# The NIH Lasker Clinical Research Scholars Program

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#### **Presentation Overview**

**Concept Clearance:** Reissue PAR-20-167, "NIH Lasker Clinical Research Scholars Program."

**Objective:** This is a career development program to develop leaders in clinical research by supporting selected researchers in early stage, fully independent positions.

Anticipated Number of Awards: 2-6 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 (9/11/2020)**

- Council approved re-issuing the FOA that allows current Scholars to receive the extramural R00 component.
- Council postponed a vote on re-issuing the FOA to solicit new applications to the program. Council did not ask for a full evaluation at this time, but requested additional information about the program and how it will be evaluated once it is sufficiently mature. Specific issues included:
  - Clarity on the program goals
  - Additional information about the mentoring component
  - What are the metrics for success?

#### **Response to Previous CoC Meeting (9/11/2020)**

- Conducted a preliminary evaluation that included a survey of the Scholars and a bibliometric analysis of the Scholars.
- Will conduct a more extensive evaluation before future requests to continue the program, to include evaluation from outside Subject Matter Experts:
  - Does the program design enhance success of clinical/translational careers and result in unique and impactful research programs, compared with standard career trajectories?
- Asking Council to vote for continuation of the NIH Lasker Clinical Research Scholars Program.

#### **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 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

### Status of the Program and Challenges to Conducting an Outcome Evaluation

- Pilot was begun in 2011-2012
- 36 total Scholars from 2012 to the present
- 4 Scholars tenured at NIH
  - 2 Scholars have applied for the R00 extramural funds
- 1 Scholar now Senior Director/Clinical Lead at Janssen/Retina Pharmaceutical
- The Lasker Scholars program is a relatively new endeavor, with small numbers and short time durations for the majority of appointments.
- The results of our evaluation indicate that the program is on the right trajectory. However, evaluation remains incomplete because of limited data size and limited duration. The program deserves continued support but requires a detailed outcome evaluation before future approvals.

### **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 provides the bulk of the funding
- 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 previous 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
  - 36 Current and Past Scholars
  - Average age 41 when starting
- 18 Women & 18 Men
- 7 Underrepresented Minority Investigators



#### **Lasker Scholars by Institute**

![](_page_10_Figure_1.jpeg)

# **Summary of Scholars**

| Year Started in Program | Number | Current Status  |
|-------------------------|--------|---|
| 2012                    | 2      | 2 tenured at NIH  |
|                         |        | 1 leaving to be Bloomberg Professor, Johns Hopkins Medical  |
|                         |        | School. Applied for R00                                     |
| 2014                    | 3      | 3 tenure-track at NIH                                       |
| 2015                    | 5      | 2 tenured at NIH  |
|                         |        | 1 now Professor and Co-Director of Cancer Immunology Center |
|                         |        | for Excellence, Rutgers Cancer Inst. of NJ. Applied for R00 |
|                         |        | 3 tenure-track at NIH                                       |
| 2016                    | 4      | 4 tenure-track at NIH                                       |
| 2017                    | 1      | 1 tenure-track at NIH                                       |
| 2018                    | 7      | 7 tenure-track at NIH                                       |
| 2019                    | 6      | 5 tenure-track at NIH                                       |
|                         |        | 1 now Senior Director/Clinical Lead at Janssen/Retina       |
|                         |        | Pharmaceutical Co.  |
| 2020                    | 6      | 6 tenure-track at NIH                                       |
| 2021                    | 2      | 2 tenure-track at NIH                                       |

#### **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
  - 8 Scholars have volunteered to mentor Scholars from other Institutes.
- 10 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

#### **Survey of Lasker Scholar Viewpoints**

- Developed with input from Office of Evaluation, Performance, and Reporting, DPCPSI, NIH
- Conducted March, 2021
- 33/34 Scholars (as of Dec. 31, 2020) responded
- 44 Questions: 33 with numerical answers, 11 with text answers
- 6 Categories:
  - Research and Career Goals, Interactions with Institute Leadership, Research Mentors, Career Development Activities, Lasker Foundation Contributions, Interactions with OIR Staff

### **Survey – Selected Highlights**

- Program Strengths:
  - Q33 Would you recommend the program to someone with research and career goals similar to yours? Yes 32/32 (1 skipped)
  - Q3 Overall, how satisfied or dissatisfied are you with the progress of your research? 97% Very satisfied or satisfied

# **Survey – Selected Highlights**

 Q17 In what ways have you benefited from working with your research mentor(s)?

![](_page_15_Figure_2.jpeg)

#### **Metrics to Determine if the Program is Successful**

- Qualitative Analysis of Scholars' Contributions and Recognition
  - Leadership positions held, service on national committees
  - National/International recognition including awards and honors, journal editorial boards, invited talks

- Bibliometric Analysis of Productivity
  - How do the productivity effects from receiving a Lasker award compare to those from clinical extramural Early Stage Investigators (ESIs) receiving their first R01?

#### **Bibliometric Analysis**

Conducted by the Office of Portfolio Analysis, DPCPSI, NIH

- Completed July 23, 2021
- Metrics:
  - Publication counts
  - Weighted Relative Citation Ratio (wRCR)<sup>1</sup>
  - Clinical impact: Publications that are clinical articles or are cited by a clinical trial or guidelines
  - Approximate Potential to Translate (APT): Al prediction of the probability a publication will be cited by a clinical trial or guideline<sup>2</sup>

<sup>1</sup>Hutchins BI et al. *PLOS Biology* 2016 14:e1002541 <sup>2</sup>Hutchins BI et al. *PLOS Biology* 2019 17(10):e3000416

#### **Methods – Group Definitions**

Lasker Scholars: 31 Awarded Lasker Scholars FY 2012-2020. The FY2021 awardees were excluded due to limited data

Clinical ESI comparison group 1: ESI-R01 awardees that have

- A clinical terminal degree (MD, RN, DDS, and equivalents)
- Evidence of clinical research: Initial R01 award has a human subjects flag or PI has published a clinical article
- The ESI comparison group is matched to have the same distribution of award start FYs as the Lasker Scholars

Clinical ESI comparison group 2: A more closely matched ESI-R01 comparison group, found using coarsened exact matching (CEM).

#### **Methods: Limitations**

- The Lasker Scholars program is a small, relatively new endeavor
- There are limited data for evaluation of Lasker Scholars because of small numbers and short time durations since appointment
  - Small Lasker PI counts mean imprecise estimates of what a larger group might look like
  - Short duration data mean limited opportunity to look at Lasker appointments' impact over time. Research productivity can take a long time to manifest and here we look at a maximum of 4 years post award
- There are challenges in identifying an accurate comparison group
  - Year 0 for Lasker Scholars is the FY of their appointment; ESI R01 investigators may have conducted one or more years of independent PI research prior to obtaining their first R01
- This work provides an illustrative analysis

#### **Summary and future bibliometric analyses**

- We cannot identify statistically significant differences between Lasker Scholar and the ESI-R01 comparison groups, given the limited data available
- Currently, we can only analyze performance metrics up to 4 years since the start of awards
- With additional data, improved analysis will be possible:
  - A larger pool of Lasker PIs will provide more representative estimates
  - Additional time since the start of awards will provide information on longer-term impacts
- With additional data, other comparisons will be possible:
  - Tabulation of productivity metrics over a 5-year period post award
  - Creating a more robust comparison of similar groups with the addition of a regression step.
    Regression subsequent to matching allows us to control for additional variables as well as for variation within each coarse matching category
- This work provides an illustrative analysis

#### **Council Action**

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