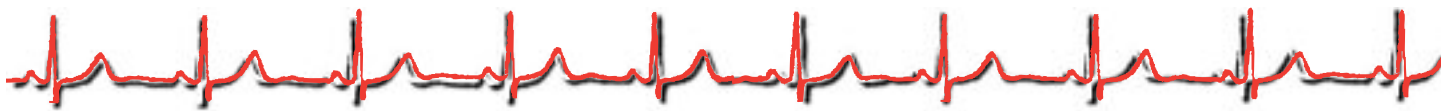


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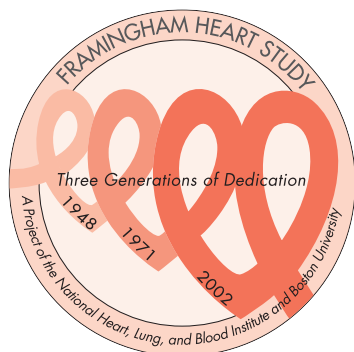
## FRAMINGHAM HEART STUDY WEBSITE

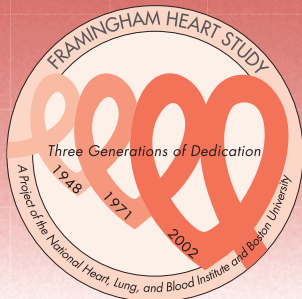
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The Framingham Heart Study has its own website. In addition to using the website of the National Heart, Lung and Blood Institute, ([www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)), it is possible to go directly to a Heart Study website through [www.framinghamheartstudy.org](http://www.framinghamheartstudy.org).

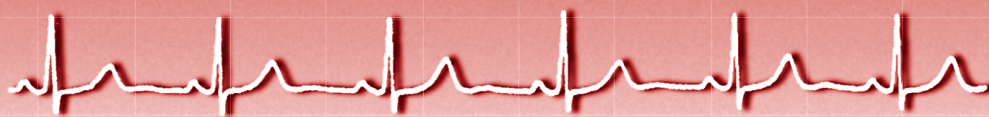
On the website you can find information about the Study there such as: contact information, examination details, policies, organization of the Study, major findings, ancillary studies, back issues of newsletters, the Framingham Heart Study bibliography, material for personal and school-related research, and links to other resources.

As always, we are very grateful to you, our participants, for your loyal dedication and continued participation, and we welcome you to visit our website. ♥





# The Framingham HeartBeat



Winter 2006

Published by The Framingham Heart Study, a Project of the National Heart, Lung, and Blood Institute and Boston University

## FRAMINGHAM HEART STUDY EMBARKS ON A MAJOR GENOME RESEARCH PROJECT TO IDENTIFY GENES UNDERLYING CARDIOVASCULAR DISEASES

The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health has announced it will fund a new genetics research project at the NHLBI's Framingham Heart Study (FHS) in collaboration with Boston University School of Medicine. "By conducting this Genome-Wide Association Study and sharing the study data with interested researchers," said Dr. Elizabeth Nabel, Director of the NHLBI, "this project will greatly accelerate discoveries regarding the causes and prevention of cardiovascular disease and other disorders." Added Dr. Karen Antman, Dean of Boston University School of Medicine, "This unique opportunity to increase our knowledge about health and disease is made possible by the wonderful gift to medical research provided by three generations of participants of the Framingham Heart Study."

In 2004 the Human Genome Project completed the "genome," the entire sequence of nearly 3 billion building blocks in humans, showing that each human being has about 25,000 genes. In 2005, a detailed catalogue of variations in the DNA building blocks--the HapMap project--showed that in humans DNA differences, known as single nucleotide polymorphisms (SNP's), occur about once in every 1000 building blocks. Recent advances in technology have allowed the development of single tests that can simultaneously examine alterations in about 500,000 building blocks, or SNP's, all miniaturized to the size of a credit card. A number of recent studies at the FHS have clearly demonstrated a familial predisposition to cardiovascular diseases.

