

P01 PROJECTS AT THE NHLBI

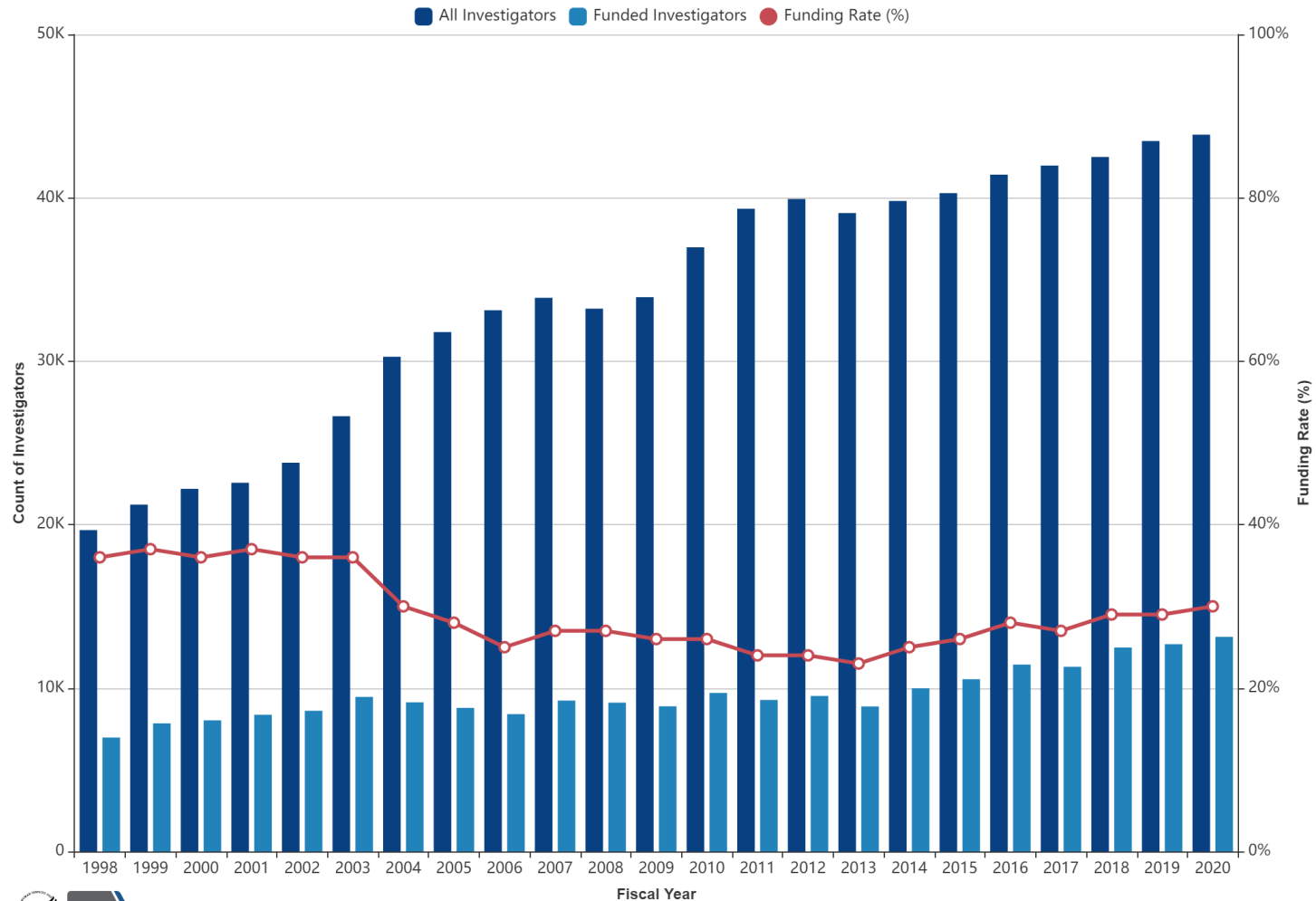
*A Presentation to the Committee on Increasing
Diversity and Inclusion in the Leadership of
Competed Space Missions*

LAURA K MOEN, PHD
27 APR 2021



NUMBER OF COMPETING INVESTIGATORS AND FUNDING RATES

Research Project Grant Investigators: Number of Competing Investigators and Funding Rates



