

Fiscal Year 2019

Trans-NIH HIV/AIDS Professional Judgment Budget

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



National Institutes of Health
Office of AIDS Research

Front cover image: 3D structure of HIV-infected (blue, green) and -uninfected (brown, purple) T cells interacting. One cell (brown) has wrapped an extension around its uninfected neighbor (purple) to reach an infected cell (blue). Data from focused ion beam scanning electron microscopy (FIB-SEM).

Credit: Donald Bliss, National Library of Medicine; Sriram Subramaniam, National Cancer Institute, National Institutes of Health

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A long filopodial extension connects an uninfected T cell (blue) and an HIV-infected T cell (yellow). Data from focused ion beam scanning electron microscopy (FIB-SEM). Credit: Donald Bliss, National Library of Medicine; Sriram Subramaniam, National Cancer Institute, National Institutes of Health

Unlocking the Answers

As a result of the American people's investment in HIV research, more than 30 highly effective medications—when used in appropriate combinations—are now available to enable people with HIV (PWH) to achieve durable suppression of the virus. PWH who are durably suppressed have a negligible risk of transmitting HIV to their HIV-negative sexual partners, a benefit known as “treatment as prevention.” Furthermore, pre-exposure prophylaxis (PrEP) medication is highly effective in preventing HIV infection in those who use it correctly and consistently.

HIV research has changed the trajectory of the pandemic, but has not yet stopped its progression. In the United States, there are approximately 1.2 million PWH and 108 diagnoses of HIV are made daily.¹ Unequal access exists among various populations and in different parts of the country. Only slightly more than half (53%) of the nearly 37 million PWH globally are on antiretroviral therapy (ART).²

The NIH Office of AIDS Research (OAR) coordinates the federal government's investment in HIV/AIDS research. OAR supports HIV research across nearly every NIH Institute and Center to advance scientific knowledge and help PWH live longer, more productive lives. OAR supports a broad research portfolio—including research to reduce the incidence of HIV; development of new therapies; research towards a cure; basic and social sciences research; and investigations to address coinfections, comorbidities, and complications faced by PWH.

OAR allocates funds to maximize the impact of the HIV investment and encourages collaboration across disciplines and among scientists. OAR works with researchers, nongovernmental organizations, PWH, and other stakeholders to establish research priorities and advance an agenda that meets the challenges of a changing pandemic.

This Professional Judgment Budget proposal outlines several areas where additional support will enable us to address critical gaps as we move toward an end to the pandemic.

An estimated 1.8 million new HIV infections occur annually worldwide. Reaching all those at risk with effective prevention and all those needing lifelong treatment has proven challenging with available tools. UNAIDS estimates that \$350 billion would be needed to implement an effective HIV prevention and treatment response in low- and middle-income countries from 2016 to 2030¹ alone.

Unlocking the Answers (continued)

As noted by Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), “Most of the major infectious diseases affecting humans—such as smallpox, polio, and yellow fever—have required effective vaccines for their control and in some cases elimination... An end to the HIV/AIDS pandemic will only be possible with the development of an effective HIV vaccine.”³

Studies currently underway may offer a path to such a vaccine. Furthermore, research into new, non-vaccine prevention modalities are needed as they could also yield dividends in reducing incidence. Despite the efficacy of PrEP, it is used by only about 10 percent of those who would benefit in the United States, and fewer globally.⁴ Additional research is needed to develop new prevention tools and strategies that will reduce the incidence of HIV.

Implementation research facilitates translation from scientific discovery into functional strategies that have an impact on public health. Implementation research can increase understanding and break down the barriers blocking more robust uptake of existing treatment and prevention modalities in all populations that could benefit.

As treatments have extended the lifespan of PWH, many are confronting coinfections associated with HIV, as well as complications of accelerated aging due to HIV. Further research is needed to understand these comorbidities, coinfections, and complications in PWH.

Strengthening our commitment to basic science remains an urgent need if we are to answer fundamental questions about HIV and develop new tools and strategies in all high-priority research areas.

What we do now will set the course for HIV research until 2030. A sustained, robust commitment is needed to get us to the end of the pandemic.



Maureen M. Goodenow, Ph.D.

