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

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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.

The NIH supports a comprehensive portfolio of biomedical, behavioral, and social science research on HIV and its associated coinfections, comorbidities, and other complications. The Office of AIDS Research (OAR), a component of the NIH Office of the Director, is legislatively mandated to coordinate, plan, evaluate, and budget for the NIH AIDS research program. Building on the most recent scientific progress and scientific opportunities to most likely contribute to ending the AIDS pandemic, developing a cure for HIV/AIDS, and achieving an AIDS-free generation, NIH has identified the highest HIV/AIDS research priorities for the next 3-5 years. NIH will use these guidelines to ensure that AIDS resources are supporting the highest HIV/AIDS research priorities. The overarching NIH HIV/AIDS research priorities are: 1) research to reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines; 2) development of the next generation of HIV therapies with improved safety and ease of use; 3) research towards a cure for HIV/AIDS; and 4) HIV-associated comorbidities and co-infections. Basic research, health disparities, and training that cross-cut these priorities also will be supported. These priorities were informed by the OAR Advisory Council’s recommendations, the Annual Trans-NIH Plan for HIV-Related Research, and input from NIH leadership. Implementation of these priorities will begin with fiscal year 2016 funding of HIV/AIDS research.

The NIH has developed a series of guidelines for determining whether a research project has a high-, medium-, or low-priority for receiving AIDS-designated funding. These guidelines do not assess/determine the scientific and technical merit of a project only the priority for receiving AIDS-designated funds. A description of these priority topics and examples of each are provided below.

High Priority topics of research for support using AIDS-designated funds

- Reducing Incidence of HIV/AIDS including: developing and testing promising vaccines, developing and testing microbicide and pre-exposure prophylaxis candidates and methods of delivery, especially those that mitigate adherence issues; and developing, testing, and implementing strategies to improve HIV testing and entry into prevention services.
- 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.

- 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 tuberculosis, malignancies; cardiovascular, neurological, and metabolic complications; and premature aging associated with long-term HIV disease and antiretroviral therapy.
- Cross cutting areas: Basic research, health disparities, and training including:
  - Basic Research: understanding the basic biology of HIV transmission and pathogenesis; immune dysfunction and chronic inflammation; host microbiome and genetic determinants; and other fundamental issues that underpin the development of high priority HIV prevention, cure, co-morbidities, and treatment strategies.
- Research to Reduce Health Disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS.
- Research Training of the workforce required to conduct High Priority HIV/AIDS or HIV/AIDS-related research.

**Medium Priority topics of research for support using AIDS-designated funds include projects that demonstrate HIV/AIDS is a meaningful component of the project and/or knowledge about HIV will be enhanced by the project, as evidenced in the specific aims.**

Several examples of research that could be considered as Medium Priority include:

- The project examines a fundamental scientific question (or questions) that has a clear or potential link to HIV/AIDS;
- The 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;
- The project addresses health and social issues that are clearly linked with HIV (transmission/acquisition, pathogenesis, morbidity and mortality, stigma) and examines them in the context of HIV (i.e., in populations or settings with high HIV prevalence or incidence), such as other infectious pathogens and diseases, non-infectious pathogens and diseases, substance use/addiction, and mental health disorders;
- The project meaningfully includes HIV/AIDS (or SIV) outcomes/endpoints; or
- The results of the project 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 topics of research will not be supported with AIDS-designated funds;** however, highly meritorious projects could be eligible for support with non-AIDS funds by an NIH Institute or Center. Several examples of research that will be considered Low Priority include:

- Research on 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 research 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 including - 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; or studies on co-morbidities of general relevance, but not in the context of HIV (e.g., diabetes, lipid defects, endocrinology);
• Data analysis and systems tools that are not HIV-related, e.g., genomics studies of little or no relevance to HIV; or
• Studies of behaviors (e.g., sexual activities, drug use activities) or social conditions 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.

Inquiries

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