APPENDICES

APPENDIX A

Consent Form

Approved: 04/27/00
Expiration Date: 01/13/01
Biomedical IRB #970352
University of Pittsburgh

CONSENT TO ACT AS A SUBJECT IN AN EXPERIMENTAL STUDY

TITLE: Bone Density and Coronary Calcification in Older Men

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SOURCE OF SUPPORT: National Institutes of Arthritis and Musculoskeletal Diseases

Description of Study: As a participant in the Study of Osteoporotic Risk in Men (STORM), I have been asked to return to participate in an additional examination. The purpose of this study is to examine the occurrence of calcification in the heart as measured by Ultrafast CT (EBCT), and to investigate the association between heart disease and osteoporosis in a population of adult men who may be at risk for calcification development at coronary arteries. 150 men from the Study of Osteoporotic Risk in Men (STORM) are being invited to participate in this study. I have been invited to participate because I am a participant in STORM. The information gained through this study may help researchers obtain a better understanding of the association between osteoporosis and heart disease in older men.

_____
Initials

Description of Clinic Visit: During the clinic visit I will be asked to complete questionnaires about my medical history, and to have the Ultrafast CT (EBCT) scan of the chest.

The EBCT scan involves taking a series of electron beam X-rays of the chest to measure the amount of calcium accumulation in the coronary arteries. Three small electrode patches will be placed on my chest by the technologist for the purpose of monitoring my heart rhythm during the EBCT. I will be asked to lie on my back on the scanner table and follow breathing instructions given by the technologist as the table is moved through a ring that emits and detects X-rays. I will be asked to hold my breath twice for approximately 20-30 seconds each time. The exam will take approximately 10 minutes. The EBCT scan will be performed at the University of Pittsburgh Preventive Heart Care Center located at 120 Lytton Ave, Suite 302 in Oakland.

Risks and Benefits: Participation in this research study involves exposure to radiation from the EBCT scan. The amount of radiation exposure received from the scanning procedure is approximately 0.407 rem to the chest for the coronary artery, with moderate exposure to other areas of the body. This is a small fraction of the annual radiation exposure limit to the lungs (40rem) or abdominal tissue (50rem) allowed for radiation workers by federal regulations. There is no known minimum level of radiation exposure that is recognized as being totally free of the risk of causing genetic defects (cellular abnormalities) or cancer. However, the risk associated with the radiation dose that I will receive from this study is considered to be moderate and comparable to other everyday risks. I will receive the result from my EBCT scan, and my physician will be informed if I request it.

I will not directly benefit from participation in this research study, but the results of this study may lead to an improved understanding of the relationship between osteoporosis and heart disease in older men.

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RIGHT TO WITHDRAW: I am free to refuse to participate, or to withdraw from this study at any time. This will not affect my care at this institution, or cause a loss of any benefits to which I am entitled. My refusal to participate will not affect my participation in the study.

NEW INFORMATION: If new information, either good or bad, about this study comes to the attention of the Investigators during the course of this study which may relate to my willingness to participate, it will be provided to me or my representative.

COMPENSATION FOR ILLNESS OR INJURY: The University of Pittsburgh and the Investigators of this study recognize the importance of my voluntary participation in this study. These individuals and their staff persons will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If I believe that I am injured as the result of the research procedures being performed, I will contact immediately Dr. Jane Cauley at (412) 624-0218 or the University of Pittsburgh

Initials

Institutional Review Board (412) 578-3424. Emergency medical treatment for injuries solely and directly relating to my participation in this research will be provided to me by hospitals of the UPMC Health System. If my research-related injury requires medical care beyond this emergency treatment, I will be responsible for the costs of this follow-up care unless otherwise specifically stated below. I will not receive monetary payment for, or associated with, any injury that I suffer in relation to this research.

COSTS AND PAYMENTS: I will not be charged for my participation in this study. Transportation to the clinic will be provided to me if I request. I will be compensated in the amount of $25 if I complete the clinic visit.

CONFIDENTIALITY: I understand that any information about me obtained from this research, including answers to questionnaires and laboratory data, will be kept strictly confidential. The information, which will carry personal identifying material, will be kept in locked files for five years after I complete the study. I understand that my research records, just like hospital records, may be subpoenaed by court order and that federal regulatory agents may have access to my records. It has been explained to me that my identity will not be revealed in any description or publication of this research. Therefore, I consent to such publication for scientific purposes.

