Framingham Heart Study

GUIDE FOR INVESTIGATORS – II

Steps to Applying to FHS and Sponsors for inclusion in FHS Generation 3 Cohorts’ Exam 4
What are the steps to Gen 3 Exam 4 Collaboration?

Step 1: Study PI obtains FHS EC Approval

Step 2: Study PI confirms appropriate budgetary support with FHS Director of Finance & Admin

Step 3: Study PI applies to Sponsors

Step 4: Study PI notifies FHS of JIT Request OR intent to resubmit to Sponsor

Step 5: Study PI notifies FHS when they receive NoA

Step 6: FHS invites Study PI to join Exam Planning Committee

Guide to Investigators Interested in FHS Gen 3 Exam 4
Step 1: WHAT & WHY

WHAT:
Applications for research need to be submitted on-line for FHS Executive Committee (EC) approval prior to submission to a sponsor for funding.

[https://www.framinghamheartstudy.org/fhs-for-researchers/data-sharing-principles/](https://www.framinghamheartstudy.org/fhs-for-researchers/data-sharing-principles/)

WHY:
- The FHS infrastructure is supported by a contract between the NHLBI and Boston University School of Medicine.
- The policies of NHLBI and Boston University are the basis of governance of the Framingham Heart Study.
- Research using FHS resources requires review and approval by at least one of the FHS Review Committees, in this case FHS EC approval is required.
- Reviews consider feasibility, scientific merit, mission and appropriate use of FHS resources.
Step 1: **HOW**

Start an on-line application for FHS based research:

https://www.framinghamheartstudy.org/research-application/

- For help in opening an FHS account to submit an application, contact Heather Arruda at harruda@bu.edu.
- For help with completing the application contact FHSEC@BU.EDU
  
  *(Conversations with FHS administrators before completing your submission can save PIs and reviewers weeks of post-submission correspondence.)*

- After submission of your application, it will routed to the appropriate Review Committee(s).
- For help understanding FHS Executive Committee procedures, contact FHSEC@BU.EDU
Step 1: WHEN

- Submit your FHS application at least **two full months before your chosen grant proposal submission deadline**.

- Plan this long lead time is imperative for you to receive FHS approval of Gen 3 Exam 4, projects since they involve new contact with FHS participants with in the FHS exam.

- All such projects are coordinated for participant burden and timing. A two-stage process of review is used:
  1. Applications **requesting specimens** should be submitted based on the Lab and/or DNA Committee(s) posted submission **deadlines**. Allow at least **two full months for review**.
  2. Those reviews are then followed by an FHS Executive Committee review to obtain ‘Approval in Concept’ for submission of a proposal by the PI to a sponsor.

To meet grant deadlines, please submit FHS applications as soon as possible. The more complex the research project, the more time needed for review and approval.
Step 2

WHAT & WHEN:
While you submit your project to the FHS Executive Committee to consider project feasibility, scientific merit, mission and appropriate use of FHS resources, you should contact the FHS Director of Finance and Administration.

WHY:
FHS projects require the integration of resources and operational procedures with the core examination. This seamless integration requires inclusion of personnel effort and other costs within your project budget.

HOW:
Email FHSEC@BU.EDU to be connected with the FHS Director of Finance and Administration
Step 3

Apply to Sponsors!

If needed, ask for a Letter of Support from the FHS PI and Executive Committee to attach to your application.
Step 4

Email FHSEC@BU.EDU with a copy of your JIT notification

OR

Email FHSEC@BU.EDU stating your intent to resubmit your application for consideration by a sponsor
Step 5

Email FHSEC@BU.EDU with a copy of your NoA
Step 6

The Director of the FHS Research Examination will email you to confirm receipt of your NoA and to invite you to join the FHS Gen 3 Exam 4 Examination Committee.

The FHS Gen 3 Exam 4 Examination Committee will guide you through practical planning of the examination and your responsibilities as PI to provide support, MOP documentation, regular QC reports, and additional important requirements for participating in an FHS exam.
APPENDIX A:
HOW DO I GET UPDATES FROM FHS?

1) Please keep checking the FHS Gen 3 Exam 4 webpage for updates:

https://www.framinghamheartstudy.org/fhs-for-researchers/fhs-guide-for-researchers-interested-in-generation-3-exam-4-collaboration/

2) Subscribe to the fhsresearchers-list

- If you would like to subscribe or unsubscribe to the distribution list, please send your request to the list owner: owner-fhsresearchers-list@bu.edu
- Along with a note requesting that you be subscribed
APPENDIX B: NIH Submission Deadlines

Gen3, Omni-2, NOS - Exam 4
Ancillary Studies Timeline:

1. Retreat 1: Present idea - January 2020
2. Retreat 2: Refine advanced proposal - March 2020
3. Prepare grant, including budget - March/early April 2020
4. Approvals: EC 7, OSMB; NHLBI if >500K DC/Yr - Mid April-End April 2020
5. Grant submission
6. Grant Award
7. Grant Award

Cycle II: June 2020
Cycle II: April 2021
Cycle III: October 2020
Cycle III: July 2021

Guide to Investigators Interested in FHS Gen 3 Exam 4
The National Heart, Lung, and Blood Institute (NHLBI) has announced plans to fund a limited clinic exam cycle in the Generation 3 and Omni 2 Cohorts of the Framingham Heart Study (FHS).

The examination is expected to begin on or about January 2, 2022.

The exam is intended in part to serve as a platform for additional, independently funded exam components via investigator-initiated grants or other independently funded projects to enrich the exam data collection with additional hypothesis-driven content.

The research aims of such exam-related ancillary projects need not be limited to those within the mission of the NHLBI but must be consistent with and/or complement FHS study objectives.

Read more: NOT-HL-19-732
### APPENDIX D: NIH Submission Deadlines

#### NIH Deadlines for FHS Generation 3 Omni 2 Exam 4 Research

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<tr>
<th>A0 (NEW) Receipt Date</th>
<th>Council (Council Cycle)</th>
<th>Earliest Grant Start Date</th>
<th>A1 (RESUBMISSION) Receipt Date</th>
<th>Council (Council Cycle)</th>
<th>Earliest Grant Start Date</th>
<th>FHS Exam Start Date</th>
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