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Snapshot of the Epidemic

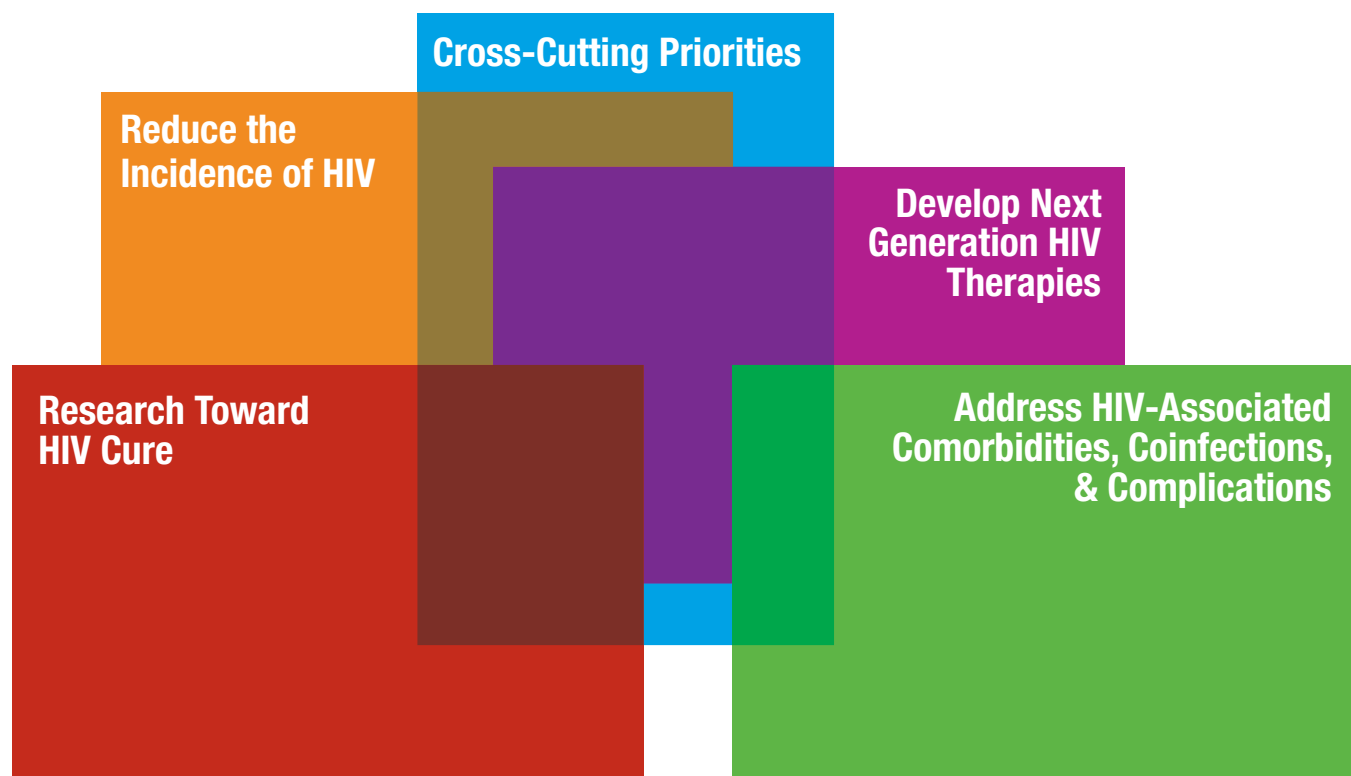
In the United States, there were new HIV diagnoses in every state in 2016. According to the Centers for Disease Control and Prevention (CDC):¹

- **Approximately 1.2 million people** in the United States are living with HIV.
- **More than 39,000 people** in the United States were diagnosed with HIV in 2016.
- **Some populations have higher rates** of HIV 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 44 percent of new HIV diagnoses.
 - **Latino men and women**, comprising 18 percent of the population, were 25 percent of all new HIV diagnoses.
 - **Youth ages 13 to 24 accounted for 22 percent** of all new HIV diagnoses.
- **45 percent of PWH** 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 the joint United Nations Programme on HIV/AIDS (UNAIDS), in 2016:⁴

- **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 160,000 children** acquired HIV globally in 2016.⁵

NIH HIV Research Priorities



Reduce the Incidence of HIV

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

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
- Epidemiology
- Implementation Strategies
- Training Research
- Behavioral and Social Sciences Research
- Information Dissemination



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 pandemic, 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 nearly 37 million PWH globally, as well as contribute to the prevention, diagnosis, and treatment of many other diseases and conditions.

