The NIH Lasker Clinical Research Scholars Program

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Presentation Overview

Concept Clearance: Reissue PAR-23-156, "NIH Lasker Clinical Research Scholars Program."

Objective: This is a career development program to support clinical researchers in the early stages of their independent careers.

Anticipated Number of Awards: 3-6 awards per year.

Award Project Period: 5-7 years intramural, 3 years extramural (or remain intramural)

Council Action: Vote for continuation of the NIH Lasker Clinical Research Scholars Program.

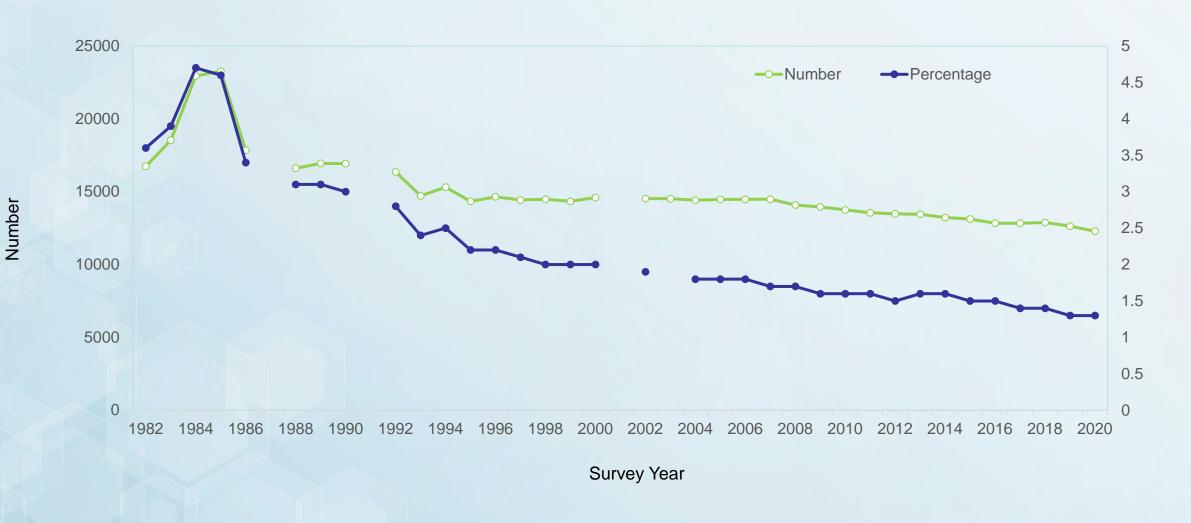
Summary of Previous CoC Meeting (9/17/2021)

 Council approved re-issuing the NOFO for 2 years with a required formal review of the program.

Response to Previous CoC Meeting (9/17/2021)

- Conducted a formal, outside review of the program on June 29, 2023 by an Advisory Committee to the Deputy Director for Intramural Research (ACDDIR) Working Group.
- The committee recommended: "We strongly support continuing and even expanding the NIH Lasker Clinical Research Scholars Program."
- Asking Council to vote for continuation of the NIH Lasker Clinical Research Scholars Program.

Research as the Major Professional Activity of U.S. Physicians



Goals of the Program

This is a career development program which aims:

- To develop leaders in clinical research by supporting selected researchers in the early stages of their independent careers.
- To allow selected clinical researchers to take advantage of the Intramural Research Program environment and resources, while simultaneously establishing themselves as peer-reviewed, NIH funded investigators.

Overview

Candidates:

- Early-stage clinical researchers, not yet tenured, with the ability to conduct independent research.
- Includes physician, dentist, and nurse researchers

Program duration 8-10 years:

- Phase 1 (Si2): NIH Intramural Research Program (IRP) full support (salary, personnel, and research support), Independent tenure-track investigator position, 5-7 years
- Phase 2 (R00): Salary and/or research support of up to \$500,000/year at outside institution for 3 years, OR continuation in Intramural Research Program.

