SUBJECT NAME: VERA FRANK SSN: [redacted]

PRINCIPAL INVESTIGATOR: David J. Baylink, M.D.

TITLE OF STUDY: A study to Determine the Efficacy of Fluoride in Combination with Didronel in the Prevention of Osteoporotic Vertebral Fractures in Males

DESCRIPTION OF RESEARCH:

1. Purpose of study and how long it will last:

I have been asked to participate in a study of fluoride, calcium, and Didronel therapy for the treatment of osteoporosis. I understand that fluoride is an investigational drug, approved by the U.S. Food and Drug Administration for testing on a limited number of patients. Several previous studies have shown increased bone density and decreased spinal fractures in fluoride treated osteoporotics. Calcium therapy is given with fluoride to decrease bone loss and to promote mineralization of newly formed bone. Didronel therapy decreases bone loss.

The objective of the study is to determine if fluoride, administered at a low dose and in a slow-release formulation, can reduce the rates of new vertebral fractures in patients with established osteoporosis; and determine if the effect of fluoride on fracture risk can be improved by the addition of Didronel.

I have been told that this is a long-term study , lasting 5 years and involving 500 male participants.

2. Description of the study including procedures to be used:

I will be assigned randomly (flip of the coin), to one of two groups. Both groups will be treated with fluoride and calcium. One of the groups (Group 2) will also receive treatment with Didronel. (Note the following exception to the random assignment: Patients currently receiving treatment with Didronel will be assigned to Group 2.)

If I agree to participate in this study, the following procedures will be done prior to therapy and during treatment at the intervals specified below. None of the procedures are experimental, only the use of fluoride is considered experimental.

A. Having approximately 2 tablespoons of blood drawn every 4 months .
B. Collecting a 24 hour urine specimen every 12 months.
C. Having the bone density of my lower back measured yearly by quantitative computed tomography (QCT), a procedure which is similar to an x-ray.

SUBJECT IDENTIFICATION (I.D. plate or give name - last, first, middle)

SUBJECT INITIALS _____

File: F-Did.VA

[redacted]93

VA FORM JAN 1990 10 - 1086

SUBJECT NAME: _____ SSN: _____

PRINCIPAL INVESTIGATOR: David J. Baylink, M.D.

TITLE OF STUDY: A Study to Determine the Efficacy of Fluoride in Combination with Didronel in the Prevention of Osteoporotic Vertebral Fractures in Males

D. Having the bone density of my hips measured yearly by dual photon absorptiometry (DPA) a procedure which is also similar to an x-ray.
E. Having annual x-rays of my back.
F. Having follow-up visits every 4 months.
G. Taking fluoride, two pills daily in divided doses after meals.
H. Taking Os Cal 500, two pills daily in divided doses before meals.
I. Taking Didronel 400 mg daily every other month.

3. Description of any procedures that may result in discomfort or inconvience and
4. Potential risks of study:

I have been told that the possible risks of my participation in these studies (including the procedures and the drug therapy) include:

A. When blood is drawn, there may be pain and minor bruising at the site of the needle insertion and possible lightheadedness upon arising after the blood is drawn. These risks will be minimized by using careful technique, adequate pressure on the site, and rising gradually.

B. The bone density measurements of the hips and spine, and the spinal x-rays are standard procedures for the diagnosis and follow-up of osteoporosis. The overall radiation exposure from these procedures is low and not considered hazardous.

C. Calcium may cause intestinal "gas" or loose stools in approximately 10% of subjects.

D. Fluoride may cause nausea in approximately 10-20 % of patients and rarely, bleeding ulcers. This risk will be minimized by taking the medication after meals and by using a formulation of fluoride which is released slowly and avoids release into the stomach. Fluoride may also cause joint pain in 20-30% of patients. This can be relieved by discontinuing the medication for a few weeks. Finally, fluoride treatment can cause a mild mineralization defect in bone (osteomalacia). Calcium therapy during treatment with fluoride will reduce the risk for this complication, as will the low dose of fluoride used in this study. Fluoride may increase the risk of hip fractures.

