

The guidelines for the ORAU/ORNL Committee on Human Studies require that all principal investigators of ongoing proposals present a yearly progress report to the Committee on the status of their proposals. Each proposal must be reviewed by the Committee yearly for research projects to continue.

Please answer the questions below and add any other information you feel pertinent and return by April 10, 1985. (If additional space is needed, please use the back of this form or attach extra sheets.)

Title of Project: The DTPA Registry Follow-Up Program

Proposal No.: 60

[Signature]

 Signature of Principal Investigator

Date Approved: 1980

3/29/85

 Date Signed

1. Report progress made in past year:
 Active follow-up of persons previously treated with DTPA began in early FY 85 starting with retired and terminated persons treated with DTPA while employed at DOE's Oak Ridge facilities. The follow-up data are being collected by means of an OMB-approved comprehensive telephone interview questionnaire. This follow-up will be completed for the approximately 200 retired or terminated workers to identify any untoward long-term effects or patterns of effects that could be attributed to DTPA therapy. The results will be reported in a publishable document. These data will be added to the computerized data base of the DTPA Registry for use in future studies.
2. Report any complications:
 None.

3. Are there any planned changes?

No.

4. Do you wish the project to be continued?

Yes.

5. Comments:

-

STATUS REPORT ON RESEARCH PROPOSALS PREVIOUSLY REVIEWED AND APPROVED
BY THE ORAU/ORNL COMMITTEE ON HUMAN STUDIES

(April 26, 1985)

61 The DTPA Registry Follow-Up Program (Lushbaugh)

Progress

Active follow-up of persons previously treated with DTPA began in early FY 85 starting with retired and terminated persons treated with DTPA while employed at DOE's Oak Ridge facilities. The follow-up data are being collected by means of an OMB-approved comprehensive telephone interview questionnaire. This follow-up will be completed for the approximately 200 retired or terminated workers to identify any untoward long-term effects or patterns of effects that could be attributed to DTPA therapy. The results will be reported in a publishable document. These data will be added to the computerized data base of the DTPA Registry for use in future studies.

Complications

None.

Changes

No changes.

Continuation

Keep active.

Comments

None.



Oak Ridge
 Associated Universities Post Office Box 117
 Oak Ridge, Tennessee 37831-0117

Medical and
 Health Sciences
 Division

April 17, 1986

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. C. C. Lushbaugh
FROM: Lynn Reeves, Secretary
 ORAU/ORNL Committee on Human Studies *Lynn Reeves*
SUBJECT: PROGRESS REPORTS

The guidelines for the ORAU/ORNL Committee on Human Studies require that yearly all principal investigators of ongoing proposals present a progress report to the Committee on the status of their proposals. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions below and add any other information you feel pertinent and return by ~~May 5~~ ¹²⁸ May 5, 1986. (If additional space is needed, please use the back of this form or attach extra sheets.)

Title of Project: The DTPA Registry Follow-Up Program

Proposal No. 61 Date 1980

 Signature of Principal Investigator Date Signed

1. Report progress made in the past year.

2. Report any complications.

3. Are there any planned changes?

see proposal 52

4. Do you wish the project to be continued?

yes

5. Comments.



Oak Ridge
 Associated Universities Post Office Box 117
 Oak Ridge, Tennessee 37831-0117

Medical and
 Health Sciences
 Division

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. C. C. Lushbaugh
 FROM: Becky Hawkins/Secretary, Committee on Human Studies *B. Hawkins*
 RE: Status Reports on Active Proposals
 DATE: May 1987

The guidelines for the ORAU/ORNL Committee on Human Studies require that all principal investigators of ongoing proposals present a progress report to the Committee on the status of their proposals each year. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions below and add any other information you feel pertinent and return by May 1, 1987. (If additional space is needed, please use the back of this form or attach extra sheets.)

Title of Project: 61 The DTPA Registry Follow-Up Program

Proposal No. 61 Date Approved: 1980

Signature of Principal Investigator

Date Signed

reporting

1. Report progress made in the past year. *6 INVESTIGATORS^{DF} used DTPA in 54 PATIENTS Treated (4 cont From previous year). 64 CA DTPA doses given - BY I.V. PUSH + 1 IRRIGATION 186 ZN DTPA doses given - BY I.V. PUSH + AEROSOL*

THIS WAS GIVEN TO
 54 { 47 persons receiving CA only
 6 persons receiving ZN only
 1 person receiving ZN & CA