VOLUNTARY CONSENT: I certify that I have read the proceeding, or that it has been read to me, and that I understand its contents. Any questions I have pertaining to the study will be answered by Dr. Jane Cauley at (412) 624-3057. Any questions I may have regarding my rights as a research subject will be answered by Institutional Review Board Office at (412) 578-3424. A copy of this consent form will be given to me.

I consent to participate in this study. I understand the nature, purpose, potential risks and benefits associated with participation, and all of my questions have been answered.
By signing this form, I freely agree to participate in this research study.

_____ _____

Participant Signature Date

I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participating in this research study, have answered any questions that have been raised, and have witnessed the above signature.

_____ _____

Witness Signature Date

_____ _____

Investigator's Signature Date

_____

Initials

APPENDIX B

Study Questionnaire

ID No. _____
Name Code _____
Date _____

STUDY OF OSTEOPOROTIC RISK IN MEN

Clinic Self-Administered Questionnaire

3/6/00
ver.

Dear STORM participants

Your dedication and participation in STORM study have made it extremely successful. You are the foundation upon which we continue to expand our knowledge and understanding of osteoporosis and the aging process in me. We couldn't do it without you – we thank you!

By participating in this ancillary study visit, you will contribute greatly to our ability to better understand osteoporosis and its relation to coronary artery diseases that prevail in men. The information that you provided will be unique and exceedingly important in enhancing our understanding of men's health. At this visit, we will ask you about behaviors and health related to cardiovascular disease, and will take a heart scan on your chest using new imaging techniques.

Your contribution to the STORM study is very important. We know that your participation in this study, filling out the questionnaires and coming to the clinic, takes time and thought. We really appreciate you in advance for taking the time to participate.

Thank you very much!

The STORM Staff

Appointment date: _____ Time: _____ A.M./P.M.

In preparation for your visit, please follow these instructions:

1. **What to bring to your appointment**

- Fill out the questionnaire forms as completely as you can and bring them with you.
- You do not need to fill it out all at once and you can get help if you want. If any parts of the questionnaires are confusing, leave them blank and they will be reviewed with you during your clinic visit
- Please bring to the clinic the bottles or containers for all medicines you've taken in the past 30 days
- Please bring eyeglasses and hearing aids if you use them.

2. What to wear to your appointment

- Please wear shirt that you can easily take off for the heart scanning.

Information obtained for this study is strictly confidential and will be used only for research purposes.

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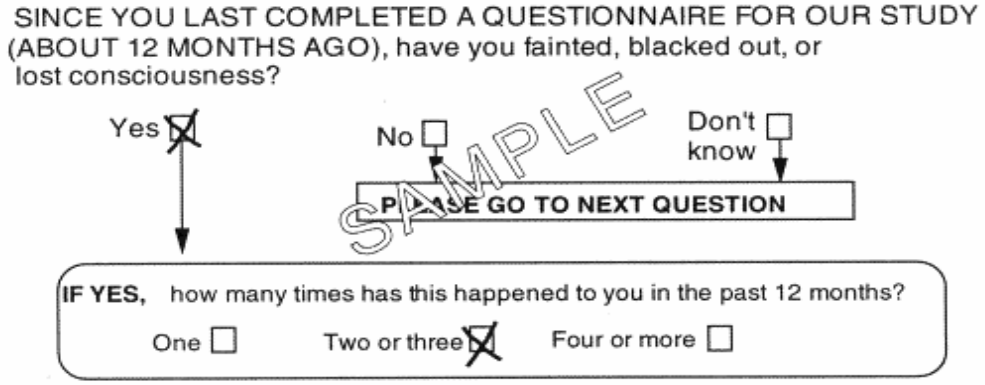
What we're asking you to do :

- Please answer the questions on the following pages as completely as you can.
- Take your time. You may get help if needed.
- Some questions have arrows that will help you find the next question.

EXAMPLE



ID No. _____
Name Code _____

Information obtained for this study is strictly confidential and will be used only for research purposes.

1a. Please check the information below for accuracy. Make any corrections, changes or additions in the space provided.

b. Corrections, changes, additions

Name _____ _____ _____
First Middle Initial Last

Address _____
Number Street Apt/Room Number

_____ _____ _____
City State Zip code

Telephone _____) _____
Area Code

2. Do you expect to move or have a different mailing address in the next year?
Yes ☐ No ☐ Don't know ☐

↓ ↓ ↓

PLEASE GO TO QUESTION 3

If you know your new address, please write it below

New address:

Address _____
Number Street Apt/Room Number

_____ _____ _____
City State Zip code

Telephone _____) _____
Area Code

☐ permanent address ☐ winter address ☐ other (please describe)
_____

3. Who is your next of kin?

a. Name _____ _____ _____
First Middle Initial Last

Address _____
Number Street Apt/Room Number

_____ _____ _____
City State Zip code

Telephone _____) _____
Area Code

b. How is this person related to you?

