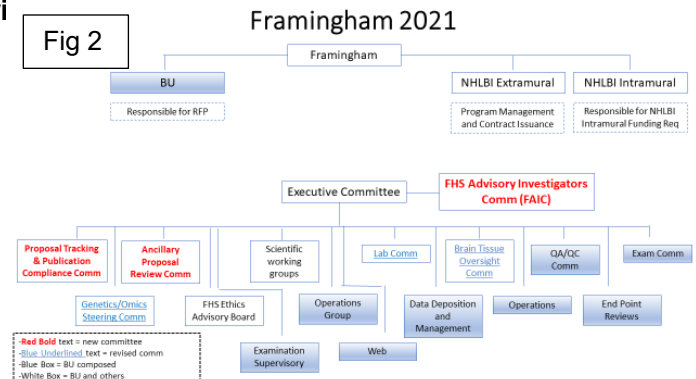
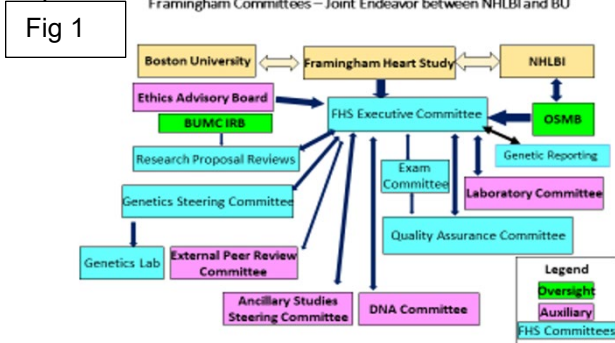


Proposed Changes to the Framingham Heart Study Committee Structure

In 2023, the Framingham Heart Study (FHS) will mark 75 years since its inception. As a groundbreaking long term cardiovascular cohort study of Framingham, Massachusetts, it has pioneered investigating the effects of diet, exercise, cigarette smoking, hypertension, cholesterol, genetic research, and the formulation of risk scores for cardiovascular disease. Since the study's advent, additional disease measures, events, and domains have been added along with four new cohorts. Technological changes have introduced a multitude of omics into the study, providing “deep phenotyping” in all five cohorts. The changes in the study's size, new technologies, domains, and interest from non-cardiovascular researchers have enhanced the research breadth and domains of interest of FHS. The evolution from a contract only study to a contract and grant-based study has also led to an increase in the number of research proposals required for the study to review and approve. As the current committee structure was born of a previous era and has shown some operational strain in adapting to demands placed on it, a new FHS 2021 Committee Structure is proposed to alleviate pressure points on the current structure especially on the Executive Committee (EC), creating new committees to adapt to increased ancillary study grant proposals (e.g., Ancillary Proposal Review Committee), to facilitate greater representation of mission-critical domain expertise, women, under-represented groups, and mid-career and early stage investigators (ESI, broadly defined across the academic continuum), and to combine committees where biological sample demands or convergent interests align (e.g., Genetics/Omics Committee). The new committee structure also introduces term limits, thereby expanding opportunities for participation in FHS activities to a larger pool of investigators.