2. Report any complications.
ONE PATIENT reported lightheadedness & Headache Following ZN & CA DTPA AFTER THE 6th 7th & 8th doses
ONE PATIENT. WAS REPORTED TO HAVE FLUSHING & RITIVES FOLLOWING ADMINISTRATION OF CA-DTPA

1144703

3. Are there any planned changes?

4. Do you wish the project to be continued?

5. Comments.

June 30, 1988

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

STATUS REPORTS ON ACTIVE PROPOSALS

Investigator: Dr. C. C. Lushbaugh

Title of Project: 61 The DTPA Registry Follow-Up Program

Date Approved: 1980

1. Report progress made in the past year.

There were 46 co-investigators reporting for fiscal year 1986-87. There were 20 patients reported to be treated with DTPA (one patient was from a previous reporting period). These 20 patients were given 35 doses of DTPA, 30 by I.V. injection, 4 by aerosol and 1 by topical application. Of these 20 patients, 17 were treated with CA-DTPA, 2 were treated with ZN-DTPA, and one patient was treated with both CA and ZN-DTPA. (Investigators indicating use of DTPA include Hanford, Los Alamos, Monsanto, Savannah River, Rocky Flats, and ORAU).

2. Report any complications.

None

3. Are there any planned changes:

No

4. Do you wish the project to be continued?

Yes

5. Comments.

1144705



Oak Ridge
 Associated Universities Post Office Box 117
 Oak Ridge, Tennessee 37831-0117

Medical and
 Health Sciences
 Division

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. C. C. Lushbaugh
 FROM: Becky Hawkins/Secretary, Committee on Human Studies
 RE: Status Reports on Active Proposals
 DATE: April 6, 1989

The guidelines for the ORAU/ORNL Committee on Human Studies require that all principal investigators of ongoing proposals present a progress report to the Committee on the status of their proposals each year. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions below and add any other information you feel pertinent and return by May 8, 1989. (If additional space is needed, please use the back of this form or attach extra sheets.)

Title of Project: 61 The DTPA Registry Follow-Up Program

Proposal No. 61

DATE APPROVED: 1980

 Signature of Principal Investigator

 Date Signed

*Reporting
 period
 June 1, 1987
 May 31, 1988*

1. Report progress made in the past year.

*TOTAL OF 16 Patients Received DTPA - 15 Received CA DTPA,
 1 received ZN DTPA + 1 received Both CA & ZN DTPA*

The Routes of Contamination were reported to be Puncture wound &

2. Report any complications.

Mitic Acid Burns as well as inhalation. Routes of Administration were reported to be I.U with diluent, I.U direct Push & aerosol - Actinides involved were plutonium, Americium, uranium, Radium & Niobium

1144706

3. Are there any planned changes?

4. Do you wish the project to be continued?

5. Comments.



Revised February 23, 1989

(Further Revisions Pending)

**THE NATIONAL DEATH INDEX (NDI): STUDIES REQUIRING APPROVAL BY AN
INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION OF HUMAN SUBJECTS**

When an IRB Approval is Required for NDI Approval:

A National Death Index (NDI) Application Form must be accompanied by documentation that the applicant's study has a current, valid IRB approval whenever the applicant plans to perform death record followback investigations. (Of concern are any contacts made to next-of-kin, physicians, hospitals or other establishments based on information appearing on death certificates obtained via use of the NDI.) For a study involving death record followback, final approval of the NDI application will be delayed until such time as the applicant submits a copy of the IRB approval.

All other NDI applicants are encouraged to submit an IRB approval because some State vital statistics offices may request such documentation before they will release copies of requested death certificates.

Rationale:

It is understood that most studies using the NDI do not involve diagnostic, therapeutic, or any other forms of physical contacts with human subjects and consequently do not receive or need to receive IRB approvals based on requirements set forth by their own institution or by the Federal IRB regulations promulgated by the NIH. On the other hand, the National Center for Health Statistics (NCHS) and many State vital statistics offices are concerned about the invasion of privacy, potential emotional harm, and undue respondent burden that can result (from contacts made to next-of-kin, physicians, hospitals, and others) as part of death record followback investigations which are felt to be essential components of some studies. Because of this concern, NCHS stresses that an IRB should at least review the followback methodology to be used in such studies, including review of all contact letters and/or telephone techniques, questionnaires, and consent forms (for release of medical records), as well as procedures for insuring that the information obtained remains confidential. Therefore, IRB approvals have been made a prerequisite for NDI approvals for studies involving death record followback investigations. We are hopeful that IRB committees will be both supportive and responsive to this requirement, even though reviews of such studies are neither customary nor required for other purposes and may even be "exempt" as defined by the NIH regulation 45 CFR 46.101(b).

