



THE FRAMINGHAM HEARTBEAT



The Framingham Heart Study is a project of the National Heart, Lung, & Blood Institute & Boston University. Winter 2016

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GET READY *for* EXAM 3!

THIRD GEN, OMNI 2 & NEW OFFSPRING SPOUSE

The third Exam cycle will start in April of 2016. This exam is packed with new research protocols as well as standard FHS measurements such as blood pressure, height and weight. You will be hearing from Maureen and Paulina soon! Please read pages 2 & 3 for details about the new exam.

SCHEDULE YOUR APPOINTMENT!

The exam will be performed Monday-Friday starting at 7:30 a.m. You will be with us for about 4 hours. There will be some Saturday appointments available during the Exam 3 cycle.

Omni 2 Make Your Mark!

Omni 2 is the newest cohort to join our study! It began in 2003-2005 to add to the number of FHS original Omni participants, who were recruited in 1994 to represent the multicultural diversity in Framingham and surrounding areas.

As we welcome the era of electronic studies, Exam 3 will be somewhat similar to previous exams, but it also has new components. Please make an effort to come and make a difference! **Your participation will enable the Framingham Heart Study to continue making valuable medical discoveries and improve the health of people worldwide!** Call your Omni Coordinator, **Paulina Drummond (508) 935-3485**, to schedule your appointment.

Brain Aging, Stroke and Alzheimer's

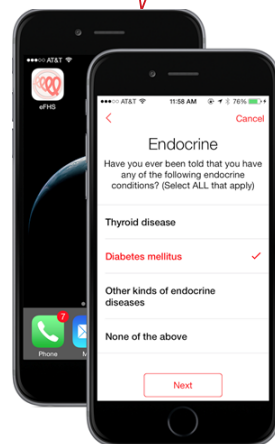


Over the past 60 years, FHS participants have helped us identify risk factors for stroke, new genes for stroke, Alzheimer's and Parkinson's diseases and how risk of these diseases has increased over time. These discoveries have been reported in leading medical journals. Many of these conditions are now known to start as subtle brain changes 20-30 years before the first symptom, and intervention at this preclinical stage may be our best bet for preventing disease. **During the upcoming exam cycle, information will be gathered to study preclinical changes. Third Gen, New Offspring Spouse and Omni 2 participants will be asked to complete brief cognitive tasks, some from previous exams and some new ones.** You also will be invited to undergo a brain MRI and to perform additional cognitive tasks at a conveniently scheduled call-back exam. Over 200 participants will be randomly selected and invited for a new type of brain imaging (PET scans for amyloid and tau). **To learn more, please call Linda Farese at (508) 935-3488.**

There's an App for That!

Thanks to the success of recently completed pilot studies, we are offering the eFHS program to the Third Gen, NOS, and Omni 2 attending Exam 3. Participants with an iPhone can download an app during their visit. The app will track their steps and include surveys for medical history updates every 3-6 months. Participants interested in tracking more health information may be offered an electronic blood pressure cuff and other devices.

Previously at FHS: In the summer of 2015 we ran a pilot study, in conjunction with the University of California, San Francisco, called the **Health-eHeart Study**. Two hundred participants with iPhones were asked to use an app that connected them to a Fitbit, an electronic weight scale, an electronic blood pressure cuff, and an electronic hand-held ECG. We are happy to report that we are still getting data from these dedicated participants. ...and in another pilot study called **BE FIT**, the FHS and the University of Pennsylvania teamed up in late 2015 to examine what motivates people to move. Participants were randomly placed on teams and asked to track their steps using either the Moves mobile phone app or a Fitbit. **Thank you to all who participated in these two pilot studies that prepared us for eFHS at Exam 3.**



FHS has a key source of evidence related to nutrition and healthy aging. More than 100 peer-reviewed FHS research papers have examined various aspects of diet and nutrition and a range of age-related health outcomes. We plan to continue to examine the role that diet of younger and middle aged adults has in maintaining health at older ages. **To that end, we plan to collect dietary information as part of the Framingham Nutrition Study from the Third Gen, NOS, and Omni 2 participants at Exam 3.**

Our future research plans incorporate these new dietary data to study:

- The role that protein intake in middle age may play in maintaining physical performance at older ages;
- Whether consuming healthy diets will help maintain healthy weight, lean body mass, and muscle strength;
- How dietary choline and omega-3 fatty acids may interact to help maintain cognitive health;
- The relationship between hydration based on intake of water and other beverages and fluids and measures of metabolic kidney and cognitive health.