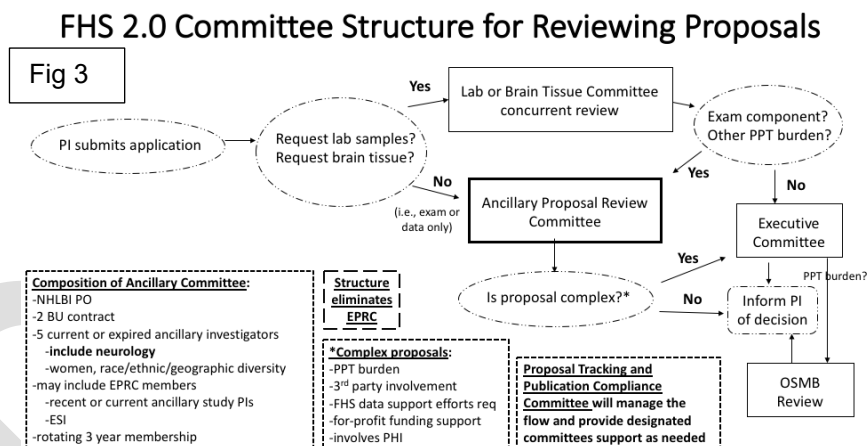
Investigators employed by the NHLBI and by Boston University (BU) have worked cooperatively to achieve the study's research goals. Currently, this joint endeavor is exemplified in the Committee and Management Structure (**Figure 1 (lower left)** and **Table 1 (end of the document)**). For all FHS committees, meeting agendas are currently distributed at least three days prior to each meeting, and minutes distributed within two weeks following each meeting. Under the new scheme, we propose changing these timelines to 7 days prior (allowing more time for new ancillary study grant applications to be reviewed) and within one week (including generating and distributing final study approval letters), respectively. To increase transparency and documentation, a non-voting secretary will continue to attend all meetings that include non-BU employees. To reduce the exceptional review burden of ancillary proposals borne by EC resulting from the study's shift from contract support to providing a platform for independently-funded ancillary studies, some changes to the FHS committee structure are proposed. Two new committees, i.e., FHS Advisory Investigators Committee (FAIC) and Ancillary Proposal Review Committee (APRC), will be formed, while some other existing committees will be combined (see details below). The proposed changes are shown in **Figure 2 (lower right)**.



In reviewing the current FHS committee structure, it was noted that normative rules for membership in FHS committees were lacking, and thus, new committee rules are also being introduced. To bring in new ideas, expertise, and potential optimization of work processes, it is proposed that staggered three-year terms, with the potential for a single renewal (for mission critical purposes with approval of PO) will be required for members of

the EC, FAIC, APRC, and all other external committees. Members should also have specific expertise for their assigned committee roles. The nominating process for committee membership will be competency-based. To encourage engagement and build leadership skills, rotation from internal and external (see definitions below) committees to EC, FAIC, and APRC will be promoted. The inclusion of women, members of populations under-represented in biomedical research, and early career investigators should be strongly considered and will be reported to the NHLBI Program and Contract Offices. Participation of Non-BU, non-FHS investigators in committees will be further expanded, with specific composition for some committees, while others, such as current Scientific Working Groups, demonstrate such commitments. Geographic diversity of membership (inclusive of all regions of the US and with consideration of international membership) is also encouraged, and it is hoped that this effort to broaden membership will also expand the pool of users of FHS data and potential ancillary study PIs. Furthermore, this new FHS committee structures shall be reviewed after approximate one-year of implementation and periodically afterwards, as well as by NHLBI prior to a contract renewal, for both performance and the ability to meet current and future FHS needs.

The proposal review process will be modified to decrease EC workload and open up the review of ancillary study proposals to the broader FHS community. A proposed flow-chart demonstrating the changes is rendered in **Figure 3 (below)**. A consequence of a revised ancillary proposal review process is the elimination of the External Peer Review Committee, which was formed several years ago to review ancillary proposals that would not eventually be peer-reviewed (e.g., industry or foundation sponsored) or those where EC members were conflicted.



FHS Committee and Management Structure

1) FHS Executive Committee: The EC is the central committee of the FHS with regard to setting study policy, strategic direction and program vision. It is ultimately responsible for study design, protocols, reports, materials, data, and safety of participants and staff at the FHS and assuring its ancillary studies consistent with the statement of work and contract with the NHLBI. The committee will determine policies and protocols to support the fair and balanced review of research proposals, including determining which research proposals will be reviewed by which sub-committee(s) (e.g., Ancillary and Lab). The EC will consist of ten members:

- Four members from BU (not necessarily supported by the contract), including the BU contract Principal Investigator (PI) or a co-PI
- Four non-BU members selected from the current or recently expired ancillary study PIs and/ or non-BU members who represent a scientific domain of increased interest appointed as needed by NHLBI
- One member from the NHLBI intramural program at Framingham, and

