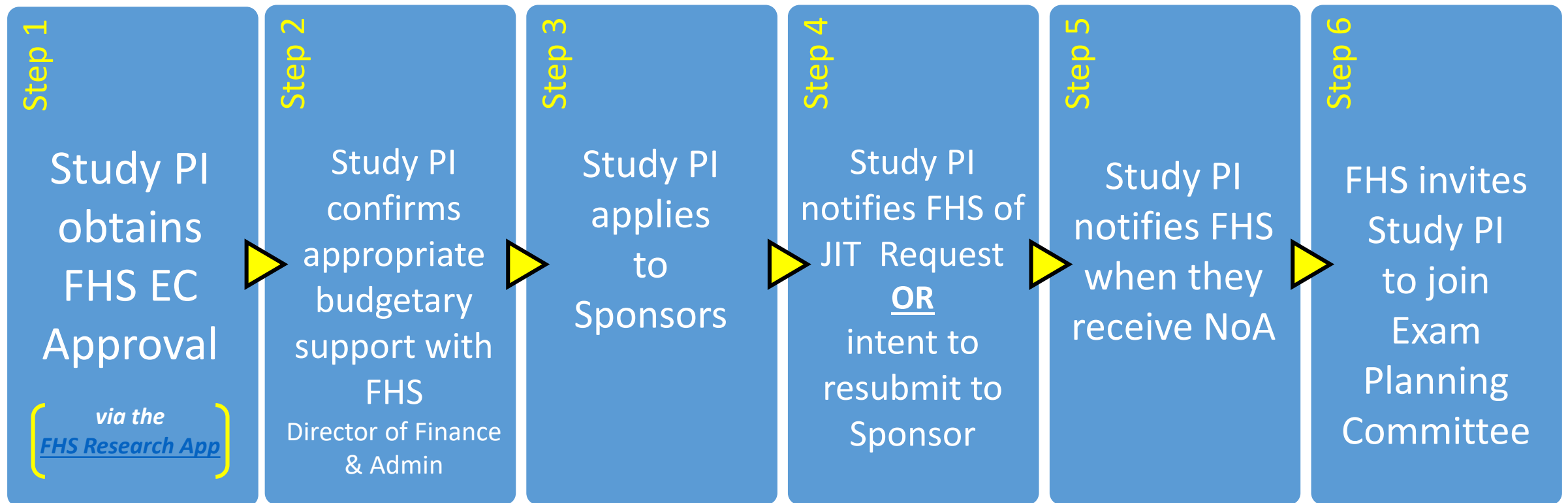


# Framingham Heart Study

## 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: 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/>

## 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](mailto:harruda@bu.edu).
- For help with completing the application contact [FHSEC@BU.EDU](mailto: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 be routed to the appropriate Review Committee(s).
- For help understanding FHS Executive Committee procedures, contact [FHSEC@BU.EDU](mailto:FHSEC@BU.EDU)

# Step 1 : **WHEN**

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.

- 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.

# 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](mailto: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](mailto:FHSEC@BU.EDU) with a copy of your JIT notification

OR

Email [FHSEC@BU.EDU](mailto:FHSEC@BU.EDU) stating your intent to resubmit your application for consideration by a sponsor



## Step 5

Email [FHSEC@BU.EDU](mailto: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/>

