Concept Clearance – Reissue of HIV/AIDS Scholars Using Nonhuman Primate Models K01 Program

The NIH Strategic Plan for HIV and HIV-Related Research for FY2019/2020 identified a national need to train the next generation of HIV researchers to support the field and to achieve specific national priorities for 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 supply of researchers using NHPs to address preclinical topics in HIV/AIDS.

The HIV Vaccine Trials Network (HVTN) and the Center for HIV/AIDS Vaccine Immunology (CHAVI) recognized the problem of an inadequate supply of new researchers working to translate findings in NHPs to human trials of HIV vaccines. Adamson et al. (2015) reported on the results of a mentored research program for Early Stage Investigators (ESIs) run by these organizations from 2008 to 2011 that combined flexible funding (up to $500,000 over two years) granted to the ESIs, networking at the semiannual HVTN and CHAVI meetings, mentorship, and training in NHP use, clinical vaccinology and career development. By 2015, the ESIs had published over 100 papers and had received 24 independent grants for $6.2 million and collaborative grants for $23.1 million. Ten of the fourteen ESIs planned to remain within the HIV vaccine field, indicating the program had achieved its goals.

Based on this successful model, ORIP, in collaboration with the Office for AIDS Research, originated a mentored career development program (K01) in 2016, the "HIV/AIDS Vaccine Scholars Program" (PAR-16-347), which was expanded in 2017 (NOT-OD-17-116) to broaden the scope to include all preclinical high priority AIDS research using NHP models. The goal of the program is to increase the supply of new researchers using NHPs for preclinical HIV/AIDS studies.

Progress and impacts from the first three years (2016-2018) of the program include:

- 9 awards among 19 applicants
- 5 awardees competed successfully for independent NIH funding that collectively included 2 R01s (NIAID), 3 R21s (NIAID), 1 RF1 (NIA), and 1 R03 (NIAID)
- 27 peer-reviewed publications, 12 as first or last author
- The first cohort consisting of 3 awardees has finished the program; all 3 awardees have permanent research positions
- The second cohort consisting of 3 awardees is in its final year; 1 awardee already has a permanent position

As a consequence of these outcomes, ORIP viewed the program as successful and reissued the funding opportunity announcement (FOA) in 2019 (PAR-19-267) with the same funding levels and requirements. Given the high costs associated with NHP research, the prior and new FOAs awarded up to $350,000 total costs per year. Up to $75,000 was for salary support, with the remainder available for research support. The larger than usual size of the awards was chosen due to the high costs associated with NHP research and the desire to provide recipients with the funds to develop independent research projects.

Shortly after the reissue of the FOA (PAR-19-267), the NIH determined that the provision of up to $275,000 per year for research support under the K01 mechanism was inappropriate. To retain compatibility with the language of the FOA and to permit receipt and review of applications to proceed, NIH limited new awards under the reissued FOA (PAR-19-267) to $350,000 total costs for a three year

project period, substantially reducing the funds available for research support. As a result, ORIP terminated the new FOA after one round of applications in order to reissue it in a manner compliant with NIH policy but with a higher level of support for research activities.

ORIP is proposing that the FOA be reissued, changing only the level of support for research. Key characteristics of the proposed reissue:

- Three years of mentored career support
- Two required mentors
    - An expert in use of NHP models
    - An expert in clinical translational research
- Salary support up to $75,000 per year
- Research support up to $100,000 per year, an amount acceptable under NIH policy
- Eligibility
    - Doctoral degree
    - At least three years of postdoctoral experience
    - No more than 10 years beyond terminal degree
    - Documented affiliation with an NHP facility with skilled staff

Given the continuing need for researchers using NHPs for preclinical HIV/AIDS studies, ORIP requests concept clearance from the Council of Councils to continue supporting the HIV/AIDS Scholars Using Nonhuman Primate Models K01 Program.