Fibroscan

Fibroscan is a fast, painless, and completely non-invasive measurement of liver stiffness that will be included at Exam 3. Storing too much fat in the liver causes high liver stiffness, yet we do not fully understand why this happens to some people. We will try to answer this question by looking at the factors related to liver stiffness. Researchers also will test how liver fat affects other conditions such as heart disease, diabetes, and stroke.

EXAM 3

Osteoporosis

The Osteoporosis Study team will offer to Framingham participants a unique opportunity to take a “fantastic voyage” into the small recesses of the skeleton that are so essential to your health and mobility. During the upcoming visit, brand new equipment will be used to measure the microstructure of your bones. The scanner will be able to determine if your body weight contributes to the strength of your skeleton. It has been said that being a little heavy might be good for the skeleton, but this is controversial. The Framingham Osteoporosis Study team will investigate whether abdominal fat could have negative effects on the skeleton and the muscular system. The bone team will perform the traditional bone density “DXA” test. We will also use a new scanner to get a 3D view of any alterations in your bones at a finer level.

Lab Components

FHS plans to collect various types of bio-specimen while participants are at Exam 3, or shortly after the visit by mail. Some samples will be analyzed right away and other samples will be preserved for future research. Blood will be separated in components and stored in tiny volumes for different projects, such as platelets, red and white cells and plasma. Urine, nasal brushings, and stool samples now can be analyzed in many ways. These laboratory measurements will add a wealth of new information to the FHS data repository. Perhaps no other study anywhere has so many types of standardized measurements, medical histories, digitized images and genetic sequencing on so many related research participants. **This priceless resource is all thanks to you.**

Traumatic Brain Injury

There are approximately 1.7 million new cases of traumatic brain injury (TBI) admitted to emergency departments in the United States annually, the majority of which are mild. This number, however, is likely an underestimation. Due to transient symptoms, many people with mild traumatic brain injury may minimize or neglect symptoms. Recent reports suggest that a history of TBI may increase a person's risk for developing late-life cognitive decline or neurodegenerative disease but most of this research has been done on athletes or on military personnel. Very little is known about the long-term effects in a general population. FHS is including a new study of TBI as part of Exam 3 to determine the relationship between a history of TBI and later-life clinical consequences, with the ultimate goal of enhancing preventative measures and clinical care associated with head injuries.

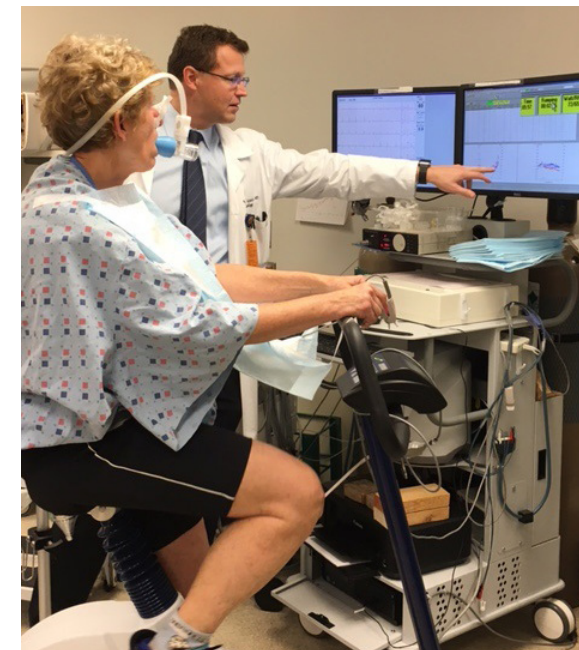
Remember:

Framingham Heart Study evaluations are designed for research. They do not replace your regular check-ups with your own doctor(s)!

How Fit Is Framingham?

Exam 3 will include a Cardiopulmonary Fitness Evaluation. We aim to learn more about how your body responds to exercise. Careful metabolic measurements taken during and immediately after gradual incremental exercise will complement information about your cardiovascular system previously collected in the resting state only. The Framingham Heart Study team now has an exercise room which contains special equipment to measure every breath you take. We look forward to studying the body's response to exercise, and how it relates to the structure and function of the heart, family traits, risk factors, and future cardiovascular health. **Bring your sneakers and get ready to ride!**

Emily Manders (right) performs a practice ride. “Nice workout!” she exclaims. “No need for the gym today!”



Motion Detectors

As you know, exercise is a part of healthy living. Once again Third Gen, New Offspring Spouse and Omni 2 participants are being asked to wear an “Actical” physical activity monitor after their FHS exam. The monitor is as small as a wrist watch and is worn on a belt. As you move, it records your activity. After 8 days, you mail it back to FHS in a prepaid envelope. The little monitors are quite costly, but FHS uses them again and again after the recorded information is transferred to an FHS computer. We already have downloaded over 4800 recordings from Third Gen, New Offspring Spouse, and Omni 1 and 2 participants.