- d. The NHLBI/Bethesda Project Officer.
- e. There will be two co-chairs who will alternate leadership of the meetings. These co-chairs will be the BU PI or Co-PI, as well as a non-BU member of the EC agreed upon by BU and NHLBI. The EC shall meet twice each month for up to two hours each time. Composition of the EC shall include separately at least one cardiologist, one epidemiologist, one geneticist/omics expert or data scientist, a neurologist, and at least one member shall be an early career investigator. To provide continuity in expertise and knowledge of FHS, staggered three-year terms will be implemented. No more than one, three-year extension for each committee member will be allowed. All committee members will be required to recuse themselves when matters pertaining to have perceived financial or scientific conflict of interest are discussed by the EC. Additions and changes to the EC will require approval by the NHLBI and the Dean of Boston University School of Medicine.

2) (NEW) FHS Advisory Investigators Committee (FAIC): The Framingham Advisory Investigators Committee (FAIC, pronounced “face”) is a collection of investigators who provide recommendations to make the study more effective, with a key charge in identifying specific gaps and opportunities in the effective use of existing data, the collection of future data and types, identification of missing critical domains of heart, lung, blood, and sleep research, as well as novel disease domains, and recommendations for outreach and meeting the needs of outside (i.e., non-BU, non-NHLBI) investigators for the use of existing data and/or submission of future research proposals. The committee can also provide other recommendations that it believes would make the study more effective. This committee and charge are distinct from the OSMB. To aid it in its work, the EC will provide timely answers to FAIC requests for information in addition to regular reports on exam progress, ancillary study proposal review (related approvals and disapprovals), data sharing, training, out-reach to the wider scientific community about opportunities to conduct research with FHS, and other topics as identified by the FAIC. Recommendations from FAIC will be sent to the FHS EC as well as to the NHLBI. The EC or NHLBI can also ask the FAIC for timely recommendations on other topics as needed. FAIC can survey the greater scientific community to aid in their efforts. There will be six committee members: two current investigators funded under an ancillary proposal (non-BU), two independent scientists not funded by the contract or an FHS ancillary proposal, a BU contract-funded scientist, and the NHLBI Program Official. The FAIC will meet at least quarterly and report directly to the NHLBI Program Official. NHLBI will select the chairperson; the chairperson shall not be from BU. Members with expertise from multiple scientific domains are encouraged and should reflect research based on current and proposed grant applications received by FHS. In order to provide continuity between this committee and the ongoing independent FHS Ancillary Studies Investigators Committee (FASIC), it is proposed that the FASIC co-chairs Drs. Susan Cheng and Jane Freedman be asked to provide some of the initial members to the new FAIC.

3) Standing FHS Internal Committees: The membership of sub-committees is drawn from the EC and includes other BU and NHLBI staff and active non-BU ancillary studies (thus the “internal” designation). The sub-committees will make recommendations and report to the FHS EC. The sub-committees will have their mission and function specified according to policies established by the FHS EC. Occasionally, the EC will form additional sub-committees. The goals of the internal study sub-committees are listed here.

1. **FHS Examination Committee:** The Examination Committee designs the FHS Research Center examination and reviews ancillary proposals for inclusion of components in the main examination and call-back exams, especially concerning participant burden and timing of the examination. The committee oversees the examinations' progress, monitors the participants' experiences during exams, and assesses the quality of data and sample collection. It will meet at least two or more times per year and reports to the EC.
2. **FHS Quality Assurance and Quality Control Committee:** The quality assurance/control committee establishes, reviews, and conducts procedures for monitoring the quality of data and sample collection, processing, and distribution. The committee works in conjunction with ancillary studies and the Framingham Examination Committee to oversee the clinic, clinic laboratory, and genetics laboratory to maintain and report data quality throughout the programs. Full committee meetings are held three times

per year and reports to the EC and NHLBI Program Officer.