E. Didronel may cause occasional bloating, gas or pain in the lower abdomen. Didronel may aoso cause osteomalacia, but calcium therapy and the intermittant low dose will reduce this risk.

I have been told to promptly report any side effects to the investigator. I have been told that these side effects may require temporary or permanent discontinuation of the drug.

SUBJECT NAME: _____ SSN: _____

PRINCIPAL INVESTIGATOR: David J. Baylink, M.D.

TITLE OF STUDY: A Study to Determine the Efficacy of Fluoride in Combination with Didronel in the Prevention of Osteoporotic Vertebral Fractures in Males

5. Potential benefits of study:

I understand that the possible benefits of this therapy to me are: increased bone mass, decreased fracture rate, decreased pain, and increased mobility. I have been told that because of the experimental nature of this therapy, it is possible that these benefits may not occur.

6. Other treatment available:

The only other antiresorptive treatment available for males is calc tonin, which must be given by injection, and this is unacceptable to many patients. Moreover, calcitonin injections are more costly than didronel oral therapy. Finally, calc tonin is not as strong an antiresorber as is didronel.

7. Special Circumstances:

I have been told that there will be no direct cost to me for participating in the this study, including the medication other than a co-payment for medication as required by the VA Medical Center.

I have been told that should my disease become worse, or side effects become severe or new scientific developments occur that indicate the treatment is not in my best interest, or should my physician feel that this treatment is no longer in my best nterest, then the treatment would be stopped and further treatment would be discussed.

SUBJECT NAME: _____ SSN: _____

PRINCIPAL INVESTIGATOR: David J. Baylink, M.D.

TITLE OF STUDY: A Study to Determine the Efficacy of Fluoride in Combination with Didronel in the Prevention of Osteoporotic Vertebral Fractures in Males

8. Withdrawal from the study:

I understand that I do not have to take part in this study and am free to withdraw at any time. My decision to not participate or to withdraw will involve neither penalty nor loss of VA or other benefits to which I might otherwise be entitled.

My participation may also be terminated without my consent if my doctor feels that it is in my best interest. I also agree to comply with the requirements needed to satisfactorily complete my obligation as a research participant.

9. Confidentiality/Use of research results:

All information obtained about me during the research study will be kept strictly confidential, it will be available only to persons connected with this study including the sponsoring agency.

Since this study involves human subjects, it is regulated by the Food and Drug Administration (FDA). The FDA may therefore choose to inspect records that will identify me.

Unless I request it, the information from this study will not be given to other medical care personnel at this Medical Center nor to the Department of Veterans Affairs.

The results of this study may be published, but my identity will not be revealed in any publication without my permission.

10. Questions or concerns related to the study:

I have / have not participated in a research study within the past three (3) months. My participation involved _____ .

If any medical problems occur as a result of participation in this study, I may call

Dr. David J. Baylink at (909) 422-3101 during the day and

Dr. _____ at (909) 796-9573, pager # _____ after hours.

For such problems I will receive emergency care from the Department of Veterans Affairs, free of charge. Further care will be based on my VA eligibility.

If I wish to contact an impartial third party not associated with this study, or have questions or concerns about the research or my rights as a research subject, I may contact Ray Quinto, Chief of Research Operations, Research Service, Jerry L. Pettis Memorial VA Medical Center, Loma Linda, CA 92357, telephone (909) 422-3050.

SUBJECT NAME: _____ SSN: _____

PRINCIPAL INVESTIGATOR: David J. Baylink, M.D.

TITLE OF STUDY: A Study to Determine the Efficacy of Fluoride in Combination with Didronel in the Prevention of Osteoporotic Vertebral Fractures in Males

11. Research subject's rights:

I have read or have had read to me all of the above. The study has been explained to me and all of my questions answered. I have been told of the risks or discomforts, possible benefits of the study, and other choices of treatment available to me.

I understand my rights as a research subject, and voluntarily consent to participate in this study. I understand what the study is about, and how and why it is being done. I will receive a signed copy of this consent form.