For the FHS Genome-Wide Association Study, DNA from each of approximately 8000 participants across all three generations will be studied for about 500,000 SNPs. Using computer programs, researchers will relate this large catalogue of genetic results to many of the clinical and laboratory measurements that have been made in study participants during their examinations. Researchers hope to be able to identify genetic variations that are most strongly related to study participant characteristics such as levels of cholesterol, systolic blood pressure, obesity, and diabetes, and to disease occurrences like heart attack, stroke and osteoporosis. Since a large amount of data will be generated for this study, experts at the NIH National Center for Biotechnology Information have been consulted to develop a secure database for this research project. In recent months, similar genome-wide studies have been conducted in other study populations, identifying genes that are related to obesity and to abnormal electrocardiograms.

The design of this genetics study is similar to a number of ongoing FHS projects that were described in the 2005 Framingham HeartBeat newsletter, but with an increased size and scope. Framingham investigators have set up safeguards to ensure the same level of confidentiality and privacy that has been in place for past research projects. Recently, meetings were held to discuss the FHS Genome-Wide Association Study with a number of external advisory committees including the Framingham Heart Study Observational Studies Monitoring Board in Washington, D.C. and the Framingham Ethics Advisory Board, which is chaired by a noted medical ethicist, Dr. Greg Koski, and consists of study participants as well as local clergy and healthcare providers. A group of FHS participants recently met to discuss questions and concerns. A set of "frequently asked questions" was developed (see related article below). Continued input by participants is important and welcome. Therefore, additional group meetings are being planned. Interested participants may sign up for one of these meetings by calling or e-mailing Esta Shindler at 508-935-3434 or [eshindle@bu.edu](mailto:eshindle@bu.edu). ♥

## OFFSPRING EXAM 8 UNDERWAY

The eighth examination cycle for the Framingham Offspring Study began in March 2005 and will continue through December 2007. The exams are scheduled each morning, Monday through Friday. The Framingham Heart Study clinic is in new quarters located on the first floor of the Perini building at 73 Mt. Wayte Avenue. There is ample parking space. Dr. Joanne Murabito is the Clinic Director and Bernadette Shaw is the Clinic Manager. Our participant coordinators, Maureen Valentino, Marian Bellwood and Sandy Bittenbender, have been phoning Offspring to schedule appointments, usually six per day. **If you live out of town and are planning to visit the Framingham area soon, please call Maureen at 800-536-4143 so she can arrange a clinic appointment for you at a convenient time.** ♥

## QUESTIONS ASKED BY PARTICIPANTS AT DECEMBER MEETING:

1. Q: What are the kinds of discoveries about health that occur from my involvement in this project?

A. Researchers are hopeful that genetic findings may lead to new understanding of the causes of common conditions like high blood pressure, diabetes and obesity. Such findings may also lead to new drugs or new ways to diagnose, prevent and treat these disorders using genetic testing. These new approaches have been referred to as "personalized medicine". However, like the long-term research that led to discoveries about high blood pressure and high cholesterol, it may take several years or even decades for benefits to result from the current genetics project.

Continued on Page 2

**2. Q: When did collection of DNA start at FHS? Have you started collecting genetic information?**

A: We began collecting DNA in 1988. We have been collecting genetic information for approximately 15 years.

**3. Q: Why are you going through this program of communication now?**

A: The genetics research we did in the past was limited in scope; now with new genetic technology we get much more information than before. It is our aim to keep participants informed about our research along the way.

**4..Q: How can I know what my genetic data is being used for?**

A: The consent form reviewed and signed by you at each exam will be scrupulously followed. This consent process includes information on the areas of research that may be pursued. There are provisions for consent (or refusal) for each of these different areas of research. Of course, we will abide by your requests.

**5. Q: How will participant privacy and confidentiality be ensured?**

A: Names and clinic ID numbers have been removed from data and DNA specimens. Randomly generated ID numbers are assigned to the data. There are also considerable safeguards and firewalls against “hackers”. Although it is not possible to guarantee the elimination of all risk, we are taking safeguards by using gatekeepers like the National Library of Medicine to help protect our data. In this way, the research database will be analyzed by internal and external investigators in a manner that adheres to the letter of the law and addresses all confidentiality and privacy issues, ensuring that data are released only according to the wishes you express on the consent form. Experts at the NIH National Center for Biotechnology Information will help us with this.