(over)

1144708

Types of IRB Approvals Acceptable for NDI Applications:

The NCHS will accept IRB approvals from institutions having Multiple Project Assurances or Single Project Assurances which have been approved by the National Institutes of Health. A full board or an expedited IRB review and approval is acceptable.

All IRB approvals must have been granted within the 12 months preceding the receipt of the NDI application by NCHS or must contain or be accompanied by some documentation indicating that the approvals are still valid. Furthermore, an IRB approval obtained from an organization other than the NDI applicant's organization is acceptable especially in situations where the NDI applicant's organization does not have a recognized IRB committee.

NOTE: The approval document must contain some indication that the review of the study also included an assessment of any potential harm which may be caused by the study's death record followback investigations. Consequently, the approval document prepared by the IRB must include language similar to the following statements (but tailored to the study which was reviewed):

I have reviewed this study in conjunction with your application to use the NDI. I am satisfied that the procedures to be used to obtain additional information on deceased study subjects (from next-of-kin, physicians, hospitals and/or others) provide appropriate protection to the respondents with respect to maintaining confidentiality, protecting their privacy and avoiding or minimizing any emotional or other harm that may affect the respondent.

My review included an assessment of all existing and/or proposed contact letters, telephone techniques, questionnaires and consent forms used in the death record followback investigations. These were all deemed to be satisfactory.

NDI APPLICANTS AND IRB COMMITTEES REQUIRING ADDITIONAL INFORMATION ON THE ABOVE REQUIREMENTS SHOULD CONTACT THE NDI STAFF ON (301) 436-8951.



Oak Ridge
Associated Universities
Post Office Box 117
Oak Ridge, Tennessee 37831-0117

Medical
Sciences
Division

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. C. C. Lushbaugh
FROM: Becky Hawkins/Secretary, Committee on Human Studies
RE: Status Reports on Active Proposals
DATE: May 2, 1990

The guidelines for the ORAU/ORNL Committee on Human Studies require that all principal investigators of ongoing proposals present a progress report to the Committee on the status of their proposals each year. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions below and add any other information you feel pertinent and return by May 17. (If additional space is needed, please use the back of this form or attach extra sheets.)

Title of Project: 61 The DTPA Registry Follow-up Program

Proposal No. 61

DATE APPROVED: 1980

Signature of Principal Investigator

Date Signed

1. Report progress made in the past year.

In the reporting period June 1, 1988, through May 31, 1989, a total of 22 patients was treated by authorized co-investigators (total 49) on DOE/ORAU's DTPA with FDA. Of these, 21 patients each received a single one-gram dose of Ca-DTPA alone and one patient received seven one-gram dose of Zn-DTPA alone. Ca-DTPA and Zn-DTPA were administered by intravenous infusion, direct intravenous push, aerosol inhalation, or topically. No side effects were reported following DTPA therapy. DTPA usage for the 1988-1989 period was reported to the FDA. Follow-up of persons previously treated with DTPA continues through co-investigators and as part of the follow-up of the ≥ 5 rem/year study population and radiation accident survivors.

1144710

2. Report any complications.

None

3. Are there any planned changes?

We plan to transfer responsibility for the Principal Investigator on this proposal from C. C. Lushbaugh, Ph.D., M.D., to another ORAU physician (TBA).

4. Do you wish the project to be continued?

Yes

5. Comments.

A proposal by DOE/OHER (Federal Register, November 1990) to extend the scope of routine use access to raw (identifiable) records maintained for DOE in this Registry, to include independent (non-contract) researchers was withdrawn in response to negative reviews.

June 28, 1990
ORAU/ORNL COMMITTEE ON HUMAN STUDIES

STATUS REPORTS ON ACTIVE PROPOSALS

Investigator: Dr. C. C. Lushbaugh

Title of Project: 61 The DTPA Registry Follow-Up Program

Date Approved: 1980

1. Report progress made in the past year.

In the reporting period June 1, 1988, through May 31, 1989, a total of 22 patients was treated by authorized co-investigators (total 49) on DOE/ORAU's DTPA with FDA. Of these, 21 patients each received a single one-gram dose of Ca-DTPA alone and one patient received seven one-gram dose of Zn-DTPA alone. Ca-DTPA and Zn-DTPA were administered by intravenous infusion, direct intravenous push, aerosol inhalation, or topically. No side-effects were reported following DTPA therapy. DTPA usage for the 1988-89 period was reported to the FDA. Follow-up of persons previously treated with DTPA continues through co-investigators and a part of the follow-up of the ≥ 5 rem/year study population and radiation accident survivors.