3. **(NEW) FHS Proposal Tracking and Publication Compliance Committee:** The FHS Proposal Tracking and Publication Compliance Committee will examine and track proposals for research projects for compliance with return of ancillary study data to the parent study. Specifically, the committee tracks and routes submitted applications, provides oversight to research proposals and publications, and monitors all ancillary studies for progress and compliance with the ancillary study policies. The submission process and the criteria for review and acceptance of ancillary studies will be clearly stated on the FHS website, and this committee will have the responsibility for additionally posting (as appropriate and feasible) abbreviated meeting minutes. The committee meets virtually on an ongoing basis, with decisions performed and discussed by e-mail. This is a reconstituted committee that had lapsed and has had its duties devolved to administrative and scientific staff. Reconstitution formalizes the functions allows for designation of duties, recording, and publication of minutes. This committee reports to the EC and has four positions: Genetics Data Manager, Non-Genetics Data Manager, Statistician and Scientist.
 4. **(Revised) FHS Genetics/Omics Steering Committee (FGOSC):** The FGOSC provides guidance for the activities of the FHS genetics laboratory and reviews its projects for scientific merit, feasibility, and quality. This committee coordinates FHS genetic and omics projects and policies, determines gaps and opportunities, and policies (e.g., return of results questions from the EC). This committee combines the former FHS Genetics and Return of Results Committees. It will meet monthly and include PIs from grants, including FHS-affiliated scientists in FHS Consortia such as TOPMed and CHARGE. This committee reports to the EC.
 5. **FHS – Other Committees:** Other FHS committees include the Web Committee, the Clinic Supervisory Committee, Genetics and Data Management Committees, Operations Committee, End Point Review Committee. The EC shall constitute other committees and subcommittees as needed.
- 4) External FHS Committees:** These committees are established to help review proposals for the distribution of FHS phenotypic and genetic data and biological material or to advise the FHS EC in policy areas and are composed of both BU and NHLBI members as well investigators from outside (thus the “external” designation). The chairs of these committees are independent of the FHS. The memberships of the committees are drawn from FHS and non-FHS investigators.
1. **FHS Ethics Advisory Board:** The FHS Ethics Advisory Board (EAB) comprises about ten FHS participants, community leaders, and experts in medical ethics, law, medicine, genetic counseling, and religion. The Board meets quarterly in-person in an FHS conference room (or remotely, via the Zoom web platform) for about 1.5 hours to consider questions posed by the FHS EC, often regarding new research areas. The members advise the FHS EC from the perspectives of ethics, law, and participant sensibilities and impact prevailing medical practice. To provide continuity in expertise and knowledge of FHS, staggered three-year terms may be approved by the NHLBI PO. No more than one, three-year extension for each board member may be approved by the NHLBI PO.
 2. **(REVISED) Laboratory Committee:** The FHS Laboratory Committee reviews proposals for the use of FHS DNA/RNA/other Omics and laboratory samples and tracks their distribution. It consists of eight members selected by NHLBI (comprising of at least one geneticist and an additional lab scientist who conducts medical laboratory analytics at scale) and six who are not from BU and two FHS investigators selected by BU. The committee's chairperson is an external researcher (i.e., not from BU) selected jointly by BU, NHLBI, and NIA. The NHLBI Project Office will attend the review meetings as a non-voting observer. The committee will meet as needed to respond in a timely fashion, balancing scientific priority with sample availability. *This committee combines the former FHS DNA and Laboratory Review Committees.* The committee will meet six times a year, with meeting dates aligned with NIH grant-submission dates. The committee reports to the EC.
 3. **(REVISED) FHS Brain Tissue Repository Oversight Committee (BTROC):** The FHS BTROC reviews proposals for the use of brain tissue laboratory samples and tracks their distribution. It consists

of six members selected by NHLBI representing stakeholders from BU, NHLBI, FHS EC, and NIA. The chairperson of the committee is an external researcher (i.e., not from BU) selected jointly by BU, NHLBI, and NIA. The NHLBI Project Office and NIA Program Official will attend the review meetings as non-voting observers. The committee will meet at least quarterly to respond in a timely fashion, balancing scientific priority with sample availability, the suitability of the region requested, and the amount of tissue requested. The committee reports to the EC.