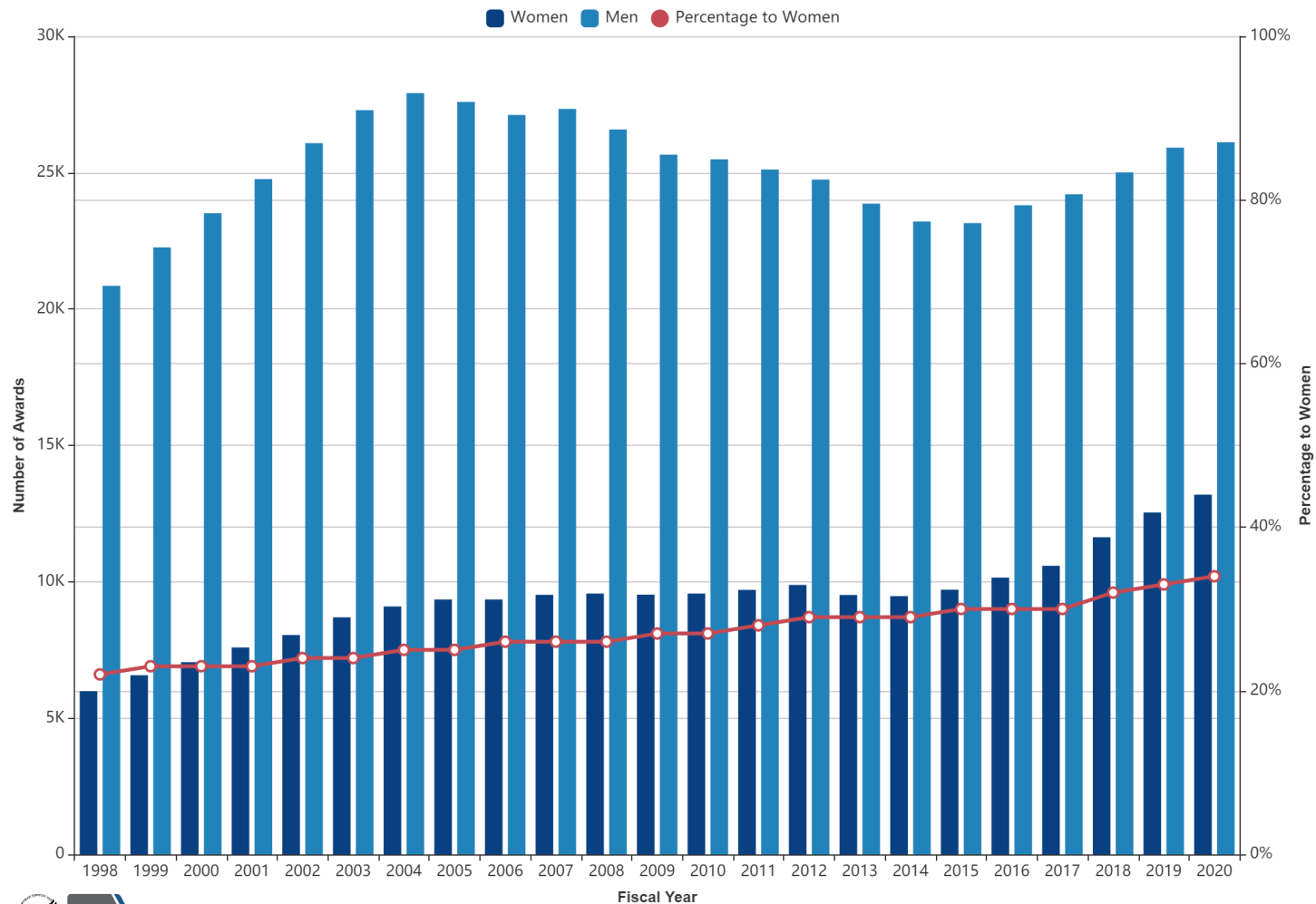
NIH National Institutes of Health
Office of Extramural Research

Data for this report are available at NIH Data Book - <https://report.nih.gov/nihdatabook/report/164> al Heart, Lung, and Blood Institute