2. Report any complications.

None

3. Are there any planned changes:

We plan to transfer responsibility for the Principal Investigator on this proposal from C. C. Lushbaugh, Ph.D., M.D., to another ORAU physician (TBA).

4. Do you wish the project to be continued?

Yes

5. Comments.

A proposal by DOE/OHER (Federal Register, November 1990⁸⁷) to extend the scope of routine use access to raw (identifiable) records maintained for DOE in this Registry, to include independent (non-contract) researchers was withdrawn in response to negative reviews.

1144712



Oak Ridge
Associated Universities Post Office Box 117
Oak Ridge, Tennessee 37831-0117

Medical
Sciences
Division

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. C. C. Lushbaugh
FROM: Karl Hubner/Chairman, Committee on Human Studies *KH*
RE: Committee Action on Active Proposals
DATE: June 28, 1990

Your project number 61 "The DTPA Registry Follow-Up Program" was reviewed and approved at our last meeting on June 28, 1990.

Progress reports of all active proposals will again be reviewed at our next meeting to be held in the spring of 1991.

bh

1144713

Oak Ridge Associated Universities
Medical Sciences Division (Draft 6 Jun 91)

INSENT for CHELATION THERAPY using Ca-DTPA and/or Zn-DTPA,
an FDA Investigational Drug

INSTITUTION: _____ DATE/TIME: _____

I have been involved in an incident in which I may have been exposed to radioactive material and may have been contaminated to some degree. My participation in DTPA chelation therapy is voluntary.

I, _____ (Patient) authorize Dr. _____ (Physician) and his staff to administer chelation therapy utilizing the drug(s) Calcium trisodium diethylenetriamene-pentaacetate (Ca-DTPA) and/or Zinc trisodium diethylenetriamene-pentaacetate (Zn-DTPA) in an attempt to: 1) determine if a medically significant amount of radionuclide is in my body and 2) if a medically significant amount is found, to enhance the removal of these radionuclides. I know that DTPA is recommended as the preferred drug for radionuclide removal by national and international radiation protection councils. If I decide to stop DTPA therapy, I understand that removal of radionuclides by other means will be less effective.

*see
ser
radio*

alternatives

I am aware that the following alternative treatments are available: _____

was informed *Have been told*
I understand that chelation therapy in general has become a part of widely accepted medical practice in removing heavy metal contamination from humans. I know that the chelator DTPA is used in lesser concentrations in many nuclear medicine diagnostic tests. I know that DTPA has been used medically since 1958 but is not available for general use. DTPA remains on investigational drug status to help ensure accurate reporting of possible contamination accidents and to record any side effects.

*see
to
radio
caution*

_____ (Physician) and his staff have described the potential risks and benefits of chelation therapy with DTPA and have described what the drug does which is, in my own words to: _____

was informed *the human exp with 2 r d. Ca Zn limited However NO significant risks for single dose of Ca-DTPA or Zn-DTPA*
I understand that if a large amount of contamination is found, treatment may require repeated doses of this drug several times a week for up to several months. I understand that there are no known significant risks from a single dose of Ca-DTPA or Zn-DTPA. I know that there are no known immediate risks in taking Zn-DTPA with daily doses of up to 2 grams.

Have been told that the chelator DTPA is for other medical purposes
I know that a major side effect occurs only with Ca-DTPA, that with long-term therapy, it may deplete the body of zinc and some zinc-dependent enzymes and is therefore its use is avoided in the case of pregnancy, certain kidney disease, and if not an adult. I will advise you if any of the above conditions exist. The drug may be injected, and injection of any drug can cause potential complications of bleeding and infection. Questions regarding current DTPA research or complications regarding its use may be directed to the personnel listed on the DTPA package insert or Oak Ridge Associated Universities.

I give permission for general information relating to my case to be used in professional medical literature, in the interest of increasing medical knowledge. I understand that confidentiality of my identity will be maintained, and I shall not be identified in any way unless desired. I know that FDA has the right to review my medical records pertaining to DTPA treatment.

I am aware that further follow-up visits with my physician will be necessary.

Patient: _____ Witness: _____

ive acting
for patient: _____ Date/Time: _____

Relationship: _____ Physician: _____

(This form has been approved for use by the ORAU/ORNL Human Use Committee, Oak Ridge, Tennessee)

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Oak Ridge Associated Universities
Medical Sciences Division (Revision 19 Aug 91)

CONSENT for CHELATION THERAPY using Ca-DTPA and/or Zn-DTPA,
An FDA Investigational Drug

INSTITUTION: _____ DATE/TIME: _____

I have been involved in an incident in which I may have been exposed to radioactive material and may have been internally contaminated. My participation in DTPA chelation therapy is voluntary and I may stop at any time.

