

Integrating approaches to Privacy across the Research Lifestyle

Fall 2013 Workshop

Tracking Consent Options at the
Framingham Study

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Other Sources Of FHS Data

(Each with policies, applications, reviews and agreements)

For GWAS, Other 'Omics Data and Phenotypes

dbGaP SHARe (National Library of Medicine,
National Center for Biotechnology Information)

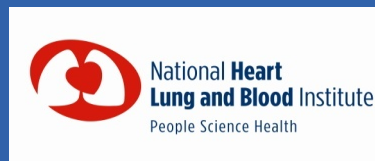
Secondary Source For Phenotypic Data Only

NHLBI Data Repository



The Framingham Heart Study Design Overview

- Population-based observational study
- **Prospective longitudinal design**
- Clinic and off-site exams
- 2 to 6 year exam cycles plus surveillance
- Repeated and novel measures
- Six cohorts



First FHS Consent Form - 1971

DECK C3 FRAMINGHAM OFFSPRING STUDY EXAM1 RECORD NUMBER _____

CONSENT FOR INTERVIEW AND EXAMINATION

I have been fully informed of the nature of this study which includes a medical history, physical examination, blood tests and electrocardiogram and give my consent to be examined. I also authorize the Framingham Study staff to secure pertinent medical information from my family, physicians, and/or hospital records for the purposes of this study.

Name _____ Date _____

NIH – 1635-3 9-71 OMB 66-R1236 Expires Dec. 31, 1974



Link to FHS Consent Forms Offspring Exam 8 and Others

www.framinghamheartstudy.org/research

[www.framinghamheartstudy.org/research/pdfs/consent/
offspring_exam8_consent.pdf](http://www.framinghamheartstudy.org/research/pdfs/consent/offspring_exam8_consent.pdf)



FHS Consent Forms Coded

Documented Consents From 1971 Through 2009

COHORT	FREQUENCY
Original Cohort	30,209
Offspring	32,877
New Offspring Spouse	124
Generation 3	6,240
Omni Group 1	1,224
Omni Group 2	415
Total	71,089



How Did FHS Offspring Respond at Exam 8?

Check Boxes (2005-2008)	Option	Frequency (Percent)
I agree to participate in the Framingham Heart Study examinations described above to study the frequency of and factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, and other diseases and health conditions.	Yes	2980 (100)
	No	0 (0)



FHS Offspring Responses at Exam 8?



Consent Check Boxes (2005-2008)	Option	Frequency (Percent)
I agree to provide a blood sample from which DNA and other components can be extracted. The DNA will be made available to researchers studying the diseases listed above.	Yes	2891 (99.9)
	No	3 (0.1)
If a cell line has not already been collected, I agree to allow a cell line to be made from a sample of my blood to provide a renewable supply of DNA. (A cell line is a frozen sample of specially processed white cells from your blood that allows us to grow more white cells and get more DNA from them in the future as needed for research projects).	Yes	2969 (99.7)
	No	10 (0.3)
I agree to participate in the genetic studies of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, and memory loss.	Yes	2978 (99.9)
	No	2 (0.1)
I agree to participate in genetic studies of other diseases and health conditions including but not limited to joint disease, bone loss, and cancer.	Yes	2974 (99.8)
	No	5 (0.2)
I agree to participate in genetic studies of reproductive conditions and mental health conditions such as alcohol use and depressive symptoms.	Yes	2970 (99.7)
	No	10 (0.3)

FHS Offspring Responses at Exam 8?



Consent Check Boxes (2005-2008)	Option	Frequency (Percent)
<p>I agree to allow researchers from private companies to have access to my DNA and genetic data which may be used to develop diagnostic lab tests or pharmaceutical therapies that could benefit many people. (Note: You or your heirs will not benefit financially from this, nor will your DNA be sold to anyone.)</p>	Yes	2739 (91.9)
	No	240 (8.1)
<p>If a genetic condition is identified that may have potentially important health and treatment implications for me, I agree to allow the Framingham Heart Study to notify me and with my permission to notify my physician.</p>	Yes	2964 (99.5)
	No	16 (0.5)

HOW ARE DATA AND SPECIMEN ACCESSED AT FHS?

- For Purposes of Research
- Proposal specific
- Web Application www.framinghamheartstudy.org
- Review by FHS Committees
- Review by Outside Monitoring Boards
- Third Party Review by NHLBI
- Data and Materials Distribution Agreement (DMDA)
- Individual Exclusions by Consent Option History