AWARDS BY GENDER AND PERCENTAGE TO WOMEN

Research Project Grants: Awards by Gender and Percentage to Women



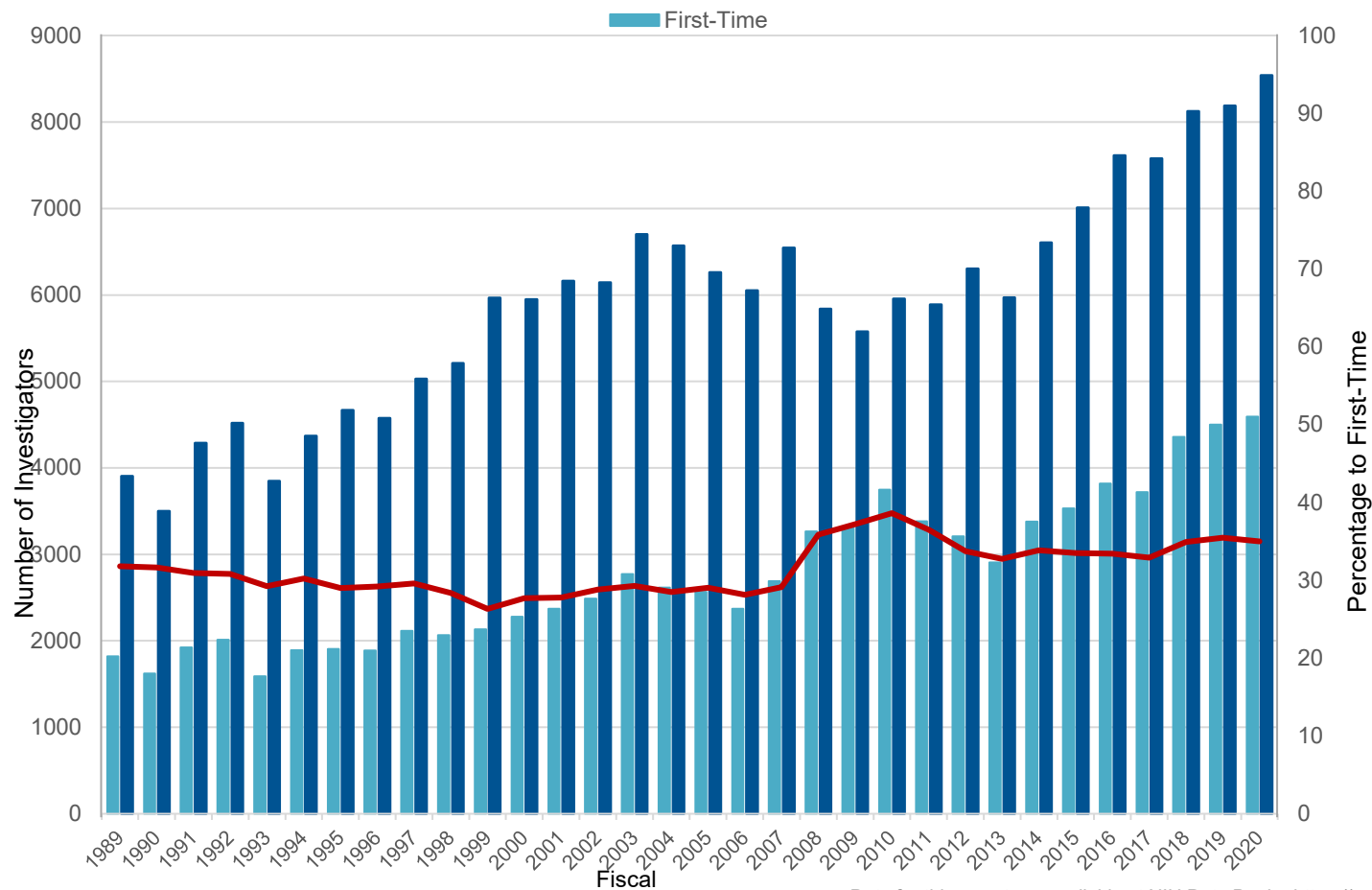
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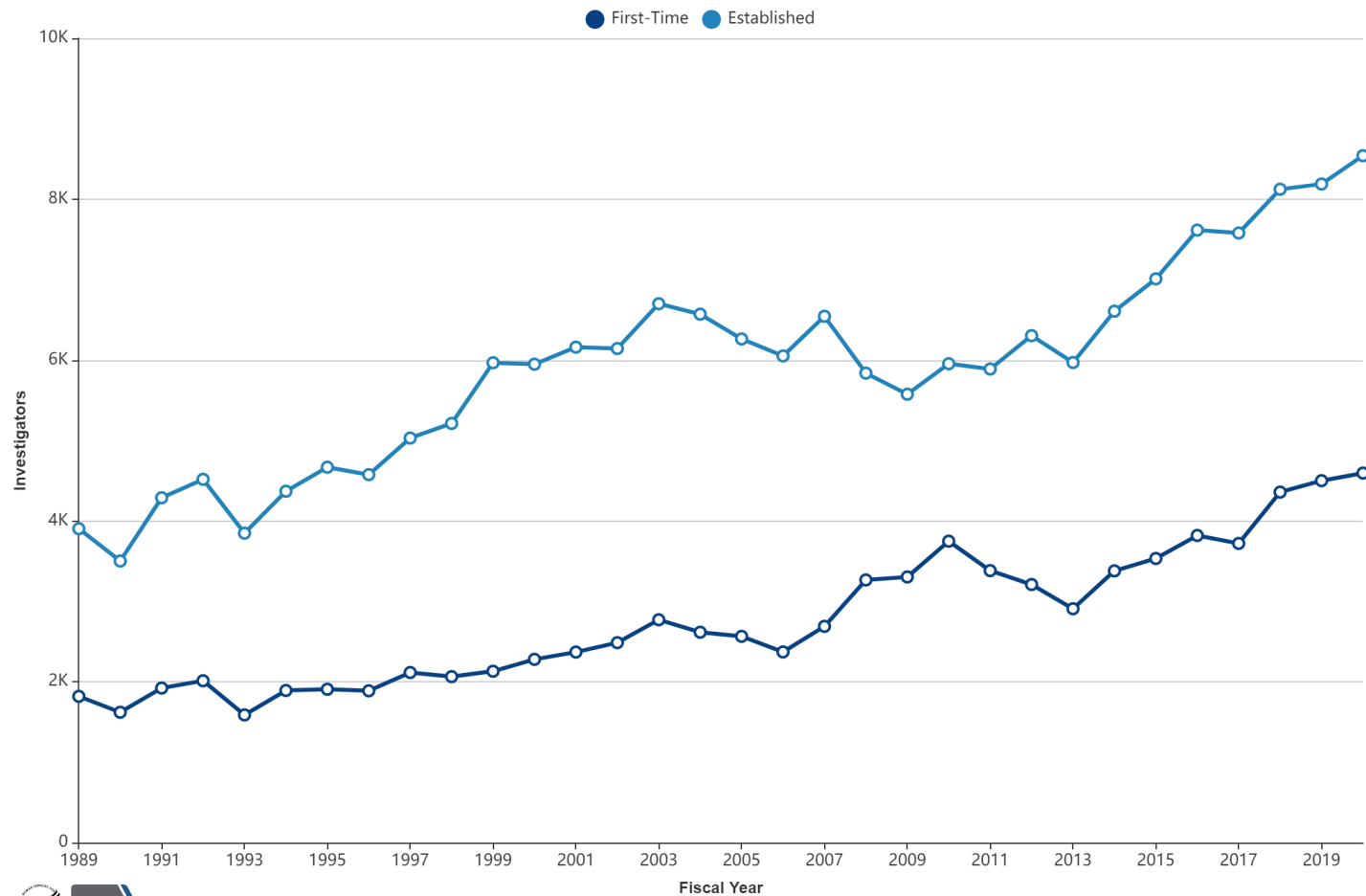
Research Project Grant Investigators: Number Supported on Competing Awards, by Career Stage of Investigator