I, _____, (Patient) authorize Dr. _____ (Physician) and his staff to administer chelation therapy utilizing the drug(s) Calcium trisodium diethylenetriamene-pentaacetate (Ca-DTPA) and/or Zinc trisodium diethylenetriamene-pentaacetate (Zn-DTPA) in an attempt to (1) determine if a medically significant amount of radionuclide is in my body and (2) to enhance the removal of these radionuclides if a medically significant amount is found. I know that DTPA is recommended as the preferred drug for radionuclide removal by national and international radiation protection councils.

I am aware that there is no other approved treatment for removing transuranic radionuclides from my body. My alternatives are, therefore, (1) DTPA treatment or (2) no treatment.

I understand that chelation therapy in general has become a part of widely accepted medical practice in removing heavy metal contamination from humans. I am aware that DTPA has been used medically since 1958 but is not available for general use as a chelator, although it is available for general use for other medical purposes. DTPA remains on investigational drug status to help ensure accurate reporting of possible contamination accidents and to record any side effects.

Dr. _____ (Physician) and his staff have described the potential risks and benefits of chelation therapy with DTPA and have described what the drug does which is, in my own words, to:

I understand that if a large amount of contamination is found, treatment may require repeated doses of this drug several times a week for up to several months. The human experience with Ca-DTPA is limited; however, there are no known significant risks from a single dose of Ca-DTPA or Zn-DTPA. I have been told that there have been no known immediate risks in taking Zn-DTPA with daily doses of up to 2 grams.

I have been told that long term therapy with Ca-DTPA may deplete the body of zinc and some zinc-dependent enzymes. Therefore, its use is avoided in the case of pregnancy, certain kidney disease, and if full growth is not completed. I will advise you if any of the above conditions exist. The drug may be injected, and injection of any drug can cause potential complications of bleeding and infection. Questions regarding current DTPA research or complications regarding its use may be directed to the Radiation Emergency Assistance Center/Training Site (REAC/TS) through the operator at Methodist Medical Center, Oak Ridge, TN (615)-481-1000.

I give permission for general information relating to my case to be used in professional medical literature, in the interest of increasing medical knowledge. I understand that confidentiality of my identity will be maintained, and I shall not be identified in any way. I know that FDA has the right to review my medical records pertaining to DTPA treatment.

I am aware that further follow-up visits with my physician will be necessary.

Patient: _____ Date/Time: _____

Relative acting
Patient: _____ Physician: _____

Relationship: _____ Witness: _____

(This form has been approved for use by physicians by the ORAU/ORNL Committee on Human Studies, Oak Ridge, Tennessee)

1144715



Oak Ridge
Associated
Universities

Post Office Box 117
Oak Ridge, Tennessee 37831-0117

Medical
Sciences
Division

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. Fun Fong
FROM: Dr. Karl Hubner/Chairman, Committee on Human Studies
RE: COMMITTEE ACTION ON ACTIVE PROPOSALS
DATE: September 7, 1991

Your project number "The DTPA Registry Follow-Up Program was reviewed and approved at our last meeting on June 6, 1991. The committee has no objection to the continuation of this project.

Progress reports of all active proposals will again be reviewed at our next meeting to be held in the spring of 1992.

bh

1144716

Proposal 61

1. Report progress made in the past year.

In the period June 1, 1990 - May 31, 1991, 53 physicians (ORISE's Principal Investigators plus 47 co-investigators in the U.S. and 1 each in Canada, England, Brazil, Japan, and Spain) were authorized on DOE's IND to administer Ca DTPA and Zn DTPA for treatment of real or suspected internal contamination with plutonium and designated transuranic elements. In this period, co-investigator physicians at five facilities treated a total of 9 patients with DTPA because of plutonium and/or americium contamination. Of these, 7 patients each received a single (1) gram dose of Ca DTPA alone because of real or suspected Pu or Am contamination incurred during this period. One patient received one 1-gram dose of Ca DTPA and five 1-gram doses Zn DTPA. One patient received 6 1-gram doses of Zn DTPA for continued chelation of americium that was inhaled accidentally in 1986 as previously reported. Administration in these cases was by IV direct push (Zn DTPA) and IV infusion or inhalation (Ca DTPA).

2. Report any complications

One patient was reported as experiencing a burning sensation at the vena puncture site after the administration of the fifth dose of Zn DTPA.