4. **(NEW) FHS Ancillary Proposal Review Committee (APRC):** The FHS Ancillary Proposal Review Committee will review research proposals to be conducted in concert with the core examinations and will also review other research proposals as determined by the EC. The committee shall consist of eight voting members: two BU, one NHLBI (PO), and five members from current or recent ancillary studies, including one or more early-stage investigators. Expertise should include scientific domains currently or recently proposed as applications to FHS (e.g., neurology in 2020). The chairperson will be selected jointly by BU and the NHLBI; the chairperson shall not be from BU. The committee shall review applications, balancing scientific priority with feasibility and burden. It will meet at least monthly (less or more depending on the load of applications). Reviews will be sent forward to the EC, which will review non-scientific issues such as sample availability, material, exam availability, and participant burden. A statistician on the committee will provide statistical guidance for statistical power calculations if requested by ancillary proposal review committees (i.e., ancillary or complex proposals for new cycle of Framingham exams).

5) Oversight Committees: The FHS EC reports to several boards and offices according to each charge and schedule.

1. Boston University

- a. **Institutional Review Board** of the Boston University Medical Center oversees all human subjects relations and matters in the FHS protocols
- b. **Office of Research Administration** at Boston University oversees the administration of the contract and subcontracts to Boston University FHS investigators.

2. National. Heart, Lung, and Blood Institute

- a. **Division of Cardiovascular Sciences (DCVS):** The DCVS oversees the conduct of the FHS contract to Boston University, which is based on a response to the RFP from the NHLBI.
- b. **Office of Acquisitions (OA) within the Office of Management:** The OA oversees contractual aspects of the FHS contract.
- c. **The Framingham Heart Study Observational Studies Monitoring Board:** The NHLBI appoints the FHS OSMB, meets annually, and acts as an independent advisory group to the NHLBI Director. It is responsible for safeguarding the interests of study participants, assessing the safety and efficacy of study procedures, and monitoring the study's overall conduct. The FHS OSMB reviews the protocols and conduct of the FHS concerning the protection of participants and to the scientific merit of proposed endeavors. The committee meets on an annual basis.
- d. **DHHS Office for Human Research Protection (OHRP):** The OHRP guides the protection of the rights, welfare, and wellbeing of persons involved in research conducted by the DHHS.

Table 1		FHS Senior Committees			
Committee	Convened by	Composition	Meeting Frequency	Reports to	Mission/Deliverables
Executive	NHLBI Project Office	Combined (Internal/ External)	Bi-weekly	NHLBI Project Office	The Executive Committee is responsible for making major decisions regarding operational and policy matters of the study. Assurance of high quality of conduct of safety, burden, and science; review proposals for grants and new participant contact/ Minutes and Annual Report
FHS Advisory Investigators Committee (FAIC)	NHLBI Project Office	Combined (Internal/ External)	At least quarterly	NHLBI Project Office	Makes recommendations and/or provide key information and materials to the FHS Executive Committee. Plays a significant outreach role, providing the EC with a fresh perspective on programmatic issues and feedback from the external scientific community.
FHS Internal Subcommittees					
Examination	Executive committee	Internal	Bi-weekly prior to new exam	Executive Committee, OSMB	Coordinate exam components for new exams/ Schedule of exam components
Proposal Tracking & Publication Compliance	Executive Committee	Internal	Virtual	Executive Committee	Coordinate publication status, ensure grant support inclusion, NHLBI review when needed, and provide statistical support/advice when needed
<i>Framingham Genetic Steering¹</i>	<i>Executive Committee</i>	<i>Internal</i>	<i>Bi-monthly</i>	<i>Executive Committee</i>	<i>Coordinate FHS genetic and policies / Minutes</i>
<i>Genetic Reporting¹</i>	<i>Executive Committee</i>	<i>Internal</i>	<i>As needed</i>	<i>Executive Committee</i>	<i>Return of Results Interpretation and Reporting / Minutes</i>
Framingham Genetics/Omics Steering	Executive committee	Combined (Internal/ External)	Monthly	Executive Committee	Coordinate FHS genetic and omics projects, Return of Results, and policies / Minutes
FHS Quality Assurance	Executive committee	Internal	Three to Four times per Year	Executive Committee	Review and monitor QC for core and ancillary studies/Quarterly reports and summary
Web	Executive Committee	Internal	Weekly, and by email	Executive	Plans, designs, maintains FHS web site with contracted web programmers/web postings.
Examination Supervisory	Executive committee	Internal	Monthly	Executive and QC committees	Standardize technique, coordinate safety training, refine exam procedures
End Point Reviews	Executive committee	Internal	Twice Weekly	Executive Committee	Reviews end points from Medical Records and Exams/End point codes
FHS Genetics/Omics Data Team	Team	Internal	Weekly and monthly	BU FHS leadership	Coordinates data posting with dbGaP and NHLBI Omics Data Depositories
Biostatistics/Data Management	FHS statisticians and data managers	Internal	Biweekly	BU FHS leadership	Coordinates production and quality assurance of FHS data sets; provides guidelines on statistical analyses
Operations Group	FHS Managers	Internal	Monthly	BU FHS leadership	Coordinates FHS activities across teams
External Ancillary Committees					
FHS Ethics Advisory Board	Executive Committee	Combined (Internal/ External)	Quarterly	Executive Committee	Reviews early plans for new areas of FHS research, consent, participants' conflicts of interest, alert proposals, protocol deviations