Data for this report are available at NIH Data Book - <https://report.nih.gov/nihdatabook/report/10>

COMPETING AWARDS, BY CAREER STAGE OF INVESTIGATOR

Research Project Grant Investigators: Number Supported on Competing Awards, by Career Stage of Investigator



Program Project Grants (PPGs) At A Glance

- NHLBI parent P01 mechanism
- Minimum of three interrelated research Projects
- Cores: Scientific and Administrative
- Budget limit: \$1.515 million/year DC
- Two-tier review:
 - First – Tailored Review Committee
 - Second – Parent Review (HLBP)

Timeline: P01 Applications

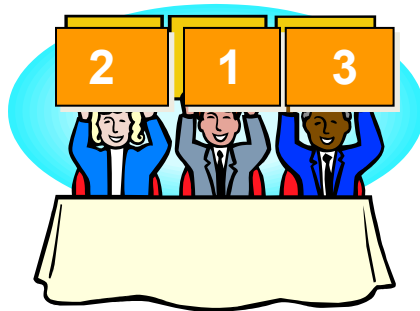


Submission Date

January 25

May 25

September 25



Scientific Review

April/May

June

September/October

December

January/February

March



Council Review

October

January

May



Award Date

December

April

July

Administrative Requirements

- Award renewal limit:
 - Each award limited to one Renewal (10 years total maximum)
 - Would not prevent submission of New applications from same group
- Administrative and Scientific Cores
 - Requirement of institutional letter describing current related infrastructure and review question to assess need for core
 - Administrative cores are no longer required, but are optional