3. Are there any planned changes?

None

4. Do you wish the project to be continued?

Yes. Follow-up on the usage of Ca DTPA and Zn DTPA must continue to establish a patient safety profile event if DTPA is no longer declared an investigational new drug.

5. Comments.



Oak Ridge
Associated Universities Post Office Box 117
Oak Ridge, Tennessee 37831-0117

To: Dr. Fun H. Fong/Robert C. Ricks
From: Dr. Karl Hubner, Chairman
Committee on Human Studies
Date: August 5, 1992
RE: Committee Action on Active Proposals

Your project number 61 "The DTPA Registry Follow-Up Program" was reviewed and approved for continuation at our last meeting on July 31, 1992.

Progress reports of all active proposals will again be reviewed at our next meeting to be held in the fall of 1992.

/mvr

1144719



Oak Ridge
Associated Universities Post Office Box 117
Oak Ridge, Tennessee 37831-0117

To: Dr. Fun H. Fong/Robert C. Ricks
From: *W. Calhoun*
Dr. William Calhoun, Chairman
Committee on Human Studies
Date: June 29, 1993
Re: Committee Action on Active Proposals

Your project number 61 "The DTPA Registry Follow-Up Program" was reviewed and approved for continuation at our last meeting on June 25, 1993.

Progress reports of all active proposals will again be reviewed at our next meeting to be held in the fall of 1993.

/mvr

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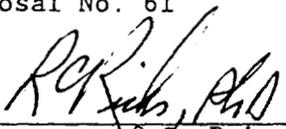
ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. Fun H. Fong/ Dr. Robert C. Ricks
From: Marta Rivera, Secretary Committee on Human Studies
RE: Status Report on Active Proposals
Date: April 28, 1993

The guidelines for the ORAU/ORNL Committee on Human Studies require that all principal investigators of ongoing proposal present a progress report to the Committee on the status of the proposals each year. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions and add other information you feel pertinent and return by May 14. (If additional space is needed, please use the back of this form or attach extra sheets).

Title of Project: "The DTPA Registry Follow-Up Program"

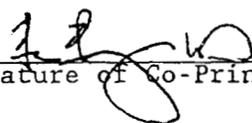
Proposal No. 61



Signature of Co-Principal Investigator

6/1/93

Date Signed



Signature of Co-Principal Investigator

6/7/93

Date Signed

1. Report progress made in the past year.
Please see pages attached.

2. Report any complications.
Please see pages attached

Proposal 61: The DTPA Registry Follow-Up Program

1. Report progress made in the past year.

In the period June 1, 1991 - May 31, 1992, 52 physicians (ORISE's Principal Investigators plus 47 co-investigators in the U.S. and 1 each in Canada, England, Brazil, Japan, and Spain) were authorized on DOE's IND to administer Ca DTPA and Zn DTPA for treatment of real or suspected internal contamination with plutonium and designated transuranic elements. In this period, co-investigator physicians at three facilities treated a total of 10 patients with DTPA due to plutonium and/or americium contamination. Of these, four patients received a single (1) gram Ca-DTPA dose intravenously alone due to real or suspected Pu or Am contamination incurred during this period. Four patients received a single (1) gram Ca-DTPA aerosol dose. One patient received a single (1) gram Ca-DTPA intravenous dose, followed by a single (1) gram Zn-DTPA aerosol dose. One patient received a single (1) gram Ca-DTPA aerosol dose, followed by three single (1) gram Ca-DTPA topical doses, and five single (1) gram Zn-DTPA aerosol doses for plutonium exposure.

2. Report any complications.

No adverse effects were reported with these administrations.

3. Are there any planned changes?

No.

4. Do you wish the project to be continued?

Yes. Follow-up monitoring on the usage of Ca-DTPA and Zn-DTPA must continue in order to continue development of a patient safety profile even if DTPA were no longer declared an investigational new drug.

5. Comments.

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. Robert C. Ricks
FROM: Marta V. Rivera/Secretary, Committee on Human Studies
RE: Status Reports on Active Projects
DATE: July 11, 1994

The guidelines for the ORAU/ORNL Committee on Human Studies require that all principal investigators of ongoing proposals present a progress report to the Committee on the status of their proposals each year. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions below and add any other information you feel pertinent and return by July 20. (If additional space is needed, please use the back of this form or attach extra sheets. Please include your name, project number, and date on additional sheets)

Title of Project: DTPA Registry Follow-Up Program

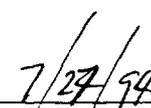
Project No. ORAU-61

First approved: October 30, 1980

Most recent re-approval for continuation: June 25, 1993.



