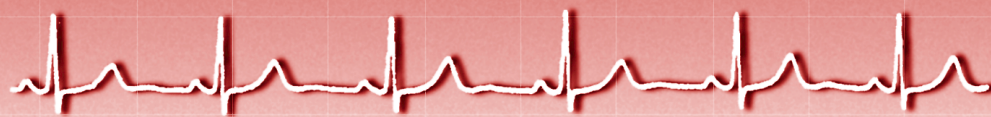


# The Framingham HeartBeat



Spring 2004

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## DEAR FRAMINGHAM HEART STUDY PARTICIPANTS,

This past year was one of great progress for the Framingham Heart Study. We published nearly 100 papers in leading medical journals and several of these studies were featured prominently in local and national news coverage. Our scientific achievements have helped our senior investigators assume leadership roles in their fields both nationally and internationally.

Since the start of our Third Generation Study in April 2002, we have recruited over 2,700 new participants and the recruitment will continue through the middle of 2005. We will enroll over 3,500 women and men into this new project. We proudly display a map of the United States on the wall in clinic with pins to indicate the home cities of our new participants; we already have seen Third Generation participants from 45 states and 8 countries. In addition, for three-generational families in which only one spouse from the offspring cohort was enrolled when the Offspring Study began in 1971, we recently began recruitment of the other spouse into the New Offspring Spouse Study.

This plan for comprehensive enrollment of three generations of participants is critical in placing the Framingham Heart Study in a unique position to investigate the genetics of cardiovascular disease and contributing conditions such as high blood pressure, elevated cholesterol, diabetes and obesity. We also are poised to explore genes related to asthma and chronic lung disease, dementia, stroke, osteoarthritis, osteoporosis, vascular disease, kidney disease, and many more diseases.

To help us with complex decision making and to advise us, at the recommendation of an Ethics Advisory Panel that met in April, 2003, we have established an Ethics Advisory Board. In addition to Dr. Greg Koski, a medical ethicist from Harvard Medical School and Massachusetts General Hospital, and Maryann Whalen, a genetics counselor from Boston University, the Board will include representatives from the participants of the Framingham Heart Study: Victor Galvani, Original Cohort; David Whittemore, Offspring Cohort; Michelle Feinberg, Third Generation Cohort; Deborah Fuller, Omni Cohort. Representing the community at large will be Drs. James Alderman and Ralph Sherman and Rev. J. Anthony Lloyd. To keep you informed about matters that may be of concern to you, we will publish summaries of the Ethics Advisory Board's opinions in our newsletters. In this issue of the newsletter we are including a review of the discussion with the Ethics Advisory Panel last April.

Your participation in this process of posing questions to and reviewing opinions of the Ethics Board is something we value greatly. If you have a question for the Ethics Board, please send it in writing to Ms. Esta Shindler, Framingham Heart Study, 73 Mt. Wayte Avenue, Framingham, MA 01702.

The Framingham Heart Study owes its success to you.

Sincerely,

Daniel Levy, MD  
Director, Framingham Heart Study

## FRAMINGHAM HEART STUDY INVESTIGATORS MEET WITH ETHICS ADVISORY PANEL

The Framingham Heart Study investigators convened an Ethics Advisory Panel to advise Framingham researchers regarding some timely questions. We were fortunate to have three nationally known panelists: Dr. Greg Koski, MD (former director of the Federal Office for Human Research Protection, now an anesthesiologist at Massachusetts General Hospital), Dr. Leonard Glantz (Professor of Health Law, Boston University School of Public Health), and Dr. Michael Watson (Executive Director, American College of Medical Genetics).

At the meeting held in April, 2003, two questions were posed to the panelists by Drs. Adrienne Cupples and Christopher O'Donnell, co-chairs of the Framingham Heart Study Genetic Research Steering Committee. Below is a summary of the panel discussion.

