

Concept Clearance – Reissue of HIV/AIDS Scholars Program (K01, R21, R13)

The [NIH Strategic Plan for HIV and HIV-Related Research](#) for FY 2021-2025 identified a national need to train the next generation of HIV/AIDS researchers and to achieve specific national priorities for diagnoses of new HIV infections. Additionally, ORIP's [Report of the Expert Panel Forum on Challenges in Assessing Nonhuman Primate Needs and Resources for Biomedical Research](#) issued in 2018 identified a pressing need to expand the pool of skilled nonhuman primate (NHP) researchers in the United States. Combined, these two recommendations point towards an inadequate number of researchers using NHP models to address preclinical areas of HIV/AIDS research. ORIP strives to form creative collaborations with NIH Institutes, Centers, and Offices that have an interest in advancing research infrastructure and resources. As a major theme of the [ORIP Strategic Plan 2021-2025](#) is to facilitate specialized research training in animal models and related resources, ORIP partnered with the Office of AIDS Research (OAR) to increase the workforce that can utilize NHPs as preclinical models for HIV/AIDS research.

In FY 2016, ORIP and OAR launched the HIV/AIDS Scholars Program (K01, R13) to provide salary and research support to early-stage investigators (ESIs) within ten years of completing their terminal professional degree or residency training for HIV-related research using NHPs as preclinical models. Scholars receive intensive research career development under the guidance of an experienced mentorship team with expertise in NHP models and translational research. This sustained period of career development and training is intended to help awardees launch independent research careers and become competitive for new research funding. Currently, the K01 grant provides up to \$100,000 salary support and \$100,000 research support per year. The R13 grant provides up to \$75,000 direct costs per meeting for an annual conference to address the needs of early-stage HIV/AIDS researchers as they translate findings from preclinical research from NHPs to human clinical trials. In FY 2020, ORIP and OAR added an R21 component to address the challenges ESIs face to acquire their first research project grant from NIH, particularly when using expensive NHP models. The R21 award is intended to help recipients develop independent research programs and provides up to \$200,000 in direct costs per year for 2 years.

The K01 and R21 Funding Opportunity Announcements resulted in 16 grants from a total of 27 applications submitted from FY 2016 to 2021. Eight out of the 16 grantees have applied subsequently to NIH for R01 or equivalent grants. Six grantees competed successfully for independent NIH funding from NIAID, NICHD, and NIA that collectively included 7 R01 grants, 1 RF1 grant, 1 U01 grant, and 1 R03 grant. After receiving HIV/AIDS Scholars Program grants, several grantees have advanced in following years to the rank of Associate Professors (2 grantees), Assistant Professors (4 grantees), Research Assistant Professors (2 grantees), industry scientists (2 grantees), an Instructor in Medicine, and a Staff Scientist. The remaining grantees have maintained their positions as Assistant Professors (3 grantees) or as a Research Assistant Professor. The 16 grantees collectively have 86 publications associated with their HIV/AIDS Scholars Program grants. Among the 86 publications are 76 research articles, including 6 clinical articles. Seven Scholars are first author on 16 research articles. Five Scholars are last author on 15 research articles, indicating their independent status. Seventy-six research articles received slightly more citations than the median NIH-funded paper in their fields, with a relative citation ratio of 1.21. The publications covered a wide range of topics including testing of HIV-1 vaccine candidates and T-cell immunology. The successes of the scholars in obtaining NIH funding, career advancement, and publications suggest that the program is helping awardees launch independent and productive research careers.

The annual Conferences for Early-Stage HIV/AIDS Vaccine Researchers are organized and evaluated by the NIH-sponsored HIV Vaccine Trials Network (HVTN). The conference includes short presentations by ESIs, as well as sessions on the ESI funding landscape, NHP statistical considerations, successful strategies to seek and maintain research, and developing and sustaining long-term career plans. The first conference series took place from 2017 to 2019 in Washington, D.C. and collectively drew 125 attendees, including 79 ESIs, from 39 institutions and four countries. The conference organizer successfully adapted to the limitations imposed by the COVID-19 pandemic and held conferences virtually in November 2020 and September 2021. These virtual conferences were well attended and ESI attendees reported an enhanced understanding of leading scientific issues in the field, improved career development skills, and a broader appreciation of what it means to be a senior investigator. Other conference benefits cited by ESI attendees included establishing new research collaborations, developing peer support groups, and expanding professional networks.

Based on the recent successes of the HIV/AIDS Scholars Program and the continuing demand for researchers using NHP models to address preclinical areas of HIV/AIDS research, ORIP requests concept clearance from the Council of Councils to continue support for the "HIV/AIDS Scholars Program (K01, R21, R13)."