(If the week following your clinic exam is not the best time for you to wear the monitor, simply ask for it to be sent to you at a date that is more convenient.) **Your physical activity recording will become part of many FHS research projects in the years to come.**

Platelets

Platelets are a critical blood cell type with roles in bleeding and wound healing, as well as playing roles in cardiovascular disease risk. In the next exam we will use your blood to conduct comprehensive studies of your platelets. This unique research will advance our understanding of variation in platelet “stickiness” and what the key genes, metabolites and risk factors are that influence how platelets react and contribute to disease risk. We hope this work will ultimately identify new targets for better anti-platelet treatments for cardiovascular disease prevention.

STATE *of the* STUDY

Dear Participants of the FHS,

I am pleased to share with you that the year 2015 saw continued growth, productivity and positive transitions within the Framingham Heart Study (FHS).

In 2015 we saw the completion of the previous contract to Boston University from the National Heart, Lung and Blood Institute (NHLBI), and the commencement of the new 5-year contract. We are now ready to launch the third examination cycle of the Third Generation, NOS, and Omni 2 cohorts, and to continue to survey all three generations and the Omni cohorts of FHS. Data sets and specimen collected under the previous contract were distributed per the contract specifications. We continue to send new FHS data sets to the NHLBI to be shared for approved research projects. Genetic, biomarker and epidemiological research activities have increased exponentially. About 180 FHS scientific papers were published in this 12-month period, most in high impact journals.

Specific Highlights.

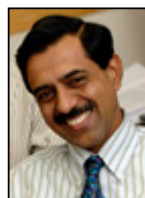
- **Planning of Gen 3/New Offspring Spouse/Omni 2 Exam 3** and integration of grant-funded ancillary studies with the core contract-supported examination, to begin in the spring of 2016.
- Designing and piloting tools to transition into paperless FHS records with electronic data capture.
- A **workshop for young investigators** was held at Boston University's Medical Campus in July 2015 to promote the awareness, value and research uses of FHS data. Additionally, we are **focusing on development of early stage investigators (ESI)** with the formation of an FHS ESI committee with 15 young investigators as members. We encourage them to move into leadership roles at FHS. Furthermore, plans are underway for a **new training program for FHS post-doctoral research fellows** at BU.
- Drafting of a **proposal to establish an imaging core at FHS** that could distribute imaging data.
- Continuing cooperation with the **American Heart Association program** to promote use of FHS data and specimen for approved research projects.

All of these FHS achievements and more rest on the extraordinary contributions of you the participants. We hope we can count on your continued involvement in the Framingham Heart Study in the coming years.

Sincerely yours,



Vasanth S. Ramachandran, M.D., DM, FACC
Principal Investigator, The Framingham Heart Study
Professor of Medicine, Boston University School of Medicine



Dawber Memorial Scholarship



Front: Hannah Steinhoff, 2015 Winner
Back: Gillian Goolkasian, 2015 Runner-up
Also pictured is John Galvani, Dr. Dan Levy and Peter Allen.

Last year, the **Friends of the Framingham Heart Study** awarded scholarships to two high school seniors planning to attend college. Once again, Friends President John Galvani and the board members are pleased to announce the essay contest for two scholarships for 2016 based on an essay contest: a \$1,000 scholarship and a \$500 scholarship.

Eligibility: Open to children, step-children, and grandchildren of FHS participants. Applicants must be graduating from high school this year and planning to attend college in the fall of 2016.

To apply, only two items are needed: an email with the applicant's name, address, telephone number, and college and career plans (roughly a two-sentence description); and a 1,000-word essay titled "How does FHS help improve public health?" Applicants are welcome to tell a story, conduct an interview, or pursue any angle of interest. Please fact-check and proofread before submitting. **Please email the essay as an attachment to Emily Manders (emanders@bu.edu) by Monday, April 4, 2016.** We'll confirm receipt of all essays within one business day. If you don't receive a confirmation, please call (508) 935-3443. The Friends will review the essays and notify recipients by May 10, 2016. Recipients will be invited to accept their awards at the FHS research center.



