



Fiscal Year 2018

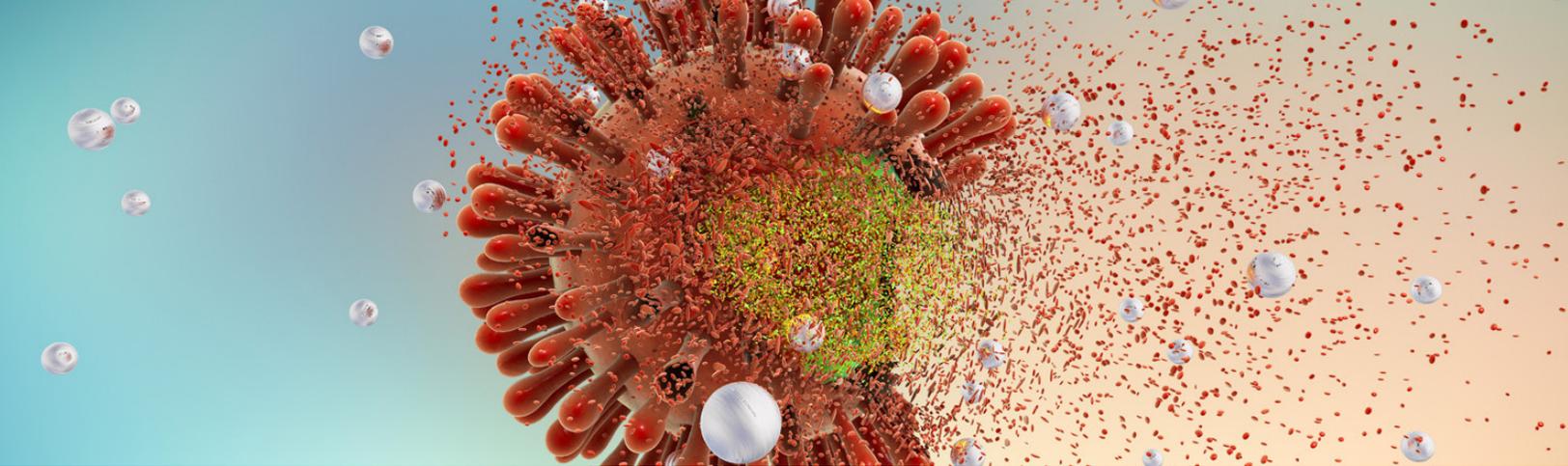
# Trans-NIH HIV/AIDS Professional Judgment Budget

Prepared by the Office of AIDS Research, National Institutes of Health



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## Racing Toward the End of the Epidemic

The sustained U.S. commitment to HIV research has produced unprecedented scientific discovery and breakthrough in just three decades. Identification of the virus causing AIDS and development of anti-retroviral therapies (ART) have radically altered the landscape by offering long-term disease management and a reduction of perinatal transmission of HIV by more than 90 percent in the United States since the early 1990s.

In recent years, research discovered that certain ART medications are highly effective in preventing HIV infection when used as pre-exposure prophylaxis, or PrEP, in people at risk of acquiring HIV. We have seen a reduction in transmission of up to 93 percent in some high-risk populations on PrEP. More research is needed to consistently achieve these rates among all high-risk populations.

NIH's investment in HIV/AIDS research has produced critical scientific accomplishments that benefit Americans at high risk of HIV or living with HIV. In addition, HIV research funds have advanced fundamental understanding of immunology, virology, microbiology, molecular biology, and the impact of genetics on human health. Safe blood banks for Americans in need of transfusions, a cure for hepatitis C, and recent breakthroughs in treatments for leukemia have all been achieved in part by scientific discoveries related to HIV research.

The NIH is proud of the scientific progress made as a result of the Trans-NIH HIV research investment. We have worked with the scientific community, people living with HIV, advocates, industry, policy makers, and other stakeholders to set the scientific priorities that will lead to an end to the epidemic.