**6. Q: If something is discovered from my DNA/genetic studies that might be critical to my health, will I be informed?**

A: You will not be informed of the results of routine research performed upon your genetic sample. Mechanisms are in the works, however, to notify study participants in the future of significant genetic findings that carry high risk for a disease and for which a beneficial treatment clearly exists. Our consent form provides for informing people who want to be notified in such cases. The consent form states that, “If a genetic condition is identified that may have potentially important health and treatment implications for me, I agree to allow the FHS to notify me and with my permission to notify my physician”.

**7. Q: If consent is withdrawn, what will happen to my DNA?**

A: It will be removed from specific use or destroyed in accordance with your requests.

**8. Q: How does a researcher request data?**

A: In order to apply to use data, investigators are required to follow a number of procedures. First, the investigator submits an application form describing the planned research. Then, he/she asks the Institutional Review Board (IRB) of his/her institution for approval for the project and signs a legally binding Data and Materials Distribution Agreement; therefore, there are multiple levels of protection.

**9. Q: Can commercial companies apply for data?**

A: Commercial companies do not currently have access; however, the current consent form asks specifically if a participant is willing to have his/her data used by “researchers from private companies” interested in developing new diagnostic tools or drugs. The database will be created to reflect each participant’s level of consent. Therefore, in the future, commercial entities may apply to conduct research with the data from this project. Like all oth-

ers, they are allowed to do so only under the terms of the Data and Materials Distribution Agreement.

**10.Q: Whom can I call if I have a question?**

A: Framingham participant coordinators are available for each of our participant groups to answer questions or refer the question to a senior investigator. Please refer to the “Contact Us” box below. ♥

## TO CONTACT US

We maintain several local and toll-free numbers for our participants to reach us here at the Framingham Heart Study:

Receptionist: 508-872-6562 or 800-854-7582

Marian Bellwood, Sr. Participant Coordinator,  
Cardiac MRI Coordinator: 508-935-3429 or 800-451-0260

Maureen Valentino, Offspring Coordinator,  
Third Generation Coordinator:  
508-935-3417 or 800-536-4143

Linda Clark, Original Cohort Coordinator, Brain Donation  
Program Coordinator:  
508-935-3426 or 800-248-0409

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

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

If you leave a voice mail message, please include a good time for us to return your call.

Please call or write us if you have a new address or new telephone numbers (home, work, or cell) or email address. Thank you!

## DR. WILLIAM B. KANNEL TALKS ABOUT HIS MENTOR, DR. THOMAS R. DAWBER

We at the Framingham Study and the medical community in general were saddened to learn of the death of Dr. Thomas Royle (Roy) Dawber on November 23, 2005. Through his efforts to initiate and maintain the Study, its contributions have been acclaimed as some of the most important to medicine. He was always grateful to the citizens of Framingham who volunteered and steadfastly participated in the Study over more than five decades.

Dr. Dawber was a mentor to many of the doctors who came to work at the Study, inspiring them to pursue a career in epidemiological research. This includes myself, Drs. Castelli, Levy, Wolf, and Friedman among others. Dr. Dawber, unlike many other epidemiologists, was mainly interested in providing information that could be directly useful to prevention-minded doctors in practice. He viewed epidemiology as clinical investigation on a community level. Under his guidance, the Framingham Study investigators produced much needed information about the prevalence, incidence, clinical manifestations and



Dr. Dawber explains EKG to participant



modifiable predisposing risk factors for development of cardiovascular disease. During his tenure as Director of the Study (1949-1966) he allowed the Framingham Study investigators to pursue their interests no matter how unorthodox they might have seemed. This resulted in Framingham investigators correcting many important misconceptions that physicians had about heart and blood vessel disease and its predisposing risk factors. Thus, scientific reports produced during his tenure alerted physicians to the ominous implications of atrial fibrillation, left ventricular hypertrophy, small amounts of albumin in the urine, systolic hypertension, arterial rigidity, obesity and high cholesterol. These and other early findings made the Framingham Study reports among the most cited references in the medical literature. These findings also made the Framingham Study a prototype for other epidemiological studies around the world and established the utility of the risk factor concept for gaining valuable insights into the development and prevention of chronic diseases. ♥