• Funding:

- Funds provided by the sponsoring NIH Institute/Center (both intramural and extramural components)
- Each year, the NIH Institutes/Centers have the option to participate

Benefits of the Program

- To Human health Promising clinical researchers are encouraged to pursue a career in biomedical research
- To Extramural NIH The intramural program supports the investigators during the challenging early stages of their careers
- To Intramural NIH More attractive environment because Scholars perceive they have more career options

Benefits to Scholars

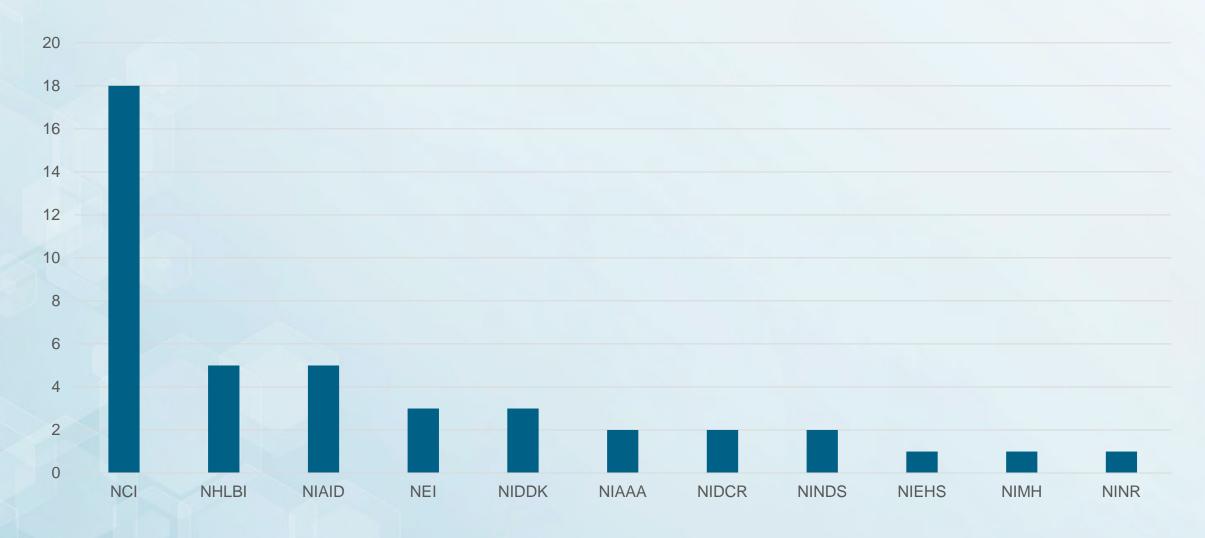
- Outstanding intramural environment for clinical research:
 - NIH Clinical Center is the nation's largest hospital devoted entirely to clinical research
 - Supports transition from lab to clinic, enabling first in human studies
 - State-of-the-art resources including imaging, molecular analyses, and sophisticated laboratory facilities
 - Favorable regulatory environment with centralized IRB and BioEthics Dept.
- Protected time during intramural phase to conduct research:
 - Fully funded by NIH intramural program
 - Reduced level of perceived burdensome academic service obligations
 - In some cases, can maintain affiliation with outside institution while at the NIH
- Extramural component provides options for Scholars:
 - 3 years of support at a research institution for scholars who successfully complete the intramural phase
 - Documented success in an NIH peer-reviewed application process

The Lasker Scholars

- Program started in 2011-2012
 - 43 Current and Past Scholars
 - Average age 41 when starting
- 23 Women & 20 Men
- 7 Underrepresented Minority Investigators



Lasker Scholars by Institute



Status of the Program

- Pilot was begun in 2011-2012
- 43 total Scholars from 2012 to the present
- 7 Scholars have been tenured at NIH
- 11 Scholars reached the Phase 2 decision point of the program
 - 3 Scholars applied for the R00 extramural funds, left NIH
 - 8 Scholars remained in the IRP as tenured or tenure-track investigators
- 3 Scholars left NIH prior to the end of Phase 1
 - 1 now Senior Director/Clinical Lead at Janssen Retina Pharmaceutical
 - 1 now Senior Medical Director, Roche Pharmaceutical Ophthalmology
 - 1 now Senior Investigator, Center for Integrated Healthcare Research, Kaiser Permanente, Hawaii