Inclusion of ESI Project Leaders

| PPG Applications including an ESI Project Leader | PPG Applications NOT including an ESI Project Leader |
|---|--|
| Minimum of 4 Projects, one of which must be led by investigator with ESI status | Minimum of 3 Projects |
| Budget: \$1,765,000/year (\$250,000 to ESI-led Project) | Budget: \$1,515,000/year |
| R00-like requirements to document independence, leadership education plan with related review questions | Not applicable |

The P01 at NHLBI – The Details

- The Program Project Grant (P01, PPG)
 - Supports research related scientific areas relevant to the NHLBI mission including the biology and diseases of the heart, blood vessels, lung, and blood; blood resources; and sleep disorders.
 - Programs may also include implementation science, health disparities, and translation research that addresses the mission of the Institute.
- NHLBI adopted the PPG mechanism in 1961 to:
 - Encourage multidisciplinary approaches to the investigation of complex biomedical problems.
 - Facilitate economy of effort, space, and equipment.

Program Projects at NHLBI

- Investigator-initiated
- 5 years of support
- Uses P01 mechanism
- May include a Phase I or Phase II Clinical Trial
- NHLBI PPG Information:
 - PAR-21-088 “NHLBI Program Project Applications (P01 Clinical Trials Optional)”
(<https://grants.nih.gov/grants/guide/pa-files/PAR-21-088.html>)
 - FAQs: <https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/program-project-grants>

Characteristics of a PPG

- A clearly defined, unifying, central theme
- Each component research project relates to the theme
- Each investigator contributes.
- A plan for establishing and fostering robust interactions among the projects and cores must be proposed.
- A minimum of 3 scientific Research Projects
- These Research Projects must be individually meritorious as well as complementary or contributory to each other.

Characteristics of a PPG - Cores

- Applicants may propose an Administrative Core and one or more shared Scientific Core(s) as necessary to facilitate the proposed research Projects.
- Scientific Core(s):
 - Must provide support to at least two component research projects.
 - Is expected to be considered essential to conduct the Program and should not duplicate existing institutional resources
 - Examples of Scientific Cores:
 - Mouse Breeding/Phenotyping/Physiology/Procedure Core
 - Biochemistry/Histology/Pathology/Analytical Core
 - Computational/Statistics/Data Sharing/Shared Instrumentation Core
 - Mass Spectrometry/Biophysics/Material Engineering Core
 - Transgenic/Gene Targeting/Bioinformatics Core
 - Human Translational Studies Core
 - Chemical Synthesis Core

Characteristics of a PPG - Program Director

- The Program Director(s) (PD/PI(s)) are expected to be a research scientist(s) of recognized stature in his/her scientific discipline with the demonstrated ability to ensure quality control, administrative oversight, and integration of all components of a Program.

Characteristics of a PPG – Project Leaders

- Participation of at least three established scientists as Project Leaders is mandatory.
- Project Leaders are expected to have demonstrated the ability to lead an R01, or R01-equivalent, grant (exception – ESI-Led Projects)
 - Option to include a fourth project led by an Early Stage Investigator (ESI) with an increased budget

Characteristics of a PPG – % Effort

- The Program Director(s) must lead his/her own project and devote a minimum of 25% effort to the whole program
- Project Leaders must devote a minimum of 20% effort to their projects
- Core Leaders should devote effort commensurate with the complexity of the Core (no minimum required)

Characteristics of a PPG – Budget

- New (Type 1) and Renewal (Type 2) applications must limit their budget request to \$1,515,000 in direct costs
- If an ESI-led Project is included and the application contains a minimum of four Projects, applications must limit their budget request to \$1,765,000 in direct costs in each year (with a minimum of \$250,000 per year in direct costs for the ESI-led Project).
- Award renewal limit:
 - Applicants are limited to one renewal (Type 2). No renewal (Type 2) applications beyond year 10 are allowed.

PPG Pre-submission Requirements

- Because of the monetary cost and complexity of these programs, potential investigators are required to meet with NHLBI staff as early as possible in the planning stages.
- As these applications are almost always over \$500,000 in direct costs, formal approval to submit an application must be sought from the appropriate Division Director.
 - This request for approval must be made six weeks before the receipt date.
 - As part of the NHLBI *Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs*, “Staff Consultations” must take place that involve Program, Review, and Grants Management Staff meeting with the Program Director(s) and other members of the applicant group.