### Question 1: What genetic materials can be distributed to investigators for research purposes?

Our informed consent form describes research using "genetic material" derived from blood samples donated by participants. Much of the genetic research to date has used one specific type of genetic material derived from the nucleus of cells. This material is known as DNA (deoxy-ribonucleic acid). However, with the discoveries about the human genome, Framingham researchers are now interested in other related types of genetic material that can be extracted and studied, including a closely related molecule known as RNA (ribonucleic acid). These materials typically are extracted from white blood cells that have been saved and frozen.

The panelists advocated that any decisions regarding genetic research need to include the very important relationship of trust that exists between the Framingham investigators and the study participants. It was felt that the term "genetic research" would generally encompass use of genetic materials such as DNA, RNA, and other genetic material derived from white blood cells. It was recommended that Framingham

participants be informed on a regular basis about research through the newsletters and that special attention remain focused on informing participants about genetic research when they sign the informed consent form.

### **Question 2: Are there circumstances when the Framingham Heart Study should inform participants about the results of genetic tests?**

Everyone has genetic material or DNA that is 99.9% the same as all other people in the world, except for a small number of variations in the sequence of DNA building blocks. Some of these variations or differences in DNA are known as genetic mutations, because they may lead to changes in proteins and increased risks for serious diseases. At present, the Framingham Heart Study does not notify participants when a mutation is detected because the research at this stage is extremely preliminary. The panelists acknowledged that in the future there may be mutations detected for which participants should be notified. They suggested that a system be established to offer such information to participants. For example, they may be provided an option to receive the information when they sign their consent form. It was stressed that one of the highest priorities is to maintain confidentiality.

It was recommended that an Advisory Board be established to make recommendations on such issues as they arise and that the Board include study participants as well as local clergy, physicians, genetic counselors and an ethicist. ♥

## **THE ORIGINAL COHORT**

We are proud to report the start of the 28th Examination Cycle for the Framingham Heart Study's Original Cohort. These loyal original members had their first exams beginning in 1948 and have participated approximately every two years, making this their 56th year in the Study!

Many of our members still come to the clinic for their exams and others have home or nursing home visits. We are delighted to visit our members offsite if it is more convenient for them. The offsite staff travels to every New England state to visit participants. For members who live outside of New England, we keep in touch by telephone, doing health updates and keeping track of medical events that occur.

The 5,209 original members were between 30 and 60 years of age when the Study began. As this newsletter goes to press, 564 are still alive, and five are over 100 years of age. Our youngest members are 83.

We are extremely grateful to all our original members, without whom there would be no Framingham Heart Study. We have continued our research with their children and now with their grandchildren. Our original participants still participate faithfully, and often agree to take part in additional studies such as MRIs of the brain, neurological testing, and foot studies. Over 80 original participants have also registered in our Brain Tissue Donation Program to be future brain donors. Their long-term commitment is extremely heartwarming to all of us and we are happy to announce the beginning of this next exam cycle. ♥

## **HEALTH HISTORY UPDATES BY PHONE OR MAIL**

One of the current goals at FHS is to obtain updated medical information for each participant every two years by means of mailings and telephone calls. If you are a participant and have not had an examination at the Framingham Heart Study during the past two years, we would like the current information regarding your medical status.

Many participants have recently completed the health history update forms. Others have provided the necessary information during brief telephone interviews with our staff. We thank you for helping us update your medical records, which are an important part of the ongoing FHS research. If you have not yet been contacted, we will send you a questionnaire or offer you an interview by phone soon.

If you need assistance completing the health history update form, please call Mary Ann Crossen at 508-935-3430 or 1-800-854-7582 (Ext. 430). ♥

## **TO CONTACT US...**

For your convenience we maintain the following local and toll-free telephone numbers to access the Framingham Heart Study.