Although we have come a long way, much work remains to be done. In the United States, 1.1 million people are living with HIV and approximately 108 new diagnoses of HIV infection are made daily.<sup>1</sup> Tremendous health disparities exist among different populations and in various parts of the country. Only slightly more than half (53%) of people living with HIV (PLWH) globally are on ART.<sup>2</sup> Maternal-to-infant transmission remains a critical issue in resource-limited settings.

## Racing Toward the End of the Epidemic (continued)

As treatments have extended the lifespan of PLWH, many are confronting significant side effects of ART, as well as complications of aging coupled with HIV. Often, the combination of HIV, ART, and/or aging further compounds the health impact of each individual condition. Further research is needed to understand these interactions and to develop effective treatments as well.

Strategies for effective vaccines and a cure remain elusive. Sustained resources adjusted for inflation are needed to ensure future discoveries in HIV that will lead to zero new infections and sustained remission.

Yet HIV research funding has remained flat for more than a decade, hindering scientific advancement. Despite careful management of funds, the NIH is unable to fund all promising proposals—even some that offer truly innovative approaches.

The current budget limits OAR's ability to fulfill its vision: To advance research to end the HIV epidemic and improve the health of people living with HIV.

An increase for HIV research of 15 percent above enacted FY 2017 levels would provide needed funding to meet NIH's goals. The proposed level will enable the NIH to fund research directed toward new treatment modalities, novel biologics for reducing incidence of HIV, and addressing comorbidities of aging with HIV. The NIH will continue to build on scientific progress and push for discovery and breakthroughs, including in vaccine and research towards a cure.

I am inspired daily by the commitment of NIH staff and researchers in the field who do the important work that will bring us to the end of the HIV epidemic. We appreciate the partnerships across the scientific community, with people living with HIV, and with other stakeholders. There is still much work to be done to achieve a Nation free of HIV.



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Director, Office of AIDS Research

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## Snapshot of the Epidemic

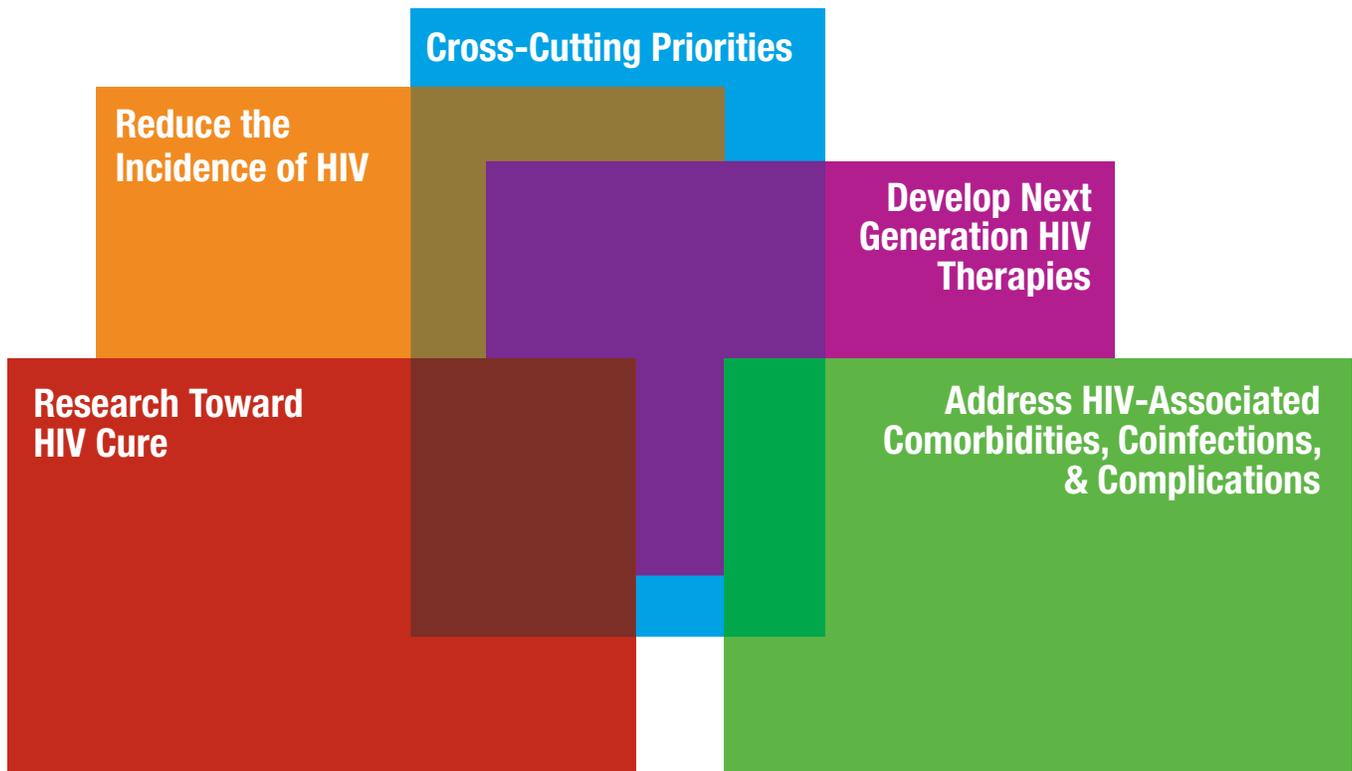
In the United States, there were new HIV diagnoses in every state in 2015.<sup>3</sup> According to the Centers for Disease Control and Prevention (CDC)<sup>1</sup>:

- **Approximately 1.1 million people** in the United States are living with HIV.
- **More than 39,000 people** in the United States were diagnosed with HIV in 2015.
- **Some populations have higher rates of HIV<sup>3</sup> infection:**
  - **Although 37 percent of the U.S. population lives in the South**, more than half of new diagnoses (52%) and deaths (49%) among persons diagnosed occur in the South.
  - **African Americans comprise** 12 percent of the total U.S. population, yet were 45 percent of new HIV diagnoses.
  - **Latino men and women**, comprising 18 percent of the population, were 24 percent of all new HIV diagnoses.
  - **Youth ages 13 to 24** accounted for 22 percent of all new HIV diagnoses.
- **45 percent of PLWH** are over the age of 55 and are more likely to face comorbidities of HIV, aging, and/or complications of treatment.

The United Nations General Assembly declared the AIDS pandemic “a global emergency and one of the most formidable challenges to human life and dignity. . . which undermines social and economic development throughout the world and affects all levels of society—national, community, family, and the individual.” According to UNAIDS, in 2016<sup>4</sup>:

- **36.7 million people globally** were living with HIV.
- **1.8 million people** were newly infected with HIV.
- **Approximately 1 million people** died from AIDS-related illnesses.
- **Only 19.5 million people**, slightly more than half (53%) of those living with HIV, were using ART.
- **In 2015, 1.8 million children under 15** years of age were living with HIV worldwide.
- **An estimated 150,000 children** acquired HIV globally in 2015.<sup>5</sup>

# NIH HIV Research Priorities



## Reduce the Incidence of HIV

- Develop Vaccines
- Pre-exposure Prophylaxis Including Microbicides
- HIV Testing
- Treatment as Prevention
- Implementation Strategies

## Develop Next Generation HIV Therapies

- Less Toxic and Longer Lasting Treatment
- Discover Novel HIV Targets & Inhibitors
- Novel Immune-Based Therapies
- Engagement, Adherence, and Retention in Care

## Research Toward HIV Cure

- Sustained Viral Remission
- Viral Eradication
- Viral Latency and Sanctuaries

## Address HIV-Associated Comorbidities, Coinfections, & Complications

- Co-Infectious Diseases
- Neurologic Complications
- Metabolic Disorders
- Malignancies
- Cardiovascular Complications
- Premature Aging and Frailty