[redacted] _____ [redacted] 9/4

Signature of Subject Date

_____ _____

Signature of Subject's Representative* Subject's Representative (print)

_____ _____

Signature of Witness Witness (print)

_____

Signature of Investigator

* Only required if subject not competent.

PROJECT DATA SHEET

1. **Name:** Baylink, David J. 2. **SSN:** XXX-XX-XXXX 3. **Project No:** 0061

4. **Project Title:** A Study to Determine the Efficacy of Fluoride in combination with Didronel in the Prevention of Osteoporotic

5. **Report Type:** ☐ N/A ☐ Initial ☐ Progress ☒ Final

6. **Just In Time:** ☐

7. **Status of PI in Project:** 01 *(01 = Awardee or Initiator 02 = Not Awardee; Responsible VA Investigator)*

8. **Co-Principal Investigators:** *(Must have a VA appointment and must be designated a Co-PI on original application.)*

Last name, first name, mi, degree	*Social Security Number*	*VAMC*

9. **Funding Source and Fund Administration:**

Source Code *(4-digits)*	Source Name	Admin Code *(2-digits)*	Admin Name
0000	None	01	No Funding

10. **Project Uses:** *(If Animal Subjects is Yes, complete Item 13.)*

Human Subjects ☒ *Yes* ☐ *No* Invest Drugs ☐ *Yes* ☒ *No* Radioisotopes ☐ *Yes* ☒ *No*

Animal Subjects ☐ *Yes* ☒ *No* Invest Devices ☐ *Yes* ☒ *No* Biohazards ☐ *Yes* ☒ *No*

11. **Project Focus:**

Agent Orange ☐ *Yes* ☒ *No* Females ☐ *Yes* ☒ *No* Prisoners of War ☐ *Yes* ☒ *No*

12. **Keywords:** *(Minimum 3, maximum 6. MeSH terms only. One term per line. Correct if marked *NOT MESH)*

1) SPINAL FRACTURES 4) BONE DENSITY

2) OSTEOPOROSIS 5)

3) FLUORIDES 6)

13. **Animal Subjects:** *(Species and, if applicable, strain of each animal approved for use by Animal Studies Subcommittee.)*

1) 2) 3) 4)

5) 6) 7) 8)

9) 10) 11) 12)

13) 14) 15) 16)

14. **Abstract:** *(If requested or missing, please attach. If submitted on a floppy disk, please write the file name and the word processor used on the disk. If typed, please format single spaced and do not justify right margin.)*

Animal Protocol No:

IRB No: **MISSING**

Abstract

Principal Investigator: Baylink, David J. **Project No: 0061**

Title: A Study to Determine the Efficacy of Fluoride in combination with Didronel in the Prevention of Osteoporotic