Review of Program Projects – Step 1

- First Step: Tailored Review Committee (working group) set up by the assigned SRO.
 - This committee usually has two members of the NHLBI Program Project Review Committee (HLBP), and several ad hoc scientists who are experts in the area of the application.
- This working group meets to:
 - discuss and score the individual projects,
 - recommend or not recommend the core units,
 - evaluate the budgetary requests, and
 - discuss the overall program and its integration.

Review of Program Projects – Step 2

- The second review step of initial review is the Program Project Review Committee (HLBP)
 - a standing committee
 - 18 members with broad expertise in heart, lung, blood, sleep and blood vessels.
 - meets three times per year
- HLBP
 - considers the results from the Tailored Review Committee,
 - makes recommendations
 - assigns an overall impact score to each application.
 - It may not change an individual Project assessment assigned by the Tailored Review Committee,
 - provides written comments to be included in the summary statement if HLBP's impression of project merit significantly differs from the Tailored Review Committee.

Review of Program Projects – Step 2

- The overall impact/priority score reflects
 - Project scores voted by the tailored review committee
 - Quality of the core facilities
 - Overall leadership
 - Coordination and Synergy of projects and cores towards achieving the central objectives of the Program
 - If the integration of the individual Projects into a single Program is more beneficial than pursuing each Project independently
 - Past productivity for a renewal application
 - Institutional Support
 - Administrative and Organization Structures
 - Synergy demonstrated by the projects
 - Overall impact on the scientific field

Review of Program Projects – Step 2

- After the HLBP meeting, a summary statement is completed, which consists of the critiques and summaries of the Tailored Review Committee, the HLBP resume, the overall impact/priority score, and final human subjects/animal codes.

FAQs - ESI

- Will applications including an ESI-led Project be reviewed differently?
 - No; however, there are some additional requirements and review-related questions for ESI-led Projects
- How will independence of ESI Project Lead be assessed?
 - Evidence for independence may include:
 - The candidate has a full-time faculty position.
 - The candidate received a start-up package for support of his/her independent research.
 - The candidate has research space dedicated to his/her own research.
 - The candidate may attend faculty meetings, be the responsible supervisor for graduate students, and/or hire technical support or postdoctoral fellows.
 - The candidate is eligible to apply for independent research funding as the PD/PI of an NIH research grant.
- Does the ESI Project Leader lose ESI/New Investigator status?
 - No. Serving as a Project Leader, but not Program Director/Principal Investigator in a PPG grant will not impact the investigator's New Investigator or ESI status.

FAQs – ESI Project Eligibility

- **When is ESI status determined?**
 - ESI status is determined at the time of the A0 submission and continues while that application is under review.
- **What happens if the ESI Project Lead has an R01 application funded between the time of submission and an award decision?**
 - The ESI Project Lead will retain ESI designation for the PPG application.
- **What happens if the ESI Project Lead has an R01 application funded between initial submission (A0) and resubmission (A1)?**
 - ESI designation will be determined at the time of A0 submission and will continue through the review of the resubmission (A1).
- **What happens if the awarded R01 application overlaps substantially with the ESI PPG Project?**
 - If interim funded R01 overlaps substantially with the ESI P01 project, the ESI project must be dropped from P01 if R01 accepted.

FAQs - Administrative

- If not including an Admin Core, how will reviewers know how the PPG is organized and managed?
 - The required information should be provided in the Overall Program component of their application.
- Two different types of applications: typical applications, with direct costs limited to \$1.515 million per year, and applications containing an ESI-led project, limited to \$1.765 million per year are listed in the FOA. What process will these applications go through to gain approval to submit?
 - All PPG applications will go through the process for applications requesting \$1.515 or less.

FAQs – Renewals/Resubmissions

- Can the PI of a currently funded application submit a renewal beyond year 10 to continue the Program?
 - No; however, the PI may submit a new PPG application, even if it is a continuation of an existing scientific Program.
- If an application was submitted to a previous FOA, but was not funded, can the PI submit a resubmission (A1)?
 - Yes; however, if the application is a renewal beyond year 10, it will not be allowed.
- Can an ESI-Led Project be added to a Resubmission or Renewal with the increased budget?
 - No, the permission letter from NHLBI is limited to the original requested budget. To do so, the applicant will need to go through the process of submitting a New application.

FAQs – Clinical Trials

- Can a clinical trial be part of a PPG application?
 - Yes, excluding Phase III clinical trials

Questions?

