

# Framingham Heart Study

## GUIDE FOR INVESTIGATORS – I

**How to apply for FHS review of a proposal prior to the start of a project and prior to submission of a grant proposal to a sponsor.**

# WHY?

## PURPOSE OF FHS APPLICATION AND REVIEW

The FHS infrastructure is supported by contract between NHLBI and Boston University School of Medicine.

The policies of NHLBI and Boston University are the basis of governance of the Framingham Heart Study.

Reviews consider feasibility, scientific merit, mission and appropriate use of FHS resources

Applications for research need to be submitted online for FHS approval **prior to submission to a sponsor for funding.**

**Research using FHS resources requires review and approval by at least one of the FHS Review Committees.**

<https://www.framinghamheartstudy.org/fhs-for-researchers/data-sharing-principles/>

# HOW?

## LINK TO FHS APPLICATION AND INSTRUCTIONS

For help in opening an FHS account, contact Heather Arruda at [harruda@bu.edu](mailto:harruda@bu.edu).

For help with Executive Committee procedures, contact Greta Lee Splansky, at [gretalee@bu.edu](mailto:gretalee@bu.edu).

- Start an on-line application for FHS based research.
- You can interrupt and save your work before you are ready to submit the application.
- Attachments may be added at the end of the application.
- For help with application contact Heather Arruda or Greta Lee Splansky. (Conversation before submission can save PIs and reviewers weeks of post-submission correspondence.)
- After submission, the application, will be forwarded by administrators to appropriate Review Committee(s).

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

# FIND YOUR TYPE!

## TYPES OF FHS RESEARCH APPLICATIONS AND THEIR ROUTING

**TYPE 1. To analyze existing FHS data, and NOT to seek funding from a sponsor...** reviewed on a rolling schedule by the FHS Research Committee ... (or you may find the data you need at the NHLBI BioLINCC repository).

**TYPE 2. To analyze existing FHS data and planning to seek funding from a sponsor...** reviewed by the FHS Executive Committee. (May qualify for a FAST TRACK EC review by email or may require full EC review)

**TYPE 3. For new contact with FHS participants...** reviewed by the FHS Executive Committee, the Exam Committee and the NHLBI OSMB, and an IRB. (**Plan for additional review time**)

**TYPE 4. With for-profit 3rd party involvement...** needs an NHLBI review of the 3rd party role and may require a 3rd party agreement. Heather Arruda, [harruda@bu.edu](mailto:harruda@bu.edu), can assist you.

**TYPES 5 & 6. Requesting FHS specimen...** reviewed by the FHS Lab and/or DNA committee(s), and the Executive Committee.

# WHAT TO INCLUDE?

## TIPS FOR SUCCESSFUL REVIEWS

**FHS reviewers need to see the following application items very well defined:**

- Specific aims and methods for a focused work scope.
- Statistical approaches that support the merit of the project analyses to arrive at valid conclusions.
- Plans for protection of participants' welfare including anticipated needs for reporting incidental findings, confidentiality of personal identifiers, role of 3rd parties and attention to data security.
- Resources FHS will need to provide for the project, such as new participant contact, specimen, copies of and plans for existing data, chart review.
- Plans for funding, including federal or for-profit, dates of submission, start and end dates of the project.
- Plans for support of FHS efforts necessary for the project, from inception to finalization, including provision of specimen and data, examination and QC management.