Signature of Principal Investigator



Date Signed

1. Report progress made in the past year.

In the period June 1, 1992 - May 31, 1993, co-investigator physicians at four facilities treated a total of four patients with DTPA because of plutonium and/or curium contamination. Of these four patients, each received a single (1 gram) dose of Ca DTPA; three by direct push and one by IV. One of the individuals also received a single (1 gram) dose of Zn DTPA by IV.

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2. Report any complications.
Some GI distress reported in one patient possibly not related to administration of DTPA.

3. Are there any changes planned?
NA

4. Do you wish his project to continue?
Yes.

5. Comments.
None

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. Robert C. Ricks
FROM: Dr. William ^{W.C.} Calhoun/Chairman, Committee on Human Studies
RE: COMMITTEE ACTION ON ACTIVE PROJECTS
DATE: August 31, 1994

Your proposal number ORAU-61 "DTPA Registry Follow-Up Program" was reviewed and approved for continuation at our meeting on July 28, 1994.

This review included an assessment of all existing consent forms used by the investigators. Changes, revisions or modifications to the consent form in use should be submitted to the Committee for review prior to the annual spring meeting. Such forms should be dated and printed on letterhead to show organization/affiliation.

Progress reports of all active projects will again be reviewed at our next meeting to be held in the spring of 1995.

/mvr

1144725

PROTECTING HUMAN SUBJECTS



Office of Health and Environmental Research

U.S. Department of Energy

PROJECT SUMMARY

Policy: Research activities that involve human subjects and that are funded by the U.S. Department of Energy (DOE), conducted in DOE facilities, or conducted by DOE personnel must be approved or exempted from review in accord with 10 CFR Part 745. Failure to comply with these regulations may prevent DOE from authorizing or funding an activity, or may lead the Department to suspend or terminate the project.

Directions: Institutions must complete this form, providing the data listed below in the format indicated, for each research activity each year. Forms must be sent to the appropriate DOE Field Office, which will forward them to DOE Headquarters (Protection of Human Subjects, Mail Station ER-70, Office of Health and Environmental Research, U.S. Department of Energy, Washington, DC 20585).

1. Project Title The DTPA Registry Follow-up Program	
2. Principal Investigator J. Glenn Davis, M.D., M.P.H.	Telephone Number (615) 576-3090
Mailing Address — Include full name of performing institution. Oak Ridge Institute for Science and Education, Medical Sciences Division, P.O. Box 117, Oak Ridge, TN 37831-0117	
3. Institutional Assurance Number (if issued) ¹ MPA 1394	4. Project Number ² ORAU 61
5. Annual Funding: Subproject of ORAU 47 and ORAU 52 Give actual funding or check the amount closest to the estimated total for the current Federal fiscal year, whether requested or obtained. Include both direct and indirect costs. <input type="checkbox"/> \$10,000 <input type="checkbox"/> \$100,000 <input type="checkbox"/> \$500,000 <input type="checkbox"/> \$1,000,000 <input type="checkbox"/> \$5,000,000 <input checked="" type="checkbox"/> Actual Funding \$ 35,000 (total for ORAU 47 and ORAU 52)	
6. Funding Sources A. Name DOE Program Office (see list in attachment), if applicable. B. Name non-DOE sources of funding (up to two), if applicable.	
A. DOE Program Office Office of Occupational Medicine (EH-43)	
Contact Person Agatha Francis	Telephone Number (301) 903-5591
B. Non-DOE Source N/A	
Non-DOE Source N/A	

¹ Under 10 CFR Part 745, institutions are required to file an assurance of compliance with the regulations with DOE or the Department of Health and Human Services. The Department involved may then issue an assurance number.

² Each project must have a unique identification number assigned by the institution—for example, ANL-94/101.

1144726

7. The Project has been reviewed and approved by the Institutional Review Board (IRB) as required under 10 CFR Part 745.

A. Type of Review
 Full Board
 For a list of research not requiring IRB review, see Attachment.

Expedited
 For an explanation of projects that qualify for expedited reviews, see Attachment.

B. Type of Approval
 New Annual Renewal Other

C. IRB Approval Date
 1980. Reviewed and approved for continuation; most recently June 25, 1993.

8. This Project involves the following collaborating institutions (list a maximum of two):

None

9. Vulnerable Populations

This project does not involve vulnerable populations.

This project involves the following vulnerable populations:

Minors Mentally Disabled Prisoners
 Fetuses, Pregnant Women, In Vitro Fertilization Economically or Educationally Disadvantaged

10. Type of Research
 Check all categories that apply.

Epidemiology (using personally identifiable data)--
 Using data collected directly from human subjects.
 Using existing data.