My son or daughter □ my grandchild □
My brother or sister □ friend/neighbor □
My niece or nephew □ someone else □
↓

Please say how related: _____

4. Please write down the names, addresses and phone numbers <u>of a person who do not live with you</u> and who would know how to reach you in case we are unable to get in touch with you. <u>A local person is preferred.</u>

Contact Person:

a. Name _____ _____ _____
First Middle Initial Last

Address _____
Number Street Apt/Room Number

_____ _____ _____
City State Zip code

Telephone _____) _____
Area Code

b. How is this person related to you?

_____

Health Care

5. Do you have a doctor or place that you usually to go to for health care or advice about your health care?

Yes □ No □

PLEASE GO TO QUESTION 6

IF YES, please write down the name, address and telephone number of the doctor or place that you go to now for your health care.

Name _____ _____ _____
First Middle Initial Last

Address _____
Number Street Apt/Room Number

_____ _____ _____
City State Zip code

Telephone _____) _____
Area Code

6. Do you want your EBCT results sent to your physician ?

Yes □ No □

PLEASE GO TO QUESTION 7

IF YES, please write down the name, address and telephone number of the doctor or place that you go to now for your health care.

a. Same as above □

b. Name _____ _____ _____
First Middle Initial Last

Address _____
Number Street Apt/Room Number

_____ _____ _____
City State Zip code

Telephone _____) _____
Area Code

Smoking

7. Do you <u>currently</u> smoke cigarettes?

Yes ☐ No ☐ Don't know ☐

PLEASE GO TO QUESTION 8

IF YES, on average about how many cigarettes a day do you smoke?

_____ cigarettes (less than one cigarette a day = 0.5)

HISTORY OF BROKEN BONES AND FRACTURES

8. **SINCE YOU LAST COMPLETED A QUESTIONNAIRE FOR THE STUDY**, ( ) has a doctor told that you had a broken or fractured bone?

Yes □ No □ Don't know □

↓ ↓

PLEASE GO TO QUESTION 9

IF YES, please write down the names of all the bones you have broken (for example, "wrist" or "spine") ?

Broken Bone	Date
_____	_____
_____	_____
_____	_____
_____	_____

9. **SINCE YOU LAST COMPLETED A QUESTIONNAIRE FOR THE STUDY**, ( ) has a doctor told that you had a osteoporosis, sometimes called thin or brittle bone ?

Yes □ No □ Don't know □

HEART CONDITIONS

10. Has a doctor **EVER** told you that you had:

IF YES, are you <u>currently</u> being treated for this condition by a doctor?

a. Heart attack or myocardial infarction?
☐ Yes ☐ No ☐ Don't know ☐ Refused → ☐ Yes ☐ No

b. Angina pectoris or chest pain due to heart disease?
☐ Yes ☐ No ☐ Don't know ☐ Refused → ☐ Yes ☐ No

c. Congestive heart failure?
☐ Yes ☐ No ☐ Don't know ☐ Refused → ☐ Yes ☐ No

c. Intermittent claudication or pain in your legs from a blockage of the arteries?
☐ Yes ☐ No ☐ Don't know ☐ Refused → ☐ Yes ☐ No

e. TIA, transient ischemic attack, or mini-stroke?
☐ Yes ☐ No ☐ Don't know ☐ Refused → ☐ Yes ☐ No

f. Stroke, CVA, or cerebrovascular accident?
☐ Yes ☐ No ☐ Don't know ☐ Refused → ☐ Yes ☐ No

g. Rheumatic heart disease or valvular heart disease?
☐ Yes ☐ No ☐ Don't know ☐ Refused → ☐ Yes ☐ No

h. Hypertension or high blood pressure?
☐ Yes ☐ No ☐ Don't know ☐ Refused → ☐ Yes ☐ No

i. Heart murmur?
☐ Yes ☐ No ☐ Don't know ☐ Refused → ☐ Yes ☐ No

CARDIOVASCULAR HISTORY

11. Have you **EVER** had any medical or surgical procedure to your heart, neck or vessels such as an angioplasty or bypass surgery?