## Cross-Cutting Priorities

- Basic Research
- Health Disparities Research
- Training Research
- Behavioral and Social Sciences Research
- Information Dissemination
- Epidemiology



## Accomplishments of HIV/AIDS Research

The NIH's overarching HIV/AIDS research priorities have been developed to ensure the highest levels of innovation and to engender the best health outcomes by reducing incidence and fostering cross-cutting research. Since the beginning of the epidemic, the NIH has moved quickly to address the critical scientific questions needed to save lives and prevent transmission of this deadly virus. The NIH investment in AIDS research has resulted in scientific accomplishments that benefit the 37 million PLWH globally, as well as contribute to the prevention, diagnosis, and treatment of many other diseases and conditions.

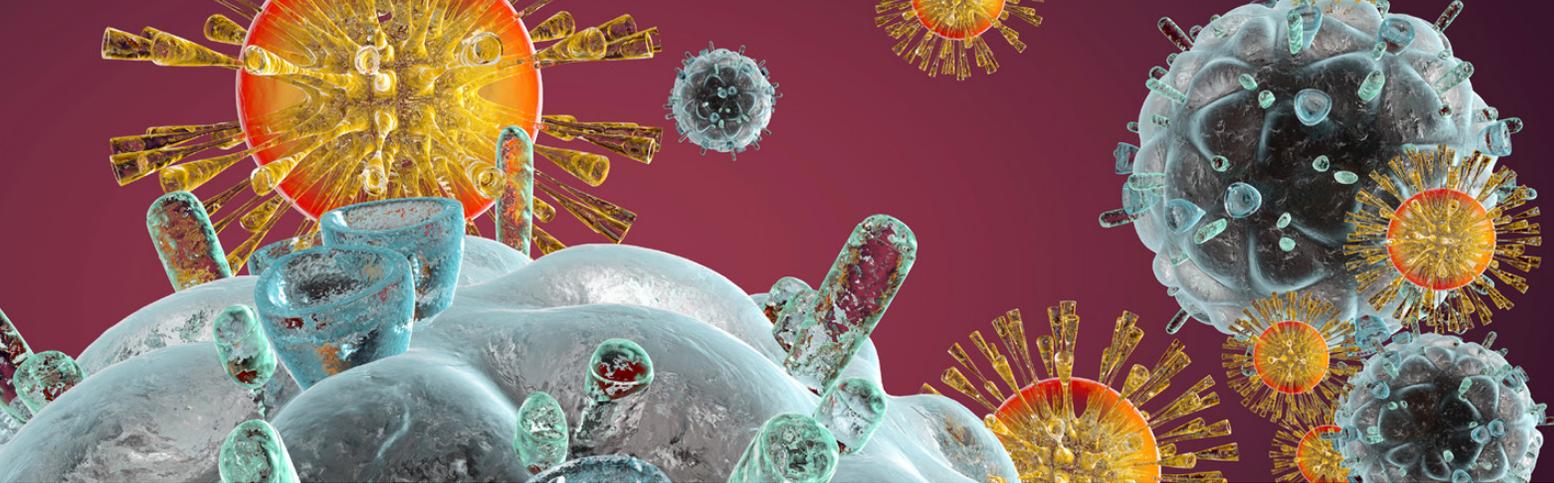
NIH-funded HIV research successes include:

- Significant understanding of the biology, transmission, and pathogenesis of HIV
- Combination treatment regimens that durably suppress HIV replication
- Treatment as prevention (TasP): PLWH who are durably suppressed have a negligible risk of transmitting HIV to their HIV-negative sexual partners
- Accurate diagnostics to identify new infections and drug resistance
- Non-vaccine prevention regimens: pre-exposure prophylaxis (PrEP)

Millions of lives have been saved because of these advances. More than 19 million people around the world are now accessing ART and non-vaccine prevention modalities as a result of the HIV research investment.

