

Update on the Office of AIDS Research

Presentation to NIH DPCPSI Council of Councils

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Scientific Opportunities

- Recent advances in our understanding of HIV pathogenesis, immune dysfunction, viral reservoirs, from the fields of immunology, virology, genomics, and structural biology are leading to a possible successful vaccine, improved therapeutic strategies, and a possible cure for HIV/AIDS
- These advances are leading to unprecedented scientific opportunities and it is critical that NIH, as the world's leading public agency supporting AIDS research, ensures that AIDS dollars are going to the highest AIDS research priorities



Preparing OAR for the Future

- OAR's role will be even more important than ever in this intense push to end the epidemic, develop a AIDS cure, and achieve an AIDS-free generation
- To ensure that OAR is prepared to take on this role:
 - Dr. Tabak has established and chairs a small working group of IC Extramural and Intramural leadership to address the scientific and programmatic role of OAR; and
 - A vigorous national and international search was launched on July 31 for a new OAR Director; search committee co-chairs Drs. Briggs and Rodgers



THE NIH DIRECTOR

Statement on NIH Efforts to Focus Research to End the AIDS Pandemic

August 12, 2015

Extraordinary progress has been made in HIV/AIDS research over the last 34 years, transforming what was once a terrifying and almost inevitably fatal disease into a treatable disorder. People with HIV/AIDS can now experience an almost normal life expectancy if antiretrovirals are started promptly and continued for life. But the disease remains a significant public health concern, with approximately 50,000 new infections per year in the United States and two million new infections worldwide. The global human and economic costs continue to be staggering.



NIH Overarching AIDS Research Priorities

Critical to ensure that NIH AIDS funds are supporting the highest priorities for next 3-5 years:

- 1. Reduced incidence, including vaccines**
- 2. Next generation of HIV therapies with better safety and ease of use**
- 3. Research toward a cure**
- 4. HIV-associated comorbidities and co-infections**

***Cross cutting areas:* Basic research, health disparities, and training**



NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS Funding

Notice Number: NOT-OD-15-137

Key Dates

Release Date: August 12, 2015

Related Announcements

None

Issued by

National Institutes of Health (NIH)
Office of AIDS Research (OAR)

Purpose

The purpose of this Notice is to inform the scientific community of the overarching HIV/AIDS research priorities and the guidelines NIH will use for determining AIDS funding beginning in fiscal year 2016 for the next three to five years.



Guidelines for High-, Medium-, and Low-Priorities for Use of AIDS Funds

- Developed based on OAR Advisory Council HIV/AIDS Research Portfolio Review Working Group Report (May 2014)
- FY 2015 Trans-NIH Plan for HIV-Related Research – reflecting input from scientific and academic community, scientific foundations, and community constituency groups
- NIH Leadership



Use of Guidelines

- Applicable to determining priority for receiving AIDS funding not scientific merit of grants, contracts, and intramural projects
- Cited in a Notice in the NIH Guide on August 12, 2015 to inform the scientific community
- Used in standardizing pro-rating level of support for projects containing both AIDS and non-AIDS aims or subprojects



High Priority Research Areas For Use of AIDS Funds

- Development/testing of AIDS vaccine candidates, microbicides, PrEP, and strategies to improve HIV testing and entry into treatment
- Development/testing of HIV treatments – long-acting, less toxic, and fewer complications
- Novel strategies for research toward a cure
- Prevention and treatment of HIV-associated comorbidities, coinfections, and related complications



High Priority Areas (continued)

- Basic research on HIV transmission, pathogenesis, and immune dysfunction
- Research to reduce health disparities in incidence and treatment
- Training to conduct high priority research



Medium-Priority Research Areas for Use of AIDS Funds

HIV/AIDS is a meaningful component of the project and/or knowledge about HIV is enhanced by the project

Examples:

- project includes people (or biological specimens from people) who are living with HIV, are HIV exposed, and/or are at elevated risk for HIV infection as part of a broader sample or as a comparative cohort;
- project addresses health and social issues clearly linked with HIV (transmission/acquisition, pathogenesis, morbidity and mortality, stigma) and examines them in the context of HIV such as other infectious pathogens and diseases, non-infectious pathogens and diseases, substance use/addiction, and mental health disorders;



Medium Priority Research Areas (continued)

- project meaningfully includes HIV/AIDS (or SIV) outcomes/endpoints; or
- project results will advance HIV treatment or prevention and/or provide tools/techniques and/or capacity beneficial to HIV research (including training and infrastructure development).