□ Yes □ No □ Don't know □ Refused

→ **PLEASE GO TO QUESTION 12**

Have you ever had any of the following medical or surgical procedures…?

a. Coronary bypass surgery, heart bypass, or CABG?
□ Yes □ No □ Don't know □ Refused

b. Angioplasty of coronary arteries, which is a dilation of arteries of the heart with a balloon?
□ Yes □ No □ Don't know □ Refused

c. Carotid endarterectomy, which is surgery on the blood vessels in your neck?
□ Yes □ No □ Don't know □ Refused

d. Bypass procedure on the arteries of your legs?
□ Yes □ No □ Don't know □ Refused

e. Angioplasty of lower extremity arteries which is dilation of arteries of the leg with a balloon?
□ Yes □ No □ Don't know □ Refused

f. Pacemaker implant?
□ Yes □ No □ Don't know □ Refused

g. Repair of an aortic aneurysm?
□ Yes □ No □ Don't know □ Refused

h. Replacement of a heart valve?
□ Yes □ No □ Don't know □ Refused

CARDIOVASCULAR HISTORY

12. Have you ever had any pain or discomfort in your chest?
□ Yes □ No □ Don't know □ Refused

13. Do you get it when you walk up hill or hurry?
□ Yes □ No □ Never hurry or walk uphill □ Don't know □ Refused

14. Do you get it when you walk at an ordinary pace on a level surface?
□ Yes □ No □ Don't know □ Refused

15. What do you do if you get it while you are walking? Do you….
    - □ Stop or slow down, or continue at same pace after taking nitroglycerin
    - □ Continue at same pace
    - □ Don't know
    - □ Refused

16. If you stand still, what happens to it? Is it relieved or not relived?

□ Relived □ Not relieved □ Don't know □ Refused

PLEASE GO TO QUESTION 18

How soon is it relived?
- □ 10 minutes or less
- □ More than 10 minutes
- □ Don't know

CLINIC USE:

17. Where do you feel this pain or discomfort?

- □ 1 Sternum, upper or middle
- □ 2 Sternum, lower
- □ 3 Left anterior chest
- □ 4 Left arm
- □ 5 Other (Please specify) _____
- □ Don't know
- □ Refused

18. Have you ever had a severe pain across the front of your chest lasting for half an hour or more?

□ Yes □ No □ Don't know □ Refused

PLEASE GO TO QUESTION 19

a. Did you see a doctor because of this pain?
- □ Yes □ No □ Don't know / don't remember

b. What did your doctor say it was?
- □ Angina
- □ Heart attack
- □ Other (Please specify)
- □ Don't know/ don't remember

19. Do you get a pain or discomfort in your leg(s) when you walk?

□ Yes □ No □ Don't know □ Refused

PLEASE GO TO QUESTION 20

a. Does this pain ever begin when you are standing still or sitting?
□ Yes □ No □ Don't know

b. Do you get it if you walk uphill or hurry?
□ Yes □ No □ Don't know

c. Do you get it when you walk at an ordinary pace on a level surface?
□ Yes □ No □ Don't know

d. Does the pain ever disappear while your are walking?
□ Yes □ No □ Don't know

e. What do you do if you get it when you are walking?
□ Stop or slow down
□ Carry on

f. What happens to it if you stand still?
□ Usually continues more than 10 minutes
□ Usually disappears in 10 minutes or less
□ Don't know

g. Do you get this pain in your calf (or calves)?
□ Yes □ No □ Don't know

h. Were you hospitalized for this problem in your legs?
□ Yes □ No □ Don't know

FAMILY HISTORY OF CARDIOVASCULAR DISEASE

20. Did your **biological father** ever have heart disease?

□ Yes □ No □ Don't know □ Not that I know of

PLEASE GO TO QUESTION 21

a. IF YES, please look at the list of heart disease, and check the diseases your father had?

- □ HEART ATTACK, OR MYOCARDIAL INFARCTION
- □ ANGINA PECTORIS OR CHEST PAIN
- □ CONGESTIVE HEART FAILURE
- □ TIA, TRANSIENT ISCHEMIC ATTACTK, OR MINI-STROKE
- □ STROKE
- □ HYPERTENSION
- □ RHEUMATIC HEALTH DIEASE
- □ DEEP VAIN THROMBOSIS (blood clot in leg)
- □ PERIPHERAL VASCULAR DISEASE (blocked arteries in legs, abdomen)
- □ Any other diseases

b. Did he have heart disease before his age 50?