Receptionist, Framingham Heart Study  
508-872-6562; 800-854-7582

Marian Bellwood, Offspring Coordinator, Cardiac MRI  
508-935-3429; 800-451-0260

Maureen Valentino, Third Generation Coordinator  
508-935-3417; 800-536-4143

Paulina Drummond, Omni Coordinator  
508-935-3485; 800-854-7582, ext.485

Patricia Kelly, New Offspring Spouse Coordinator  
508-935-3403; 800-854-7582, ext.403

Linda Clark, Cohort Coordinator, Brain Donation Program  
508-935-3426; 800-248-0409

**Important Note: The toll free number which appeared in the Spring 2003 newsletter is incorrect. The correct number for the Framingham Heart Study is 800-854-7582.**

## **CLAUDE LENFANT RETIRES FROM NATIONAL HEART, LUNG AND BLOOD INSTITUTE**

Claude Lenfant, M.D., Director of the National Heart, Lung and Blood Institute, retired on August 30, 2003, after twenty-one years of leadership. National Institutes of Health Director Elias A. Zerhouni, M.D., praised Dr. Lenfant as a "talented and capable administrator and a first-class scientist". Secretary of Health and Human Services Tommy Thompson said "Claude Lenfant has made a lasting impact on his institute and on the health of Americans and people all over the world". The Framingham Heart Study is funded by the National, Heart, Lung and Blood Institute, and Dr. Lenfant was a staunch supporter. He spoke to our participants both at our 50th anniversary celebration and at a more recent public forum, stating that the research success of the Study and its contributions to worldwide public health are directly attributable to the commitment and dedication of its participants. ♥

## FHS LOVES THE RED SOX



Team spirit is a hallmark of the staff of the Framingham Heart Study. We are all dedicated and committed to the mission of the Heart Study and to all our participants who make that mission possible. In September that spirit spilled over in excitement and support for our Boston Red Sox in their valiant attempt to get to the World Series.

Clinic Staff Clockwise: Patricia Kelly, Emily Sartini, Patti Kay, Donna Salett, Bernadette Shaw

## NEW OFFSPRING SPOUSE STUDY

The Framingham Heart Study is now recruiting spouses of Offspring participants who were not enrolled in the Offspring Study when it began in 1971. To be eligible for recruitment, a New Offspring Spouse participant must be the biological parent of two or more Generation 3 participants who have come to the clinic for their first examination. We hope to examine approximately 500 "New Offspring Spouses (NOS)" for this study. The New Offspring Spouse examination will be identical to the examination the Generation 3 participants receive. The first NOS participants were examined in October, 2003 and examinations will continue through June, 2005. For more information please contact Patricia Kelly who can be reached at 508-935-3403 or 800-854-7582 (Ext. 403). ♥

## SECOND GENERATION OF OMNI STUDY

We are pleased to welcome the second generation of Omni participants into the Framingham Heart Study. The recruitment of this new generation began last year and will continue until July, 2005. So far we have seen 52 participants and are hoping to see many more. If you are an Omni participant and have children or siblings who are at least 20 years of age, or who will be 20 before July, 2005, we want to invite them to take part in the Study. Preference will be given to family members who live in Massachusetts, and who express interest in participating in a study involving long-term follow-up.

Please make your children and siblings aware of the opportunity to contribute to the improvement of public health worldwide by participating in this study.

For more information or to obtain a form so that we can contact your children and siblings, contact the Omni Coordinator, Paulina Drummond, at 508-935-3485 or 1-800-854-7582 (Ext. 485). ♥

## CONTINUED SUCCESS OF GEN 3 ENROLLMENT AS FINAL YEAR APPROACHES

The examination of the Third Generation (Gen 3) of the Framingham Heart Study began in April, 2002. The response of the Gen 3 volunteer participants to join the Study has been tremendous. To date we have seen over 2,700 participants.

The enrollment period will run through June, 2005. We are espe-

cially interested in having as many brothers and sisters as possible from each family participating in the Study. If you are a member of the Offspring Study, you can help by encouraging all your children to participate. If you are already a participant in Gen 3, please tell your siblings about our Study.