A Message from the Friends of the Framingham Heart Study

Greetings, fellow participants. We are volunteers from the FHS Second Generation, Third Generation, and Omni cohorts who meet periodically throughout the year as members of the Board of Trustees for the Friends of the Framingham Heart Study. With funds donated to the Friends, we provide support for items and activities at FHS, such as occasional travel grants to FHS investigators attending scientific conferences, audio-visual equipment for long-distance conferencing with collaborators, annual scholarships to high-school graduates going to college, and the ECG cards sent to participants after clinic visits. With your help, we'll be able to do more to support FHS in its ground-breaking research for improving public health related to heart disease, diabetes, cancer, sleep disorders, aging, and Alzheimer's disease.

The Friends of the FHS is a 501(c) (3) nonprofit organization supported solely by donations. We invite you to contribute a personal donation or one in the memory of, or in honor of a family member or friend. No donation is too small or too large and all are tax deductible.

To make a donation:
please mail a check made out to:
"Friends of the FHS." Address it to:

Lynda Norton
ATTN: Friends of the FHS
73 Mt. Wayte Ave., Suite 2
Framingham, MA 01702

If you experienced a recent stroke

or received medical care for stroke symptoms, we at FHS would like to know. You can call us either soon after your urgent care has taken place or at anytime thereafter. We can be reached at (617) 630-3627. We would like to talk to you and set up an appointment when it is safe and convenient for you. **This is a research evaluation only and is not meant to provide any medical care or advice. We greatly appreciate your efforts to help us understand healthy brain aging as well as debilitating conditions, like stroke and Alzheimer's disease.**

FHS has an ongoing brain donation program.

The best way for us to learn about brain health is to examine the brain itself. This program permits innovative research, gives a gift of hope to future generations, and provides families with definitive diagnoses if their loved ones suffer from a neurological illness. **To be part of this research, please contact Linda Farese at (508) 935-3488.**

THE SCIENCE DESK

Genome

Whole genome sequencing of approximately 4100 FHS participants is expected to be completed early in 2016. FHS investigators are leaders in several nationwide working groups of genetic researchers. The WGS project is part of NHLBI's TOPMed program and serves as an initial step for the larger initiative. The elements of this project stem from recommendations noted in the WGS Working Group Report. This project will obtain WGS data for individuals who have well-defined clinical phenotypes and outcomes from earlier NHLBI-funded studies.

Read more about the NHLBI WGS TOPMed program at <http://www.nhlbi.nih.gov/research/resources/nhlbi-precision-medicine-initiative/topmed>.



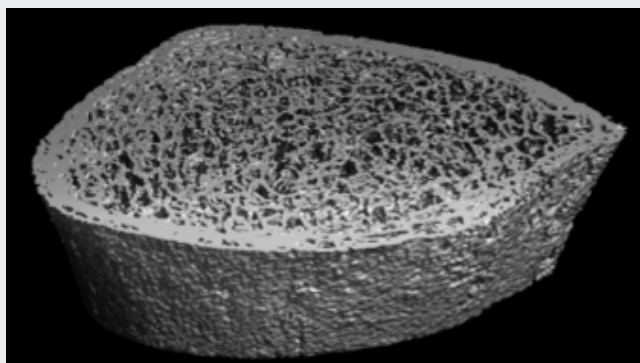
Research

Every month recent articles based on FHS data are added to the FHS bibliography on the web. You can get a sense of the important research results based on your contributions to FHS just by reading the titles or some parts of these articles. Some articles are written by FHS authors and their colleagues; others are written by researchers from other institutions who applied to use the FHS data and samples.

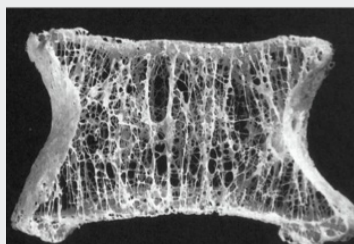
Go to <http://www.framinghamheartstudy.org/fhs-bibliography/index.php>.
Click on any year to see what was published.

Bone

Osteoporosis is a silent disease that can result in fractures and loss of independence. Yet less than **25%** of the U.S. population over 65 years of age has their bone density tested for osteoporosis.



The 3D architecture of a forearm bone showing the inner honeycomb part and the outer layer of compact bone. With this type of scan you can see the small holes in the outer layer that may contribute to weakening the strength of the bone.



Osteoporotic bone

Sleep

The Sleep Study for the Second Generation (Offspring) and Omni 1 is the first FHS project to use new wearable devices to gather sleep measures easily at home. The Sleep Study is now in its second year and already nearly 800 Second Gen/Omni 1 have participated. The study is being conducted entirely by mail. Participants are asked to wear a small device that includes a fingertip sensor attached to the wrist to measure oxygen in the blood and another device on the chest to collect electrocardiogram data. Sleep is found to be increasingly important for both heart and brain health. Gen 2/Omni 1 participants will be receiving calls about participation, or **you may call (508) 935-3473 to enroll**.

