

NIH HIV/AIDS Research Priorities

Presentation to Advisory Committee to the Director

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Scientific Opportunities

- Recent advances in our understanding of HIV pathogenesis, immune dysfunction, and viral reservoirs from the fields of immunology, virology, genomics, and structural biology are leading to unprecedented scientific opportunities with potential for developing successful AIDS vaccines, improved therapeutic strategies to treat HIV disease, and an eventual cure for HIV/AIDS.
- It is critical that NIH, as the world's leading public agency supporting HIV/AIDS research, ensures that AIDS-designated dollars are funding the highest HIV/AIDS research priorities.



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

It is 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.



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 re compete 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 to be presented to ACD meeting on December 11, 2015.



Methodology

- Using the new overarching priorities as guidelines, OAR senior scientific staff and a small panel of IC extramural and intramural scientific staff independently assessed each project—reviewing initial project aims/goals, recent progress reports, and publications—and assigned each a rating of high, medium, or low priority for determining AIDS funding.
 - Each project was reviewed and rated by 3 individuals
 - Final rating was determined by majority rating
- ICs were provided the preliminary list of low priority projects for discussion with OAR
- Final determinations were made by Acting OAR Director based on all available data
- ICs will be provided with final list of low priority projects



Primary Outcomes

Primary outcomes of the portfolio review:

- Rating of each project as either high, medium, or low priority
- Identification of total amount of funds that could be redirected from low priority projects that will not be supported with AIDS dollars when they recompile in FY16
- Funds identified from the low priority projects will go into a common high AIDS relevance pool to support overarching HIV/AIDS priority projects



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)



Portfolio Review Overall Approach

FY 2014 HIV/AIDS Project Review and Decision Flow Chart



Pro-rating Pilot Feasibility Exercise

- In preparation for a trans-NIH approach to pro-rating projects involving partial support with AIDS dollars, OAR developed a draft guidelines document
- A sample (N=256) of the FY14 extramural projects rated high and medium priority were re-assessed by the OAR and IC reviewers to determine the feasibility of using this guidance to assign an appropriate level of prorating (0%, 25%, 50%, 75%, 100%)
- Each project was assessed by 3 reviewers



- 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.



Contract Portfolio

- 11 contracts or task orders, totaling \$6.89M were eligible to re compete in FY 2016
- 1 contract/task order (totaling \$1.26M) was deemed low priority.



Findings from Pro-Rating Pilot Feasibility Study

- Results of this pilot suggested that the draft guidelines alone are not sufficient for determining an appropriate pro-ration level for individual projects.
 - Reviewers' pro-ration levels varied significantly within projects.
 - Pro-rating was highly subjective
- Pro-rating guidelines should be further developed with additional input from and discussion among ICs and the OAR.



Overall Conclusions

- The portfolio review process using the overarching priorities and new guidelines for determining use of AIDS funds can successfully differentiate the relevance of AIDS projects and identify projects that are no longer a priority for support
- Panels of OAR and IC scientific staff can independently assess an extensive and complex portfolio of AIDS projects with a high level of concordant priority ratings of projects
 - A level of subjectivity in assessing projects is inevitable but can be balanced by engaging multiple reviewers
- Implementing a feasible pro-rating scheme will require further input from the ICs and refinement of the process



Recommendations

- Conduct a similar annual portfolio review over the next 3-4 years to further focus the NIH HIV/AIDS research program to be aligned with the new overarching priorities.
 - Include a more comprehensive review of the intramural program.
- Consider revising the priorities in FY 2017 (and subsequent years) to reflect emerging scientific opportunities, changing dynamics of the epidemic, and most recent scientific findings/advances.
- Clearly communicate the NIH HIV/AIDS research priorities and portfolio review processes to the scientific community, research advocates, and other stakeholders.
- Further refine trans-NIH pro-rating guidelines through close collaboration between OAR and the ICs in order to implement them in FY 2017.





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