

«ID»

«LName»

«FName»

1

OMB#: 0925-0216

Exp. 12/2007

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«ID»

«LName»

«FName»

2

OMB#: 0925-0216

Exp. 12/2007

**Thank you Letter, No Abnormalities Noted**

Date

Mr. John Smith

XXXXXXXXXX

Framingham, MA 01702

Dear Mr. Smith:

Thank you for taking part in the CT scan examination at MGH West in Waltham, Ma.

This study would not be possible if it were not for your willingness to participate. Your involvement has taken us one step closer to finding answers regarding cardiovascular health.

Your coronary calcium score did not indicate any significant findings. This CT scan is designed for research purposes only, and as such, it may not detect clinically important abnormalities. Therefore, this scan should not be used instead of a clinical CT scan.

If you have any questions regarding this study, please do not hesitate to contact Barbara Inglese at (508) 935-3451.

Sincerely,

Christopher J. O'Donnell, M.D., MPH

Director, CT Study

Framingham Heart Study

**Thank You Letter, High Calcium Score Noted**

«ID»                      «LName»                      «FName»

Date

Mr. John Smith

XXXXXXXXXX

Framingham, MA 01702

Dear Mr. Smith:

Thank you for taking part in the CT scan examination at MGH West in Waltham, Ma.

We are sending the report of your CT scan to your physician. This CT scan is designed for research purposes only and is not as complete as a scan used for medical diagnosis. Therefore, this scan should not be used in place of a clinical CT scan. Because the Framingham Heart Study does not provide any clinical diagnosis or treatment, we recommend that you follow-up with your physician regarding the results of this report.

Again, thank-you for your participation. This study would not be possible if it were not for your willingness to participate. Your involvement has taken us one step closer to finding answers regarding cardiovascular health.

If you have any questions regarding this study, please do not hesitate to contact Barbara Inglese at (508) 935-3451.

Sincerely,

Christopher J. O'Donnell, M.D., MPH  
Director, CT Study  
Framingham Heart Study

**Thank You Letter, Incidental Finding Noted**

Date

Mr. John Smith

«ID»                      «LName»                      «FName»

XXXXXXXXXX

Framingham, MA 01702

Dear Mr. Smith:

Thank you for taking part in the CT scan examination at MGH West in Waltham, Ma.

A radiologist has reviewed your scan and has encountered a finding that may be important to you and your physician. We are sending the report of your CT scan to your physician. This CT scan is designed for research purposes only and is not as complete as a scan used for medical diagnosis. Therefore, this scan should not be used in place of a clinical CT scan. Because the Framingham Heart Study does not provide any clinical diagnosis or treatment, we recommend that you follow-up with your physician regarding the results of this report.

Again, thank-you for your participation. This study would not be possible if it were not for your willingness to participate. Your involvement has taken us one step closer to finding answers regarding cardiovascular health.

If you have any questions regarding this study, please do not hesitate to contact Barbara Inglese at (508) 935-3451.

Sincerely,

Christopher J. O'Donnell, M.D., MPH

Director, CT Study

Framingham Heart Study

**Letter to Physician**

February 27, 2003

John Doe, M.D.  
73 Mt. Wayte Avenue  
Framingham, MA 01701

Dear Dr. Doe:

Jane Doe, a patient of yours, is a participant at the Framingham Heart Study and recently underwent a test to screen for coronary calcium using a MultiDetector (spiral) Computed Tomography (CT) scanner at Massachusetts General Hospital West, Waltham, MA. This test was performed as part of a research study. Limited scans of the chest and abdomen were obtained. This letter is being sent to notify you of the coronary calcium score and of any clinically important incidental findings.

Your patient has an Agatston coronary calcium score of 51. Compared to available age and sex-adjusted distribution of coronary calcium, this score is considered:

- High (greater than 90<sup>th</sup> percentile)
- Not High (less than 90<sup>th</sup> percentile)**

A high calcium score might be helpful in determining whether a patient is at an increased risk for coronary heart disease; conversely, a low calcium score might be helpful in determining whether a patient is a low risk for coronary heart disease. However, there is currently lack of consensus regarding the utility of the coronary calcium score, and it is not known whether the calcium score adds to the information provided by other measurements such as cholesterol and blood pressure in predicting future heart disease risk. More information regarding the most recent consensus guidelines for the use of this test can be found at: <http://www.acc.org/clinical/consensus/electron/dirIndex.htm>.

In the event that potentially important incidental findings were subsequently identified during a partial review of the CT scan, a report will be enclosed describing these findings.

Report Enclosed: [NO: ] [YES: X ] if yes, please review the enclosed report

The Framingham Heart Study is designed exclusively for epidemiologic research. However, we routinely send letters to a participant’s physician if he/she has a high calcium score or an important incidental finding, or if the participant requests that the results be sent. If you have any questions about this test, please direct inquiries to me via our CT Study Coordinator, Barbara Inglese at (508) 935-3451. We greatly appreciate your support of the Framingham Heart Study.