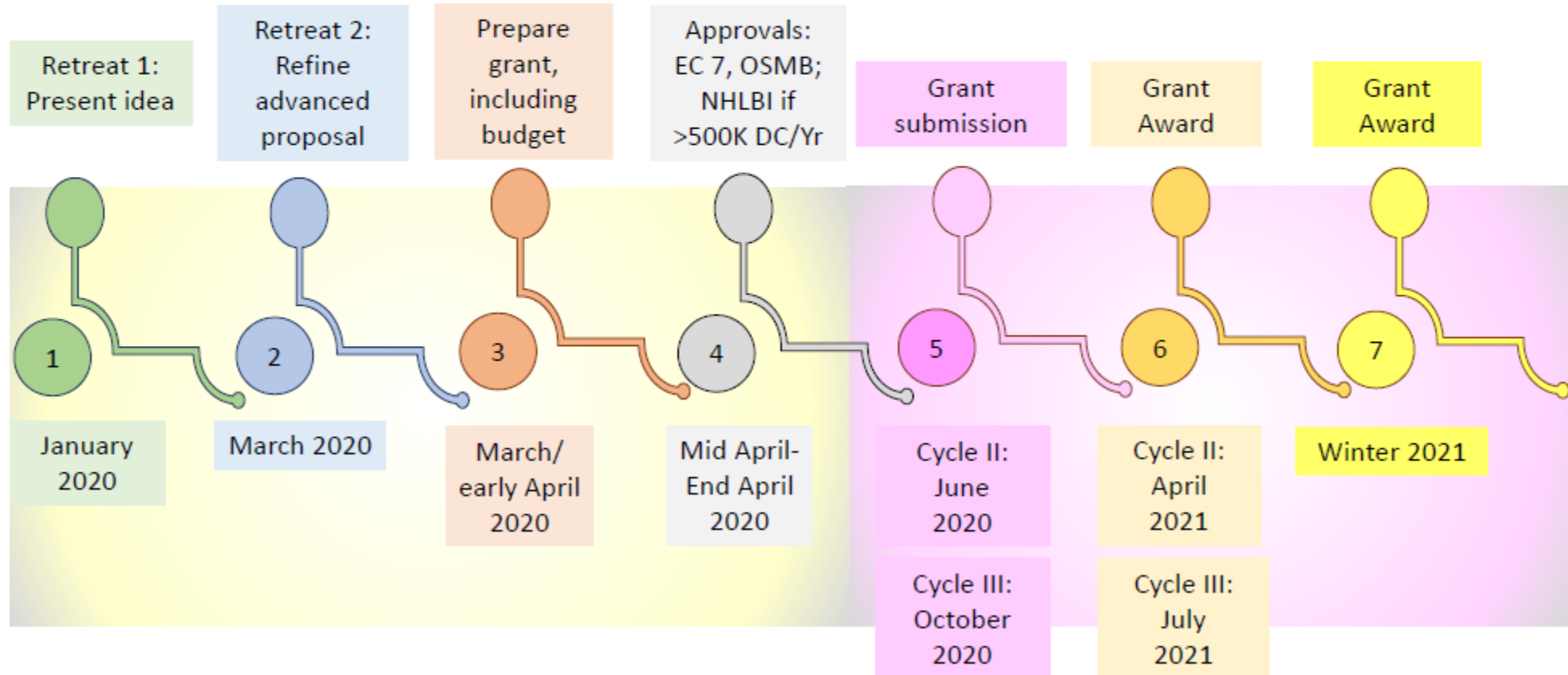
**2) Subscribe to the fhsresearchers-list**

- 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](mailto: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 :

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# APPENDIX C: NIH Notice NOT-HL-19-732

**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

NOTICE OF NIH FHS RECEIPT DATES FOR GEN3 AND OMNI2 EXAM 4						
A0 (NEW) Receipt Date	Council (Council Cycle)	Earliest Grant Start Date	A1 (RESUBMISSION) Receipt Date	Council (Council Cycle)	Earliest Grant Start Date	FHS Exam Start Date
Jan 25 – May 7, 2020 (R01: Feb 5, 2020)	October 2020 (Cycle I)	December 2020	Sept 25, 2020 – Jan 7, 2021 (R01: Nov 5, 2020)	May 2021 (Cycle III)	July 2021	January 1, 2022  (exam preparation begins 9/1/2021)
May 25 – Sept 7, 2020 (R01: June 5, 2020)	January 2021 (Cycle II)	April 2021	Jan 25 – May 7, 2021 (R01: March 5, 2021)	October 2021 (Cycle I)	December 2021	
Sept 25, 2020 – Jan 7, 2021 (R01: Oct 5, 2020)	May 2021 (Cycle III)	July 2021	May 25 – Sept 7, 2021 (R01: June 5, 2021)	Jan 2022 (Cycle II)	April 2022	