October 27, 1995. Progress Report: OBJECTIVE: To determine if fluoride, administered at a low dose and in a slow release formulation can reduce the rates of new vertebral fractures in patients with established osteoporosis; and determine if the effect of fluoride on fracture risk can be improved by the addition of Didronel. A secondary objective will be to examine the effect of this treatment combination on bone density of the spine and hip, and on biochemical indices of bone turnover.
RESEARCH PLAN: Males with at least one vertebral compression fracture but not more than five will be enrolled for a treatment period of 5 years. Each patient will receive fluoride prescribed as MFPsr (10 mg F/Pill) two pills daily in divided doses after meals. In addition, patients will have a total daily calcium intake of at least 1500 mg., which will include two pills of 500 mg calcium supplement daily taken in divided doses before meals and the use of calcium containing dairy products. Each patient will be randomized to one of the two treatment groups: 1) fluoride and calcium or 2) fluoride, calcium and Didronel. The only exception to the randomization will be patients currently receiving Didronel therapy at the onset of the study will be assigned to the treatment group receiving Didronel.
METHODS: All patients will receive treatment with fluoride as MFPsr (10 mg F/pill), two pills daily; and calcium as OsCal 500, two pills daily. In addition, 50% of the patients will also receive treatment with Didronel (400 mg daily) every other month. Spinal x-rays will be obtained annually, and new fractures will be assessed by two radiologists who are blinded to the treatment regimen of the patients. New fractures will be defined by a 25% reduction in anterior, middle or posterior height. Bone mass measurements will be obtained annually using QCT to measure the spine and QDR to measure the hip. Biochemical indices of bone turnover, including septum PTH, urinary calcium and hydroxyproline will be determined annually; and serum alkaline phosphatase will be measured every 6 months. Additional tests include annual serum fluoride measurements, CBC, and chemistry profile.
FINDINGS: Enrollment is ongoing. 40 patients are currently enrolled.
August 19, 1997. Enrollment is ongoing. 39 patients are currently enrolled. There have been 6 new study participants enrolled since last report period. There now is a total of 112 active study participants.
August 12, 1998: FINDINGS: Enrollment is ongoing. There have been 5 new study participants enrolled since last report period. There now is a total of 117 active study participants.
August 17, 1999: FINAL REPORT: This report has been terminated.
October 25, 1999: FINAL SUMMARY: The study was terminated early because of issues related to the formulation, manufacture and supply of the study drug. A total of 251 subjects were enrolled into the study. Twenty-five subjects discontinued before completing 3 years of therapy. One hundred fifteen subjects were active participants at the time of termination. All active subjects were notified by mail 10/98. Data analysis is not anticipated due to insufficent number of subjects and data.

VAMC LOMA LINDA, CA 92357
605 909-422-3187 (0812/)
Rx# [redacted] 1997 Fill 1 of 6
VERA,FRANK [redacted]
TAKE 1 CAPSULE TWICE A DAY AFTER MEALS

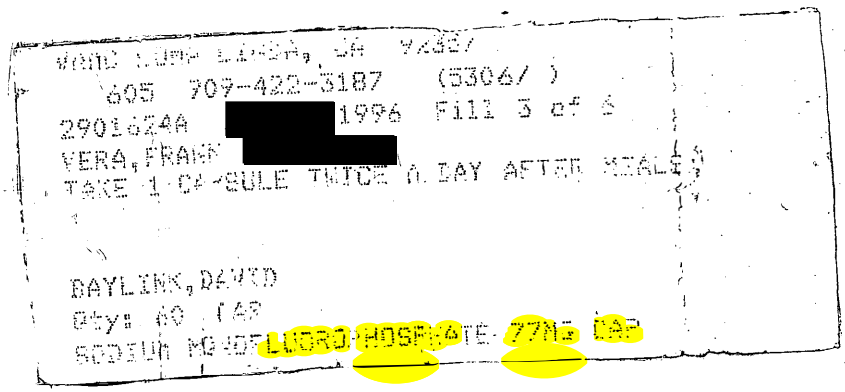
BAYLINK,DAVID
Qty: 60 CAP
SODIUM MONOFLUOROPHOSPHATE 7.7MG CAP
5 Refills remain prior to MAY 7,1998
NO COPAY Days Supply: 30

605-10050335

[redacted]

*Indicate address change on back of this form
[ ] Permanent
[ ] Temporary until __/__/__

Signature_____


VERA,FRANK
TAKE 1 CAPSULE TWICE A DAY AFTER MEALS
BAYLINK,DAVID
FLUORO-PHOSPHATE 77NS

Frank Vera III
[redacted]

[redacted] 2007

Craig L. Curtis
Supervisor-HIMS/Mailroom
Freedom of Information Act (FOIA) Officer
909-825-7084 Ext. 2923

Re: My medical and administrative records pertaining to my involvement in osteoporosis research. The principal investigator for this research was Dr. David J. Baylink.

Dear Mr. Curtis:

This request is being filed under the Freedom of Information Act (FOIA) and the Privacy Act.

Please conduct a thorough search for any and all records that pertain to my involvement in osteoporosis research and send me a copy of them.