Summary of Scholars

| Year Started in Program | Number | Current Status |
|-------------------------|--------|---|
| 2012 | 2 | 2 tenured at NIH 1 now Bloomberg Professor, Johns Hopkins Medical School 1 now Clinical Professor of Medicine, George Washington University |
| 2014 | 3 | 1 tenured at NIH 2 tenure-track at NIH |
| 2015 | 5 | 3 tenured at NIH 1 now Professor and Co-Director of Cancer Immunology Center for Excellence, Rutgers Cancer Inst. of NJ 2 tenure-track at NIH |
| 2016 | 4 | 4 tenure-track at NIH |
| 2017 | 1 | 1 tenured at NIH |
| 2018 | 7 | 5 tenure-track at NIH 1 now Professor of Medicine in Residence, University of California, San Diego 1 now Senior Director/Clinical Lead at Janssen Retina Pharmaceutical Co. |
| 2019 | 6 | 5 tenure-track at NIH 1 now Senior Medical Director, Roche Pharmaceutical Ophthalmology |
| 2020 | 6 | 6 tenure-track at NIH |
| 2021 | 4 | 3 tenure-track at NIH 1 now Senior Investigator, Center for Integrated Healthcare Research, Kaiser Permanente, Hawaii |
| 2022 | 1 | 1 tenure-track at NIH |
| 2023 | 4 | 4 tenure-track at NIH |

Outside Review of Lasker Scholar Program

- Reviewed by a Working Group of the FACA-approved Advisory Committee to the Deputy Director for Intramural Research (ACDDIR).
- Reviewed on June 29, 2023
- Chair:

Aviva Abosch, M.D., Ph.D.

Professor and Chair, Department of Neurosurgery

Nancy A. Keegan and Donald R. Voelte, Jr. Chair in Neurosurgery

University of Nebraska Medical Center

Materials Provided to Review Committee

- Overview and history of the program
- Summary of all Scholars, including research abstracts and top 2 publications
- Bibliometric analysis of individual Lasker Scholars
 - Conducted by NIH Office of Portfolio Analysis, DPCPSI, in May, 2023
- Bibliometric comparison of Lasker Scholars cohorts to extramural clinical Early Stage Investigators (ESIs)
 - Conducted by NIH Office of Portfolio Analysis, DPCPSI, in May, 2023
- Summary of individual Scholar activity on clinical protocols, through May, 2023
- Results of a survey of Scholars' perceptions about the program, conducted March, 2021
- List of Scholars who are proceduralists
- Letter of Support from the Lasker Foundation
- Also at the review meeting Scientific presentations from 2 tenured Scholars; Open discussion with a panel of 6 current Scholars

The Committee Report

 "The Committee felt strongly that continued support for the NIH Lasker Clinical Research Scholars Program is crucial... The features of the program that are most critical to success include provision of sufficient protected time for research, sufficient research funding, mentoring, research infrastructure, and help with transition to independence."

The Committee Recommendations

- "We strongly support continuing and even expanding the NIH Lasker Clinical Research Scholars Program."
- "We endorse continued efforts to improve the mentoring within the program."
- "Program staff, scholars, and graduates should focus on increasing program visibility."
- "We strongly encourage the NIH and the Lasker Foundation to consider options for engaging academic medical centers and expanding the program and its funding."
- "The Committee also felt strongly that documenting the background, goals, structure, and accomplishments of the Program in a peer-reviewed publication will help justify to academic medical center deans and clinical department chairs the importance of provision of sufficient protected time and clinical research infrastructure for the creation of successful clinicianinvestigators."

Mentoring of Scholars

- Scholars expected to select a mentoring committee
- Dr. Carl Hashimoto, Director of Faculty Development, OIR
- Faculty Professional Development Workshops
- Informal peer mentoring from other Scholars -
 - Some within same Institute
 - 12 Scholars have volunteered to mentor new Scholars.
- 12 Scholars are also members of the NIH Distinguished Scholars Program (DSP)
 - Supports investigators who have a documented history of improving diversity and inclusion in the biomedical workforce
 - Provides additional mentoring and cohort activities

Council Action

Vote for continuation of the NIH Lasker Clinical Research Scholars Program.