Diagnostic studies using radiation or chemical agents in tracer amounts.

Therapeutic studies using ~~radiation~~ ~~or~~ chemical agents.

Studies of exposure, effects, health, or monitoring using human urine, blood, other body fluids, cells, or tissues--
 Specimens collected directly from human subjects for this project.
 Specimens obtained from secondary sources (e.g., hospitals, laboratories).

Instrument development and testing using human subjects.

Surveys that collect personally identifiable data.

Environmental studies using human subjects to evaluate weatherization options, habitat alteration, or similar.

Other. Please identify _____

11. Abstract

Provide a brief abstract that includes the following information:

- A. Summarize the objectives and methodology of this research project. (Explain clearly why it belongs in the categories checked in Item 10).

Objectives: To compile data for persons treated with Ca and Zn-DTPA as a basis for (1) annual reporting of DTPA usage to FDA under INDAs #4041 and 14603, and (2) follow-up of treated persons.

Methodology: Co-investigators on the INDA report their use of DTPA to ORISE annually; this includes treatment data for individuals treated. The data are entered into a need-to-know only, password secured computerized data base that is maintained for DOE by ORISE as DOE System of Records, N073.

- B. Specify the number of human subjects involved each year.

Varies, generally a total of about 10 among co-investigator physicians at ≥ 50 facilities.

- C. Describe the involvement of human subjects and the risks, if any, to which they are exposed.

Consent to be treated with DTPA includes consent to compile the patient's data and include them in the Registry, and their use for Registry purposes.

As a DOE System of Records, Registry data are protected by the Privacy Act (1974) and subject to the Freedom of Information Act thus registrant's privacy and data confidentiality are protected to the extent possible under law. There are no physical risks to health.

- D. List the chemical or radioactive materials, if any, that are used in the study, and identify the route of exposure.

none

See reverse for approval signatures.

The official signing below confirms that the information provided on this form is correct and that the institution assumes responsibility for future reviews, approvals, and submissions of project summaries, which are all required at least once a year.	
Signature of Institution Official <i>J. Glenn Davis</i>	Date 2/28/94
Printed or Typed Name J. Glenn Davis, M.D., M.P.H.	Telephone Number (615) 576-3090

For DOE USE Only

Date Received by ER-70	Date
	Accepted _____
	Returned to Originator _____
Reason for Return	
DOE Reviewers	

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. Robert C. Ricks
FROM: Marta V. Rivera/Secretary, Committee on Human Studies
RE: Status Reports on Active Projects
DATE: July 11, 1994

The guidelines for the ORAU/ORNL Committee on Human Studies require that all principal investigators of ongoing proposals present a progress report to the Committee on the status of their proposals each year. Each proposal must be reviewed by the Committee yearly for research projects to continue. Please answer the questions below and add any other information you feel pertinent and return by July 20. (If additional space is needed, please use the back of this form or attach extra sheets. Please include your name, project number, and date on additional sheets)

Title of Project: DTPA Registry Follow-Up Program

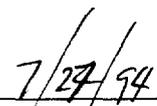
Project No. ORAU-61

First approved: October 30, 1980

Most recent re-approval for continuation: June 25, 1993.



Signature of Principal Investigator



Date/Signed

1. Report progress made in the past year.

In the period June 1, 1992 - May 31, 1993, co-investigator physicians at four facilities treated a total of four patients with DTPA because of plutonium and/or curium contamination. Of these four patients, each received a single (1 gram) dose of Ca DTPA; three by direct push and one by IV. One of the individuals also received a single (1 gram) dose of Zn DTPA by IV.

1144730

2. Report any complications.
Some GI distress reported in one patient possibly not related to administration of DTPA.
3. Are there any changes planned?
NA
4. Do you wish his project to continue?
Yes.
5. Comments.
None

ORAU/ORNL COMMITTEE ON HUMAN STUDIES

TO: Dr. Robert C. Ricks
FROM: Dr. William Calhoun^{W.C.}/Chairman, Committee on Human Studies
RE: COMMITTEE ACTION ON ACTIVE PROJECTS
DATE: August 31, 1994

Your proposal number ORAU-61 "DTPA Registry Follow-Up Program" was reviewed and approved for continuation at our meeting on July 28, 1994.

This review included an assessment of all existing consent forms used by the investigators. Changes, revisions or modifications to the consent form in use should be submitted to the Committee for review prior to the annual spring meeting. Such forms should be dated and printed on letterhead to show organization/affiliation.

Progress reports of all active projects will again be reviewed at our next meeting to be held in the spring of 1995.

/mvr

1144732