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 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
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


- 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 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

- Reducing incidence of HIV/AIDS including:
  - developing/testing of promising vaccines,
  - developing/testing of microbicide and PrEP candidates and methods of delivery, especially those that mitigate adherence issues,
  - developing/testing and implementing strategies to improve HIV testing and entry into prevention services,
  - strategies to improve HIV testing, and entry into treatment.
High Priority Research Areas For Use of AIDS Funds (continued)

- Next generation of HIV therapies with better safety and ease of use including: developing and testing HIV treatments that are less toxic, longer acting, have fewer side effects and complications, and easier to take and adhere to than current regimens. Additionally, implementation research to ensure initiation of treatment as soon as diagnosis has been made, retention and engagement in these services, and achievement and maintenance of optimal prevention and treatment responses.
High Priority Research Areas For Use of AIDS Funds (continued)

- Research toward a cure including: developing novel approaches and strategies to identify and eliminate viral reservoirs that could lead toward a cure or lifelong remission of HIV infection, including studies of viral persistence, latency, reactivation, and eradication.

- HIV-associated comorbidities, coinfections, and complications including: addressing the impact of HIV-associated comorbidities, including TB, malignancies; cardiovascular, neurological, and metabolic complications; and premature aging associated with long-term HIV disease and antiretroviral therapy.
High Priority Cross-Cutting Areas

- 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., 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)
Pro-rating Projects with AIDS and Non-AIDS components

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FY14 AIDS Portfolio Review

- **Charge:** In August 2015, Dr. Collins charged the Acting OAR Director with conducting a portfolio review to assess the extent to which the current AIDS research program is aligned with the new overarching HIV/AIDS research priorities.

- **Approach:** All grants and contracts supported with AIDS dollars in FY 2014 and eligible to recompete in FY 2016 were assessed in this evaluation. Investigator-initiated intramural projects funded in FY14, reviewed by IC’s BSC in FY15, and awaiting a FY16 funding decision were included in the portfolio review.

- **Timeframe:** Portfolio review was conducted from August through November 2015. Results presented to ACD meeting on December 11, 2015.
Scope of Portfolio Review

- In FY 2014, the NIH AIDS research budget totaled $2.98B representing 5,243 unique extramural grants, 435 intramural projects, and 68 contracts.
- Approximately $435.65M of these funds were eligible to recompete in FY 2016 including:
  - 1207 extramural projects (totaling $407.41M);
  - 56 intramural projects (totaling $21.35M); and
  - 11 contracts (totaling $6.89M).
Results from the OAR FY 2014 Portfolio Review
Extramural Portfolio

- Of the 1207 extramural projects, representing $407.41M:
  - 832 projects (69%) totaling $300.73M were rated as high priority;
  - 133 projects (11%) totaling $41.46M were rated as medium priority; and
  - 242 projects (20%) totaling $65.22M were rated as low priority.

- Low priority projects included studies on basic virology and immunology, genomics, infectious pathogens outside of the context of HIV; and training projects with no indication of an AIDS component.
Intramural Portfolio

- A total of 56 intramural projects (totaling $21.35M) were funded in FY14, reviewed by the IC’s BSC in FY15, and pending a funding decision in FY16.

- Of the total 56 intramural projects,
  - 18 projects (32%) totaling $10.07M were rated as high priority
  - 12 projects (21%) totaling $4.67M were rated as medium priority
  - 26 projects (47%) totaling $6.60 M were rated as low priority

- Low priority projects included studies on: basic research, pathogenesis and treatment of infectious pathogens not in the context of HIV (i.e., Chlamydia, Cryptococcus, Neisseria gonorrhea, hepatitis viruses and fungal infections); basic studies on tumor immunology and genetics, T cell development, autoimmunity and cancer; and evaluation of biological and behavioral effects of drug dependence and treatment with no AIDS component.
Common High AIDS Relevance Pool

- Funds from low priority grants and contracts identified in FY14 AIDS portfolio review transferred from ICs into common pool totaling ~$65M

- All ICs were eligible to submit proposals for common pool funds by 1/19/16; funds will be transferred to ICs by 3/1/16 and will remain in IC’s AIDS commitment base until project recompetes

- Funds from low priority Intramural Research Projects are allowed to continue to support projects in FY16, but will be supported with non-AIDS dollars in FY17 and beyond unless PI realigns project to high priority AIDS research
New OAR Processes in FY 2016

- Revision of CSR Referral Guidelines and restructuring of AIDS IRG study sections
- Review of FOAs – OAR reviews draft FOAs and RFPs to ensure that these are properly aligned
- Following the FY16 Omnibus Bill, OAR in consultation with NIH Director utilized its 3% transfer authority to transfer AIDS funds between ICs
- OAR reviews and approves all new and competing renewal projects (grants, contracts, intramural projects) to ensure they are aligned with the highest AIDS priorities
- OAR Discretionary Funds used to support only peer reviewed grants, contracts, and IRPs
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 provided guidance 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 developed the NIH AIDS Budget in consultation with the NIH Director
- OAR ensures that ICs’ proposed initiatives are aligned with the NIH priorities consistent with their AIDS funding levels
NIH... Turning Discovery Into Health