Furthermore, there are currently promising studies of new advances with potential for significant impact on the prevention, treatment, and care of HIV/AIDS:

- A large clinical trial is testing whether an experimental vaccine regimen safely prevents HIV infection among South African adults.
- The discovery of broadly neutralizing antibodies against HIV represents a significant advancement with the potential to develop an array of new tools, including long-acting treatment and prevention modalities, as well as novel vaccine strategies.
- Long-acting formulations for treatment and PrEP are in active development and are likely to have significant impacts on adherence to treatment and prevention regimens alike.



## Challenges and Threats to Scientific Advancement

Although much progress has been made, major challenges threaten the advances to date. The complexity of HIV infection has precluded the development of an effective vaccine to prevent new infections or a cure for those who are infected. Current ARTs are effective at suppressing viral replication, but require lifelong treatment with associated toxicities and costs. Innovative behavioral and social sciences research is essential to understand and address the diverse needs of high-risk populations to ensure uptake and adherence to prevention and treatment regimens.

Recent findings also indicate that even with antiviral treatment, the inflammatory consequences of HIV infection continue to cause diseases that result in poorer health outcomes for PLWH. PLWH often experience comorbidities and coinfections as result of their HIV infections. With aging, PLWH are more likely to develop cancer, cardiovascular disease and neurological complications than people who do not have HIV. Basic and translational research to understand the genesis of these diseases in PLWH is critical to improve health outcomes.

PLWH are also more likely to develop active tuberculosis (TB) disease because of HIV-caused immune deficiency. In 2014, TB resulted in 390,000 deaths among PLWH and is the leading cause of death among those with HIV infection. HIV coinfection also can complicate treatment of TB and vice-versa. Increased research to prevent, diagnose, and treat TB in PLWH is urgently needed.

The growing epidemic of opioid misuse and addiction is one of the largest public health threats to the United States today. In 2015, about 10 percent of new HIV infections were attributed to injection drug use. If current trends continue, 1 in 23 women who inject drugs and 1 in 36 men who inject drugs will be diagnosed with HIV in their lifetime.<sup>1</sup> Multidisciplinary research across the NIH is needed to address the intersecting epidemics.



## Challenges and Threats to Scientific Advancement

Continued research is needed to address the gaps and challenges that hinder progress:

- Lack of an effective preventive vaccine
- Lack of a cure for HIV infection
- Ongoing transmission of HIV infection and the expansion of the U.S. epidemic in the South, particularly in rural areas
- Domestic and international expansion of the epidemic, particularly in young populations
- Disparities in prevention and treatment in high-risk populations
- Increased risk of comorbidities and co-infections among PLWH on treatment

In the face of significant challenges, the current NIH portfolio represents a rich cache of scientific investments that have the potential to dramatically change the trajectory of the HIV epidemic. OAR anticipates emerging HIV/AIDS research opportunities, such as discovery of novel mechanisms of viral-host interactions to guide translation into 21st century biomedical approaches, accelerating discovery for vaccines and viral suppression, and treatment and management of major comorbidities and coinfections.

The requested budget will enable the NIH to reap the returns on its past investments in HIV research. Staying the course of the NIH HIV research agenda will also enable full realization of discoveries which have the potential to benefit the health of many and significantly impact the epidemic's trajectory in the race to a Nation free of HIV.

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# Policy

## FY 2018 Trans-NIH HIV/AIDS Professional Judgment Budget

OAR is Congressionally mandated to develop an annual trans-NIH research budget. This budget estimate must be based solely on current research opportunities and the NIH HIV/AIDS research priorities. These priorities are established by the NIH in consultation with internal and external stakeholders.

The FY 2018 Trans-NIH HIV/AIDS Professional Judgment Budget request:

- Addresses critical scientific gaps across the priority areas,
- Capitalizes on emerging research opportunities by providing additional funding for newly identified areas of study, and
- Enhances the research foundation needed to implement the major goals of the National HIV/AIDS Strategy 2020 and the accompanying Federal Action Plan.