### ATTENDANCE AT EXAM 1 IS NECESSARY FOR FUTURE PARTICIPATION IN THE STUDY.

If you are eligible for the Gen 3 exam, we will send you an enrollment form. Please fill it out when it arrives and return it as soon as possible. If you do not live near Framingham, please phone and let us know when you plan to be in the area so an exam can be scheduled at your convenience. For information, please contact Maureen Valentino at 508-935-3417 or 800-536-4143. ♥

## DID YOU KNOW

A few of our participant families actually have four generations represented in the Framingham Heart Study! How can this be? Well, back in 1948, not only did Mom and Dad agree to participate, but in a few families eligible children did too. Our original cohort ranged in age from 29 to 62 years. Thus, even in 1948, participation had already become a family affair. ♥

## FAN MAIL

We have said it many times in the past but it bears repeating. If it were not for the loyal participation and commitment of all of our participants, the Framingham Heart Study would not have been able to achieve the research success that has improved the knowledge and health of the public worldwide. It is very rewarding to know that many of our participants view their commitment as being of mutual reward and benefit, as expressed in the letter below:

*Dear Doctor Levy,*

*"I am a Third Generation Framingham Heart Study participant. I live on lower Cape Cod. In order for me to be involved ..., I needed to use a vacation day from work, hit the highway at 5:00AM, plan for five hours or so of tests at your Mt. Wayte facility, after which I drove to Waltham for a CT scan ... a very long day of tests and driving.*

*However, upon my arrival .... I was graciously escorted in ...*

*Dr. Levy, I must tell you that each and every staff member treated me personally. They were extremely kind and considerate, yet professional and adept at his/her job. I actually enjoyed my time with your employees! ... They were all excellent at their professions, They're also wonderful people to boot.*

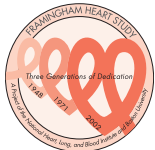
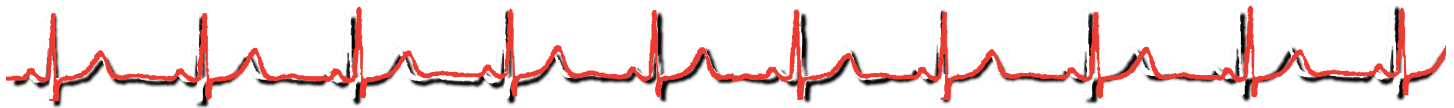
*When all was completed, I was escorted to the door and given directions to Waltham's PHRC building. I must tell you that my expected long and stressful day was turned into an informative, warm and well-cared-for experience ..."*

Trustees of Boston University  
National Heart, Lung and Blood Institute  
Framingham Heart Study

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Framingham, MA 01702

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## A Family Tradition

In 1948 5,209 men and women, all of whom resided in the town of Framingham, became the original participants in the Framingham Heart Study. Thus began a family tradition that has been passed on to two subsequent generations. The Offspring of these participants have faithfully returned to the Study for their clinic visits since 1971 regardless of where they live, whether in the far-reaching states of America or countries around the world. Their children, our Third Generation participants, are now coming from all over the United States and from many countries as far away as Japan, Australia, Guam and Indonesia to participate in our ground-breaking study.

We are truly thrilled, each and every day, to see how eager the participants of the "Third Gen" are to be a part of the Framingham Heart Study. We will continue with Exam 1 of the Third Generation through June, 2005.

2,639 Third Generation participants have been examined at the Framingham Heart Study as of December 31, 2003. They came from the following states of the Union. A few more travelled from outside the USA.

AK-4	GA-12	MD-24	NJ-18	TN-4
AL-2	HI-2	ME-52	NM-1	TX-11
AZ-8	ID-1	MI-6	NV-1	UT-3
CA-47	IL-5	MN-3	NY-51	VA-18
CO-11	IN-5	MO-4	OH-3	VT-15
CT-68	KS-1	MT-1	OR-5	WA-8
DC-4	KY-1	NC-12	PA-17	WI-5