Low-Priority Research Areas

Low-priority projects will not be supported with AIDS dollars:

- Natural history and epidemiology that is entirely focused on a co-morbidity and does not have any focus on or inclusion of HIV (e.g., malaria, TB, and drug abuse)
- Basic virology on pathogens that are co-infecting, but not in the context of HIV infection; and basic immunology studies of general relevance, but not specific to HIV. Examples of these include:
 - Basic virology and neurobiology research of co-infecting pathogens not in the context of HIV infection (e.g., Herpesviruses, HPV, TB, Malaria, hepatitis C and B, syphilis, Cryptococcus, flaviviruses, JC virus, etc.)
 - Basic cancer-related immunology studies not in the context of HIV infection
 - Studies of co-morbidities of general relevance, but not in the context of HIV (e.g., diabetes, lipid defects, endocrinology)



Low-Priority Areas (continued)

- Data analysis and systems tools that are not HIV-related, e.g., genomics studies of little or no relevance to HIV
- Studies of behaviors (e.g., sexual activities, drug use activities) or social conditions (e.g., economic distress) that have multiple negative outcomes where HIV/AIDS is only one of many outcomes being studied without a focus on how HIV/AIDS is unique in that context (i.e., it is just mentioned as potentially relevant)



Special Areas for Priority Considerations

- The special areas of consideration include NIH-wide programs involving a component of HIV/AIDS research, for example:
 - CTSAs
 - NPRCs
 - Cancer Centers



Pro-rating Projects with AIDS and Non-AIDS Components

<i>Scientific/Programmatic Focus</i>	<i>Proration of AIDS Dollars</i>
<i><10% AIDS</i>	<i>0% AIDS</i>
<i>10-25% AIDS</i>	<i>25% AIDS</i>
<i>26-50% AIDS</i>	<i>50% AIDS</i>
<i>51-75% AIDS</i>	<i>75% AIDS</i>
<i>76-100% AIDS</i>	<i>100% AIDS</i>



FY14 AIDS Portfolio Review

- Purpose: OAR and a small panel of IC scientific staff will conduct an AIDS portfolio review of all grants, contracts, and intramural projects scheduled to recompete in FY16
- Outcome - Identify projects that are “low priority” research; these projects will not be supported with AIDS dollars when they recompete in FY16 -- or are considered for funding after most recent BSC review for intramural projects. Funds identified will go into a common high AIDS relevance pool.
- Results of portfolio review will be presented at ACD meeting on December 10-11, 2015



New OAR Processes in FY 2016

- Revision of CSR Referral Guidelines and restructuring of AIDS IRG study sections
- Review of FOAs – OAR will review draft FOAs and RFPs to ensure that these are properly aligned
- Following the FY16 Appropriation, OAR in consultation with NIH Director may utilize its 3% transfer authority to transfer AIDS funds between ICs
- OAR will require that all new and competing renewal projects (grants, contracts, intramural projects) are aligned with the highest overarching AIDS priorities
- All new and competing renewal projects will be pro-rated on the basis of their AIDS proportion



FY 2016 3rd and 4th Quarter Review and Analysis

- Goal: Ensure all projects are aligned with the highest priorities and appropriately coded by Strategic Plan code and SIC code
- OAR scientific staff members review coding of all new projects reported into the ARIS to ensure appropriate coding
- OAR staff members work with ICs to resolve any issues of matching to priorities and coding



FY 2017 Trans-NIH AIDS Budget

- OAR will provide guidance shortly for development of the IC AIDS Budget Submissions
- Each new, recompeting, and expanded initiative must be aligned to one or more of the overarching AIDS research priorities
- OAR will develop the NIH AIDS Budget in consultation with the NIH Director
- OAR will provide each IC with a list of the initiatives that will be supported and the AIDS funding level





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