

## **Concept Clearance:**

### **Reissuance of Lasker Clinical Research Scholars Program (Si2/R00), [PAR-20-167](#)**

The NIH Lasker Clinical Research Scholars (Lasker Scholars) Program is a career development program for independent clinical researchers. The program aims to develop leaders in clinical research by supporting selected researchers during their development in fully independent positions. It allows them to take advantage of the NIH Intramural Research Program (IRP) environment and resources, while simultaneously establishing themselves as peer-reviewed, NIH funded investigators.

The NIH funds research and research training at extramural institutions, as well as within the IRP, to support the development of clinical treatments for disease and to improve human health. However, these efforts can be hindered by barriers to clinical and translational research. Such barriers include limited research time for clinical investigators, increases in the length of time to independent careers, and access to hospital facilities and patient enrollments.

To address these barriers, the NIH created the Lasker Scholars program in 2011. The program supports a small number of exceptional clinical researchers, starting in the early stages of their independent careers. The program is described in the following website: <https://www.nih.gov/research-training/lasker-clinical-research-scholars>.

The program represents an unprecedented intramural–extramural partnership involving the IRP, the Extramural Research Program, and the Albert and Mary Lasker Foundation to support top-notch clinical scientists. The program combines a period of research experience as a tenure-track Investigator in the IRP (5-7 years) with additional years of independent financial support, either by continuation in the IRP or with R00 support at an extramural institution. For applications submitted since 2015, the R00 component provides 3 years of up to \$500,000 per year in direct costs (Scholars who applied between 2011 through 2014 could receive up to 5 years of R00 support). The individual NIH Institutes and Centers have the option whether to participate each round, depending upon their projected resources and needs.

Since the inception of the program in 2011-2012, there have been 36 current and past Scholars, including physicians, nurses, and dentists, selected from 135 applicants. 11 NIH Institutes support one or more Scholars, the largest number being supported by NCI. The program started slowly, with one Scholar selected from the 2011-12 candidates and one from the 2012-13 candidates, but since then has averaged more than 4 Scholars per cohort.

The Council of Councils discussed the program at its meeting on September 11, 2020. The Council was supportive in principle to the concept of a dedicated pathway for developing clinical researchers through the NIH. The Council approved re-issuing the FOA that allows current Scholars to receive the extramural R00 component. However, the 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, and clarity on the metrics for success.

We thank the Council for its insights and have taken its concerns to heart. We conducted a preliminary evaluation that included a survey of the Scholars and a bibliometric analysis of the Scholars. The survey was developed, with input from the NIH Office of Evaluation, Performance, and Reporting (OEPR),

DPCPSI, to assess the views of the Scholars about the effectiveness of program components including mentoring; 33 of the 34 Scholars contacted (those appointed prior to December 31, 2020) responded. In addition, the NIH Office of Portfolio Analysis (OPA), DPCPSI, conducted a bibliometric analysis of the Scholars. The metrics included publication counts, weighted Relative Citation Ratio (wRCR), Clinical Impact, and Approximate Potential to Translate (APT), and the Scholar group was compared to extramural comparison groups.

In summary, the analyses indicate that the Program is on the right trajectory. For example, 32/32 Scholars responded in the survey that they would recommend the program to someone with similar research and career goals (one respondent did not answer this question). 4 Lasker Scholars have now been tenured by the IRP, of whom 2 have applied for the R00 component.

However, evaluation remains incomplete because of the limited data size and limited duration of the program. It is not yet possible to identify statistically significant differences by bibliometric analysis between the Lasker Scholar and the extramural comparison groups.

The program deserves continued support but requires a more extensive evaluation before approving future requests to continue the program. We will conduct an assessment that includes evaluation from outside Subject Matter Experts, addressing whether the program design enhances success of clinical/translational careers and results in unique and impactful research programs, compared with standard career trajectories.

We are asking the Council of Councils to vote for continuation of the NIH Lasker Clinical Research Scholars program.