

ORIP

OFFICE OF RESEARCH
INFRASTRUCTURE PROGRAMS

Division of Comparative Medicine



CONCEPT CLEARANCE
Program Announcement: HIV/AIDS Vaccine
Scholars Program

Jack Harding, PhD
Division of Comparative Medicine
ORIP / DPCPSI



BACKGROUND AND PURPOSE

- Development of an AIDS vaccine remains a high priority.
- New approaches to vaccine development, including understanding key aspects of immunology and pathogenesis, require nonhuman primate (NHP) preclinical models.
- There is a need to increase the number of Early Stage Investigators (ESIs) who use NHP models and who can collaborate with scientists and clinicians in designing human trials.
- In general, moving ESIs to positions of independence is a high priority for the NIH.
- ORIP and the NIH Office of AIDS Research are collaborating on a joint initiative to develop a HIV/AIDS Vaccine Scholars Program.
- The purpose of this initiative is to help ESIs who are using NHP models in the area of AIDS vaccine research attain independence.

FEATURES OF THE PROGRAM ANNOUNCEMENT

- R25 grant mechanism.
 - From the NIH website: The R25 is “used in a variety of ways to . . . provide additional training in specific areas.”
- Will solicit applications from institutions that have primate capabilities to support up to three candidates for three years.
- A Candidate must be an ESI by the NIH definition.
 - Has not previously competed successfully as a PD/PI for a substantial independent research award (i.e., R01).
 - Can have competed successfully for an R03 or R21.
 - Must be within 10 years of completion of the terminal degree.
- Associate professors or tenured faculty are not eligible.
- A Candidate must have research space and support from the host institution.

EXAMPLES OF RESEARCH TOPICS

- Tests of new vaccines in NHP pre-clinical models.
- Strategies to block early events in viral transmission, focused on understanding early virus-host interactions.
- New challenge models in NHPs for vaccine trials, including development of multi-clade SHIVs and HIV-adapted viruses.
- B cell and mucosal immunity in NHP vaccine models.
- Others

GOVERNANCE AND FUNDING

- In addition to the ESIs, a mandatory advisory committee comprised of experts in NHPs and in human studies.
- Each ESI to be funded at ca. \$350,000 total costs per year, for up to 3 years.
- A modest allowance to the institution for administering the program and supporting the advisory committee.
- Expected funding for FY 16: \$1.5 million.
- At this level, 2-4 ESIs total per year. Expect at least 2 sites per year.
- Possibility for expansion in FY 17 to include a second group of 6 or more ESIs and perhaps more sites.
- In addition to standard yearly NIH progress reports, the advisory committee and NIH staff will assess progress at the end of the second year, to help ESIs plan for the third year of support.

QUESTIONS AND COMMENTS?