DNA Review²	NHLBI Project Office	Combined (Internal/ External)	NHLBI Project Office And Executive Committee	NHLBI Project Office And Executive Committee	Conservation and Use of Genetic Specimen/ Minutes, Inventory Updates
Laboratory Review²	NHLBI Project Office	Combined (Internal/ External)	NHLBI Project Office And Executive Committee	NHLBI Project Office And Executive Committee	Conservation and Use of Biospecimen/Minutes, Inventory Updates
Laboratory Review	NHLBI Project Office	Combined (Internal/ External)	Six times/ year	NHLBI Project Office and Executive Committee	Conservation and Use of Genetic and Biospecimens/ Minutes, Inventory Updates
Brain Tissue Committee³	NHLBI Project Office/NIA	Combined (Internal/ External)	Quarterly	NHLBI Project Office and Executive Committee	Conservation and Use of Biospecimen/Minutes, Inventory Updates
Scientific Working Groups	Executive Committee	Combined (Internal/ External)	Monthly	NHLBI Project Office and Executive Committee	Involved in analysis and publications in respective domains. Publications may be FHS, TOPMed, or part of Consortia such as CHARGE
External Peer Review	Executive Committee	Combined (Internal/ External)	Monthly (As Needed)	NHLBI Project Office and Executive Committee	Involved in reviewing proposals that will not be undergoing traditional peer review (e.g., foundations)
Ancillary Proposal Review	Executive Committee	Combined (Internal/ External)	At least monthly based on number of applications	NHLBI Project Office and Executive Committee	Reviews research proposals to be conducted in concert with the core examination, and other proposals that will not undergo peer review by NIH or another federal funding agency, as determined by the Executive Committee. Includes research proposals for data analysis only (no lab, DNA, participant or grant involvement)
Oversight Committees					
IRB	BU Medical Center	Internal	As Needed	BU, which will inform NHLBI	Oversees all human subjects relations and matters in the FHS protocols
Office of Research Administration	BU	Internal	As Needed	BU, which will inform NHLBI	Oversees the administration of the contract and subcontracts to Boston University FHS investigators.
OSMB	NHLBI Project Office	External	Annually	NHLBI Project Office	Review of participant safety and burden/Minutes
Office of Acquisitions	NHLBI Office of Management	External	As Needed	NHLBI Project Office and BU ORA	Oversees contractual aspects of the FHS contract
OHRP	DHHS	External	As Needed	OHRP and FHS	Provides guidance in the protection of the rights, welfare, and wellbeing of persons involved in research conducted by the DHHS

Table 1: Outline of the NHLBI proposed new FHS committee structure. Existing committees that will be phased out are highlighted in gray and new proposed committees are highlighted in yellow.

Footnotes: 1) Framingham Genetic Steering and Genetic Reporting Committees have been folded into the Framingham Genetics/Omics Steering Committee. 2) DNA and Laboratory Review Committees have been folded into the Laboratory Committee. 3) NIA membership has not been clearly defined. 4) Functions replaced by Ancillary Proposal Review Committee.