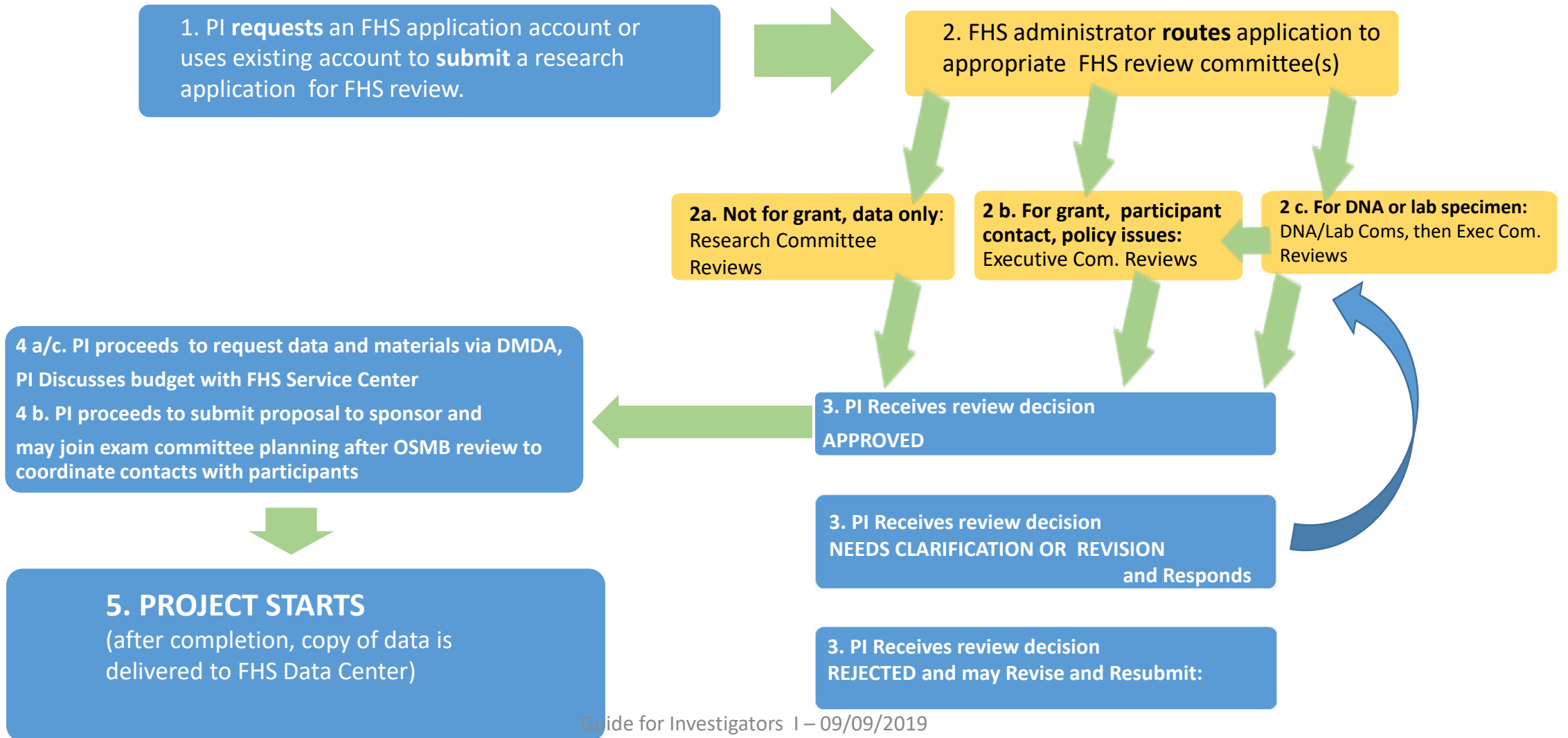
# WHEN?

To meet grant deadlines, please submit FHS applications as soon as possible. FHS reviews of applications for grants for data analyses only may have faster turnaround. The more complex the research project, the more time needed for review and approval.

## FHS REVIEW COMMITTEE SCHEDULES

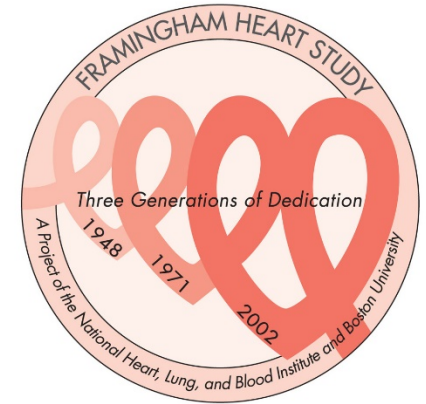
- Submit your FHS application at least **two full months before grant proposal submission deadline**.
- Projects for analysis of existing FHS data only, seeking no new grant support, without use of personal identifiers, are reviewed by the **Research Committee on a rolling schedule. Allow at least two weeks for initial review.** (If the project raises policy questions, Executive Committee review may be required.)
- 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**.
- **Plan for a longer lead time for approval of projects that involve new contact with FHS participants.** All such projects are coordinated for participant burden and timing. A two-stage process of review is used:
  1. Preliminary review by the FHS Executive Committee to Approve in Concept for submission of a proposal by the PI to a sponsor.
  2. Final reviews of funded exam components are by the FHS Examination Committee and NHLBI OSMB to coordinate upcoming FHS primary examinations and follow-up exams.

# REVIEW OF YOUR FHS APPLICATION



# WHO?

## A COMMUNITY OF FHS RESEARCHERS, ALL OF US WORKING TOGETHER



Our common goal is to advance meaningful health science by using the resources of FHS and other institutions, in accordance with the highest standards of research methods, with utmost respect for the obligations to protect the interests of the generous FHS participants.