### Coordination With Other Federal HIV/AIDS Efforts

The [National HIV/AIDS Strategy for the United States \(NHAS\)](#), is a 5-year plan to guide the collective federal response to the HIV epidemic.<sup>6</sup> The 2015 updated NHAS charts a course of action across the federal government and society for moving closer to the vision of making new HIV infections rare in the United States. OAR's high-priority areas of HIV/AIDS research closely align with the goals stated in the NHAS:

- Reduce new infections
- Increase access to care and improve health outcomes for people with HIV
- Reduce HIV-related health disparities and health inequities
- Achieve a more coordinated national response to the HIV epidemic

## FY2018Trans-NIHHIV/AIDSProfessionalJudgmentBudget

The Professional Judgment Budget addresses intramural and extramural HIV/AIDS research, as well as funding for buildings and facilities, research training, and program evaluation. The budget supports a comprehensive research program, including basic, clinical, behavioral, social science, and translational research on HIV and its associated malignancies; and research relating to comorbidities, complications, and coinfections.

The FY 2018 Professional Judgment Budget estimate for the trans-NIH AIDS research program is \$3.45 billion, an increase of \$450 million, or 15 percent, above the FY 2017-enacted level. This request reflects the reallocation of resources to address only the highest priority HIV/AIDS research.

FY 2018 Trans-NIH HIV/AIDS Research Professional Judgment Budget by Research Priorities  
(U.S. dollars in thousands)

Research Priority	FY 2016 Actual	FY 2017 Enacted	FY 2018 Professional Judgment	FY 2018 +/- FY 2017	Change (%)
Reducing Incidence of HIV/AIDS	\$1,042,552	\$1,058,969	\$1,240,717	\$181,748	17.2%
Next Generation Therapies	478,335	484,988	490,704	5,716	1.2%
Develop a Cure for HIV/AIDS*	230,653	243,247	250,864	7,617	3.1%
Improve Treatments for HIV-Associated Comorbidities and Coinfections	564,094	538,573	678,189	139,616	25.9%
Crosscutting: Basic Research, Health Disparities, and Research Training, BSSR†	684,427	674,284	789,596	115,312	17.1%
<b>TOTAL</b>	<b>\$3,000,061</b>	<b>\$3,000,061</b>	<b>\$3,450,070</b>	<b>\$450,009</b>	<b>15.0%</b>

\*Beginning in FY 2017, Toward a Cure is a separate activity; the FY 2016 amount is comparable.

†Behavioral and Social Sciences Research.



## Conclusion and Looking Forward

The NIH's investment in HIV/AIDS research has produced significant scientific discoveries benefiting millions of people at risk of and those living with HIV. The investment has also opened the door to scientific discoveries in far ranging scientific fields.

This FY 2018 HIV/AIDS Professional Judgment Budget represents collaborative expertise among diverse stakeholders from across the country regarding the research priorities and investment of NIH HIV/AIDS resources. OAR is confident that the FY 2018 Professional Judgment Budget request provides the resources needed to accelerate the groundbreaking research discoveries that will end the HIV/AIDS epidemic.

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## References

- 1 CDC. "Diagnosis of HIV Infection in the United States and Dependent Areas, 2015." HIV Surveillance Report 2016:27.
- 2 UNAIDS 2016. [AIDS by the Numbers](#).
- 3 AIDSVu. Annual Release of New Maps and Resources. <https://aidsvu.org/launch2017/>
- 4 UNAIDS. Fact Sheet – Latest Statistics on the Status of the AIDS Epidemic. <http://www.unaids.org/en/resources/fact-sheet>
- 5 UNAIDS. Preventing mother-to-child transmission of HIV. [http://www.unaids.org/en/resources/presscentre/featurestories/2016/october/20161024\\_EMotherToChildT](http://www.unaids.org/en/resources/presscentre/featurestories/2016/october/20161024_EMotherToChildT)
- 6 NHAS. National HIV/AIDS Strategy: Updated to 2020. <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/nhas-update>