Sincerely,

Christopher J. O’Donnell, M.D., MPH  
Director, CT Study  
Framingham Heart Study

Cc: Thomas Brady, M.D.  
Massachusetts General Hospital

Date of call \_\_\_/\_\_\_/\_\_\_\_\_

**Framingham Heart Study CT Scan Incidental Finding Follow-up Questionnaire**

«scan\_date»                   **Date of CT Scan**  
«letter\_date»                 **Date of IF letter**

«percent90»

|\_|\_|\_|                   **Interviewer ID.**

***Introductory script:***

*On \_\_\_\_\_ you underwent a CT scan examination for the Framingham Heart Study at MGH West in Waltham, MA. The Heart Study sent you and your physician a letter regarding a finding on the CT scan identified by a radiologist as part of the normal review of your scan. Most such findings were not dangerous however in some cases your doctor may have recommended additional testing. We are*

«ID»                      «LName»                      «FName»

*conducting a brief follow-up survey to determine the type of medical testing you may have undergone. We would also like to ask you a few questions about the letter you and your doctor received regarding the CT scan to better understand what difficulties you may have encountered as a result of participating in this study.*

***Is this a good time? if no, when would be a good time to call back?***

Date: \_\_\_\_-\_\_\_\_-\_\_\_\_

Time: \_\_\_\_:\_\_\_\_ am/pm

- «C01»
- «C02»
- «C03»
- «C04»
- «C05»
- «C06»
- «C07»
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- «C19»
- «C20»
- «C21»
- «C22»
- «C23»
- «C24»
- «C25»

**1. Who is completing this form?**

- Participant
- Spouse
- Other relative
- Other (write in relation to participant)

**2. Do you remember receiving a letter after the scan?**

- Yes
- No
- Unknown

**If no or unknown, skip question 3.**

**3. When you received the letter regarding the CT scan findings, did you feel anxious or worried?  
(read all responses)**

- Not at all
- Mildly but it didn't bother me much
- Moderately, it wasn't pleasant
- Severely, it bothered me a lot

**4. Did you and your doctor discuss the findings on the CT scan? (check all that apply)**

- No
- Yes, phone contact
- Yes, office visit

**If yes, please specify the following:**

Name of physician \_\_\_\_\_  
 Address of physician \_\_\_\_\_  
 Phone number of physician \_\_\_\_\_

**5. Do you know the type of finding and its location (eg, "spot" or "abnormality" on the lung, liver, kidney)?**

- No
- Yes, specify the type of finding and its location briefly:

\_\_\_\_\_

**If yes, did you know previously that the finding existed?**

- No
- Yes

**6. Were you referred to a specialist?**

- No
- Yes

**If yes, please specify for each specialist:**

Type of specialist	
Name of specialist	
Address of specialist	
Phone number of specialist	

Type of specialist	
Name of specialist	
Address of specialist	
Phone number of specialist	

Type of specialist	
Name of specialist	
Address of specialist	
Phone number of specialist	

**7. Please estimate the total number of office visits to any physician (primary care physician and specialists) to address the finding(s) on the CT Scan examination?**

- No physician visits
- One visit
- More than one visit



**8. Did you undergo any of the following tests for the finding on your CT scan? (read each test)**

If yes obtain name and address of facility where testing was performed and date of test

YES	NO	PROCEDURE	DATE	FACILITY
<input type="checkbox"/>	<input type="checkbox"/>	Ultrasound	__-__- ____	_____
<input type="checkbox"/>	<input type="checkbox"/>	CT scan	__-__- ____	_____
<input type="checkbox"/>	<input type="checkbox"/>	MRI scan	__-__- ____	_____
<input type="checkbox"/>	<input type="checkbox"/>	Endoscopy (look into GI tract)	__-__- ____	_____
<input type="checkbox"/>	<input type="checkbox"/>	Bronchoscopy (look into lungs)	__-__- ____	_____
<input type="checkbox"/>	<input type="checkbox"/>	Biopsy Specify site _____	__-__- ____	_____
<input type="checkbox"/>	<input type="checkbox"/>	Angiogram (put "dye"/contrast in blood vessels) Specify site _____	__-__- ____	_____
<input type="checkbox"/>	<input type="checkbox"/>	Other Write in name of test _____	__-__- ____	_____

**9. What special treatments did you undergo as a result of the finding on your CT scan?**

a) 

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

**Surgery**

if yes, Specify each specific surgery, surgery date, and hospital

SURGERY	DATE	HOSPITAL
1.		
2.		
3.		

b) 

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

**Medication**

if yes list all medications

LIST OF MEDICATIONS
1.
2.

3.
4.

**10. If you discussed the CT scan findings further with your doctor and/or if your doctor recommended further testing, did you feel anxious or worried? (read all responses)**

- Not at all
- Mildly but it didn't bother me much
- Moderately, it wasn't pleasant
- Severely, it bothered me a lot

**11. Did the discovery of the CT scan finding and the evaluation by your physician require you to miss any of your full-time responsibilities (eg, work or care of your children)?**

- No
- Yes, less than one day ( 0-8 hours) total
- Yes, 1-2 days
- Yes, > 2 days

**12. Did you incur any financial costs related to the CT scan finding?**

- No
- Yes

**13. If you had further testing for the finding on the CT scan examination, please tell us the final medical diagnosis for the finding**

write in \_\_\_\_\_

**14. Do you have any comments about the CT examination you would like to share with the study investigators?**

- No
- Yes

If yes write in

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**Thank you for completing this survey.**