Nutrition

Over the next 30 years the number of Americans aged 65 and older and aged 80 years and older are expected to increase by 36 million and 10 million, respectively. The financial and social costs associated with this increase will present major challenges for both the government and individual families. It is vital to identify interventions that can decrease the prevalence of age-related disease and accompanying disability. Many age-related conditions that result in disability and premature death, such as weight gain, inflammation, insulin resistance and type 2 diabetes, cardiovascular disease, cancer, vision and musculoskeletal disorders, and cognitive decline have strong nutritional components. However, the development of nutritional recommendations and public health interventions requires a greater understanding of the role that nutrition plays in healthy aging. (Read how the FHS Nutrition Study plans to address these problems in Exam 3 on page 2 of this newsletter.)

Stem Cell

When participants of the Third Gen, Omni 2 and New Offspring Spouse attend Exam 3, a portion of the blood they donate, with their permission, can be stored for future stem cell research. A small sample of white blood cells will be separated from other blood components. This sample will be sent by daily courier to the FHS genetics research laboratory at Boston University, where the cells will be carefully processed and frozen in a way that preserves their ability to function. In fact, these **induced Pluripotent Stem cells (iPSc)** can be treated to behave just like cells from other parts of the body, like heart or liver cells, for example.

How Is New Research Approved For Launching At FHS?

New research ideas come to investigators as they study published articles in their field of interest. Often the reports contain the next questions and hints for moving science to the next level of understanding. Investigators may write proposals and apply to do further research using FHS data, specimen and even to contact FHS participants to gather new information in new ways. The proposals go through many formal reviews to see that the science is novel and well grounded, the procedures are safe, that data and specimen are available, and that the costs of conducting the research will be covered. Here are the names of committees and boards that may review new FHS research proposals:

The FHS Executive Committee is made up of senior FHS physicians and statisticians from BU and NHLBI. They are the first to review major FHS proposals. **The FHS Ethics Advisory Board** provides guidance and the perspective of FHS participants, local physicians, attorneys, clergy and professional genetic counselors and IRB physicians to the executive committee. **The FHS DNA**

The many research uses of the iPSc will be described in the new consent form. **Please read the consent form, ask questions, and consider giving FHS permission to use this new research tool.** (The FHS Second Generation and Omni 1 participants were offered the opportunity to donate blood for iPSc research at their most recent FHS examination. Through their generosity and overwhelmingly positive response, we now have a wonderful start for iPSc research. We hope to expand this repository with donations from you.)

and Laboratory Committees, with membership from inside and outside FHS, has the mission to conserve and distribute precious FHS stored samples appropriately for good use. **The Institutional Review Boards of Boston University and of other institutions** look to protect the welfare of study participants and the proper conduct of research. **The review boards of the supporting funding agencies** score new proposals for scientific value and then select the most valuable projects to be awarded new grants and contracts. **The NHLBI Observational Studies Monitoring Board** reviews the new proposals and oversees the ongoing conduct of studies to make sure the participants are protected and the science is worthwhile.

Thanks to the input of all these serious reviewers, the quality of FHS research has been held to very high standards. **Therefore, the contributions of the FHS participants have had important impact over the decades and will have added value in the future.**

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

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Medical History Update

It's Important!

One of your most important contributions to the Framingham Heart Study is your medical history information. The facts you provide help us find patterns in the population that show how disease develops over time. Your regular visits and medical history updates make our understanding of disease more accurate and focused. Even if you feel well or your health has not changed in several years, please send us these updates to help us document your health status. If you receive a Medical History Update form in the mail, a password is enclosed allowing you to complete the form online. You also have the option of returning the form by mail or completing it on the telephone with one of our staff. Please call Lois Abel (508) 935-3428 if you have any questions about the form or would like to complete it on the phone. We greatly appreciate your efforts to keep our records current.

CONTACT US

Receptionist

(508) 872-6562 or (800) 854-7582

Brain Donation, Brain MRI, Cognitive Testing, Stroke Coordinator

Linda Farese

(508) 935-3488, (800) 248-0409 or lfarese@bu.edu

Original, Second Generation (Offspring), Third Gen, New Offspring Spouse Coordinator

Maureen Valentino

(508) 935-3417, (800) 536-4143
or maureenv@bu.edu

Omni Coordinator

Paulina Drummond

(508) 935-3485, (888) 689-1682, or pautras@bu.edu

Planning a trip to Framingham from out of town?

Please call Maureen (800) 536-4143 or Paulina (888) 689-1682 to schedule!