- This request is to include, but not be limited to my: consent form, medical records, administrative records, notes, nursing notes, x-rays, CAT scans, DEXA scans, adverse incident reports, and prescriptions. This request is to include minutes, reports, letters, emails, faxes, phone logs, adverse incident reports, and notes, to any and all oversight entities and agencies, e.g. Intuitional Review Board (IRB) for LLVAH and LLU, Veterans Administration Inspector General, Food and Drug Administration, and National Institute of Health with which my case was discussed directly or indirectly.

- If the requested records are not in your possession, please forward this request to the custodian of these records.

- If any records are withheld or redacted, please include a "Vaughn Index" [(1)].

If you have any questions, please call me.

Thank you,

[redacted]
Frank Vera III

(1) VAUGHN INDEX - The term "Vaughn Index" originated from Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973), cert. denied, 415 U.S. 977 (1974), wherein the court rejected an agency's conclusory affidavit stating that requested FOIA documents were subject to exemption. Id. at 828. "A Vaughn Index must: (1) identify each document withheld; (2) state the statutory exemption claimed; and (3) explain how disclosure would damage the interests protected by the claimed exemption." Citizens Common on Human Rights v. FDA, 45 F.3d 1325, 1326 n.1 (9th Cir. 1995). This detailed affidavit " 'permit[s] the court system effectively and efficiently to evaluate the factual nature of disputed information.' " John Doe Agency v. John Doe Corp., 493 U.S. 146, 149 n.2 (1989) (quoting Vaughn, 484 F.2d at 826).

Loma Linda VA Medical Center
11201 Benton St
Mail Stop: 136-A
LOMA LINDA, CA 92357

DEPARTMENT OF VETERANS AFFAIRS

DATE: [redacted]/2007
In Reply Refer To: [redacted]

FRANK VERA
[redacted]

RE: ROI Request by VERA, FRANK

Dear MR VERA:

This is in response to your Freedom of Information Act (FOIA) request dated 7/18/2007 in which you asked for information about the Department of Veterans Affairs Research Department Loma Linda.

This information has been disclosed to you from records whose confidentiality is protected by Federal Law. Federal Law and Regulations (5USC552a, 38USC5701, and 38 CFR.511) prohibit you from making further disclosure of the information without the specific written consent of the person to whom it pertains, or as otherwise permitted by that regulation.

We have enclosed a copy of the document(s) you requested.

If you have any further questions, please contact J. Patrick Johnson, Ph.D.; Administrative Officer, Research; 11201 Benton Street (151), Loma Linda, CA 92357. Phone: 909-825-7084 Ext. 6050.

You may appeal the determinations made in this response to:

General Counsel (024)
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420

If you should choose to make an appeal, please submit your appeal within 60 days from the date of this letter, include a copy of this letter with your appeal and clearly state why you disagree with each determination you decide to appeal.

Sincerely,

Craig Curtis

Craig L Curtis
HIMS/MAIL CENTER SUPERVISOR

VA LOMA LINDA
HEALTHCARE SYSTEM

Memorandum

Date: [redacted] 2007

From: J. Patrick Johnson, Ph.D., Administrative Officer, Research Service (151)

Subj: Frank Vera, FOIA Request

To: Craig Curtis, FOIA Officer (HIMS)

1. I have completed reviewing the paper medical records that the facility received on the above-referenced patient.

2. One consent form was found related to a research study, which I have attached.

3. With the above information I was able to pull two pages from our database related to the study in question. I have also attached these two pages.

4. A check of our records for this study indicate that the research records, which had been sent to storage, have been destroyed in accordance with record retention policies with respect to research records.

5. If you have any further questions or need further clarification please feel free to contact me. Additionally, if Mr. Vera would like to contact me personally regarding his involvement in research at this facility, he may contact me in writing or by telephone at the following:

J. Patrick Johnson, Ph.D.
Administrative Officer, Research
11201 Benton Street (151)
Loma Linda CA 92357
(909) 825-7084, ext. 6050

J. Patrick Johnson, Ph.D.

cc: Research Compliance Officer (RCO)
Public Affairs Officer