□ Yes □ No □ Don't know

21. Did your **biological mother** ever have heart disease?

□ Yes □ No □ Don't know □ Not that I know of

↓ ↓ ↓

PLEASE GO TO QUESTION 22

a. IF YES, please look at the list of heart disease, and check the diseases your mother had?

□ HEART ATTACK, OR MYOCARDIAL INFARCTION
□ ANGINA PECTORIS OR CHEST PAIN
□ CONGESTIVE HEART FAILURE
□ TIA, TRANSIENT ISCHEMIC ATTACTK, OR MINI-STROKE
□ STROKE
□ HYPERTENSION
□ RHEUMATIC HEALTH DIEASE
□ DEEP VAIN THROMBOSIS (blood clot in leg)
□ PERIPHERAL VASCULAR DISEASE (blocked arteries in legs, abdomen)
□ Any other diseases

b. Did she have heart disease before her age 50?

□ Yes □ No □ Don't know

22. How many biological brothers related by blood, if any, did you have?

□ None

↓

PLEASE GO TO QUESTION 23

□ One or More biological brothers

↓

a. **IF YES**, DID any of your biological brothers ever have heart disease?

□ Yes □ No □ Don't know □ Not that I know of

b. Did he or they have heart disease before his age 50?

□ Yes □ No □ Don't know

23. How many biological sisters related by blood, if any, did you have?

□ None

PLEASE GO TO QUESTION 24

□ One or More biological sisters

a. **IF YES**, DID any of your biological sisters ever have heart disease?
□ Yes □ No □ Don't know □ Not that I know of

b. Did she or they have heart disease before her age 50?

□ Yes □ No □ Don't know

MEDICATIONS

24. **SINCE YOU LAST COMPLETED A QUESTIONNAIRE FOR THE STUDY**,( )
HAVE YOU TAKEN any medications for osteoporosis?

Yes □ No □ Don't know □

PLEASE GO TO QUESTION 25

IF YES, please look at the list of medications, and write down name(s) of these medications .

Sodium Fluoride (Fluoride)
Calcitonin injections or nasal spray
Etidronate (Didronel)
Bisphosphonate (Foxamax)
Any Other medication

Name(s)	Pill size (milligrams or grams)	Number of pills per day or week
_____	_____	_____
_____	_____	_____

25. **HAVE YOU EVER TAKEN** any medicines to lower your blood cholesterol level?

Yes □ No □ Don't know □

PLEASE GO TO QUESTION 26

a. IF YES, Are you currently taking medications?

Yes □ No □ Don't know □

b. PLEASE wirte down names of these Medications

Name(s)	Pill size (milligrams or grams)	Number of pills per day or week
_____	_____	_____
_____	_____	_____
_____	_____	_____

26. **SINCE YOU LAST COMPLETED A QUESTIONNAIRE FOR THE STUDY,** ( )
HAVE YOU TAKEN any diuretic (water) pills?

Yes □ No □ Don't know □

→ **PLEASE GO TO QUESTION 27**

IF YES, please write down name(s) of these medications .

Name(s)	Pill size (milligrams or grams)	Number of pills per day or week
_____	_____	_____
_____	_____	_____

27. SINCE YOU LAST COMPLETED A QUESTIONNAIRE FOR THE STUDY, ( )
HAVE YOU TAKEN any predisone pills, cortisone pills, or other steroid pills?

Yes □ No □ Don't know □

→ **PLEASE GO TO QUESTION 28**

IF YES, please write down name(s) of these medications .

Name(s)	Pill size (milligrams or grams)	Number of pills per day or week
_____	_____	_____
_____	_____	_____

28. SINCE YOU LAST COMPLETED A QUESTIONNAIRE FOR THE STUDY, ( )
HAVE YOU TAKEN any medications for pain, arthritis, headaches?

Yes □ No □ Don't know □

a. IF YES, please write down name(s) of these medications .

Name(s)	Pill size (milligrams or grams)	Number of pills per day or week
_____	_____	_____
_____	_____	_____

b. Have you taken any of the medications every day or almost every day for a year or longer?

Yes □ No □ Don't know □

This ends the questionnaire.

Thank you for your time and effort!

PLEASE BRING YOUR MEDICATION BOTTLES
WITH YOU TO YOUR CLINIC APPOINTMENT

PLEASE BRING THIS QUESTIONNIRES WITH YOU TO YOUR CLINIC APPOINTMENT

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