## FRAMINGHAM HEART STUDY LABORATORY



Front Row (L to R): Jiaoshi Dong,  
Judy Antonucci  
Back Row (L to R): Mary Nazzaro,  
Patrice Sutherland, Meme Holden

We thank each and every Framingham Heart Study participant for donating blood samples over the years. Dr. Sander Robins is the director of the FHS laboratory and Patrice Sutherland is the manager. Our lab staff is trained and certified to draw blood, to process the samples quickly for research projects and to

store precious samples carefully for future use. The samples from each participant are now split and stored in many tiny vials (usually at -80 degrees centigrade). To protect against loss in case of an unforeseen disaster, we have freezers in several locations in Massachusetts and all have back-up generators to keep them running for days in the event of a power loss. Bar coded labels and special lab numbers are used without participant names to protect their identity. Samples are often sent to other laboratories for special measurements.

Laboratory data are just as important to our research as blood pressure, height, weight, ECG and other measurements. As new lab tests are developed, we will be ready to use them in Framingham, thanks to the generosity of the participants and the skills of our lab staff. ♥

## OMNI EXAM 3 TO BEGIN

We will be contacting Omni participants soon regarding the next exam cycle here at the Framingham Heart Study. It will be the third examination cycle.

If you have changed your address or telephone number or for any other questions, please call the Coordinator, Paulina Drummond, at 508-935-3485 or 800-854-7582, ext. 485. We are also inviting those Omni participants who have had a brain MRI to also have a cardiac MRI. If you would like to participate in the cardiac MRI study, please contact Paulina Drummond at the number above or Marian Bellwood at 508-935-3429 or 800-451-0260. ♥

## KEEP IN TOUCH BY COMPLETING HEALTH HISTORY UPDATES

Participants are asked to complete a health history survey once every two years either by mail or by phone. In the survey we ask for information about your health since your last exam or health update. Lois Abel is in charge of collecting and recording the health history updates. Any new health information is reviewed by a panel of three physicians and becomes a valuable part of the database used for FHS research. Even if you have had no health problems, please complete and return the form when you receive it or call a participant coordinator (see contact phone numbers on Page 2) or Mary Anne Crossen at 508-935-3430. ♥

## CARDIAC MRI STUDY ALMOST COMPLETE

Over 1700 Offspring participants and 180 Omni participants have had heart scans at the Beth Israel-Deaconess Medical Center. Scheduling will resume in February 2006 for another 200 participants before the project, under the direction of Drs. Christopher O'Donnell and Warren Manning, is completed.

If needed, transportation may be provided. Please call Marian Bellwood at 508-935-3429 or 800-451-0260 for further information. ♥

## THE OFFSPRING "CALL-BACK" EXAM

After participants in the Offspring Study have attended Exam 8, they become eligible for the "call-back" exam. This two hour exam is held at the MetroWest Wellness Center on Route 9 westbound in Framingham, under the direction of Drs. Rhoda Au, Philip Wolf, Douglas Kiel and Marian Hannan. The exam includes an MRI of the brain, a test of cognitive skills, a bone scan to measure bone density for detecting osteoporosis, measurements of the foot, and a few related questionnaires. Barbara Inglese is the coordinator for the callback exam. She can be reached at 508 935-3451 or 800-601-3582 to schedule an appointment. ♥

## DAWBBER MEMORIAL SCHOLARSHIP

In memory of Dr. Thomas R. Dawber, Director of the Framingham Heart Study from 1949 to 1966, The Friends of the Framingham Heart Study plan to award a \$500 scholarship to a deserving high school senior upon graduation. The Friends are sponsoring a contest that is open to all children of Framingham Heart Study participants who will be graduating from high school in the spring of 2006 and going on to college. The prize will be awarded to that student whose essay of 1,000 words is judged the winner of the competition. The topic of the essay is "What It Means to be a Participant in Medical Research". Essays should be sent as a word document attached to an e-mail to Esta H. Shindler at [eshindle@bu.edu](mailto:eshindle@bu.edu) no later than March 31, 2006. Included in the e-mail message should be future college and career plans after graduation, as well as name, address, and phone number. ♥