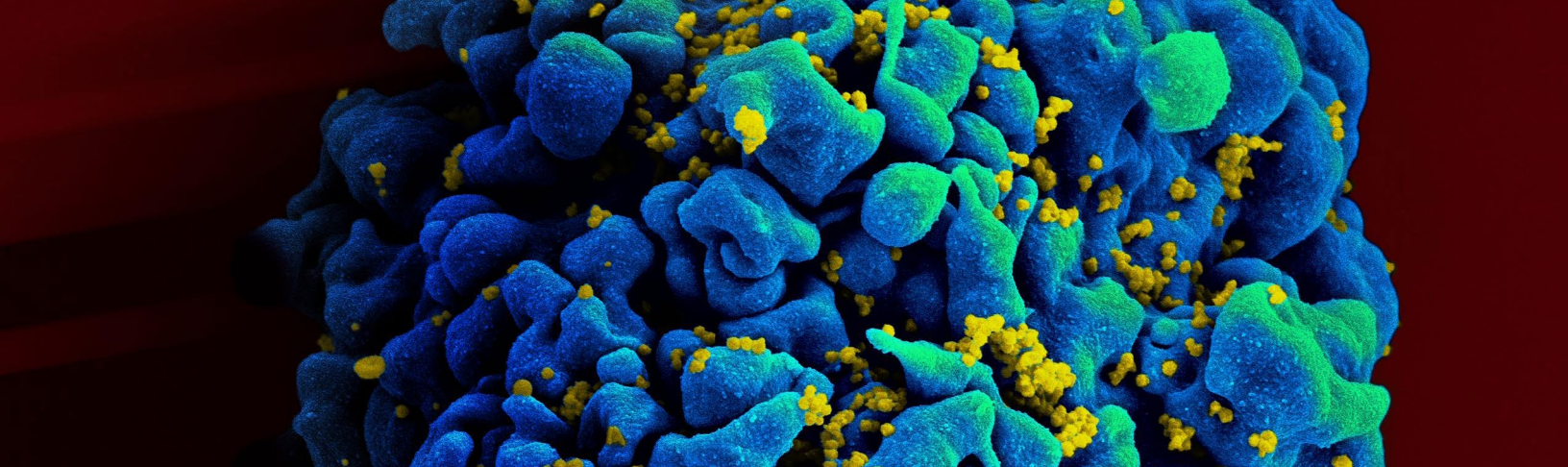
NIH-funded HIV research successes include—

- Significant understanding of the biology, transmission, and pathogenesis of HIV
- Combination treatment regimens that durably suppress HIV replication
- Treatment as prevention (TasP): PWH who are durably suppressed have a negligible risk of transmitting HIV to their HIV-negative sexual partners
- New diagnostics to identify rapidly new infections and drug resistance
- Non-vaccine prevention regimens: PrEP
- Improved strategies to prevent tuberculosis (TB) disease in PWH

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 because 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 (HVTN702, Imbokodo HVTN705).
- 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 (AMP).
- Implementation science studies to better understand how to increase uptake and adherence to PrEP and other HIV prevention approaches in young black men who have sex with men, the group with the highest number of new HIV diagnoses in the United States.
- Studies are underway to identify biomarkers and disease mechanisms for cardiovascular disease (CVD) in persons with HIV that can be used to determine who will benefit from early CVD prevention interventions.
- Long-acting formulations for treatment and PrEP are in active development and testing and are likely to have significant impacts on adherence to treatment and prevention regimens alike.



Scanning electron micrograph of an HIV-infected H9 T cell.
Credit: National Institute of Allergy and Infectious Diseases, National Institutes of Health

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. Combinations of 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 indicate that even with antiretroviral treatment, the inflammatory consequences of HIV infection continue to cause diseases that result in poorer health outcomes for PWH, who often experience comorbidities and coinfections as result of their HIV infections. With aging, PWH 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 PWH is critical to improve health outcomes.

PWH are more likely to develop active tuberculosis (TB) disease because of HIV-caused immune deficiency. In 2014, TB resulted in 390,000 deaths among PWH and is the leading cause of death among those with HIV infection. HIV coinfection can complicate treatment of TB and vice-versa. Increased research to prevent, diagnose, and treat TB in PWH 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.¹ Multidisciplinary research across the NIH is needed to address the intersecting epidemics.



Challenges and Threats to Scientific Advancement (continued)

Continued research is needed to address the gaps and challenges in the response to the epidemic:

- 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
- Barriers to uptake of prevention and treatment modalities in populations most affected by HIV
- Increased risk of comorbidities and coinfections among PWH on treatment
- Need for more investment in basic science to advance research to the next level

Further investment in basic science will help answer fundamental questions to address current challenges in HIV treatment, cure, and prevention. Improved understanding of the mechanisms underlying comorbidities, coinfections, and complications of HIV and the development of new interventions are needed to improve the health outcomes of PWH.

The NIH research portfolio addresses the full scope of research priorities and promises to advance scientific knowledge to end the pandemic and improve management of HIV-related conditions. A sustained commitment to the trans-NIH HIV/AIDS research agenda will ensure full realization of discoveries that have the potential to benefit the health of many PWH and significantly reduce new infections in the race to a Nation free of HIV.

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POLICY

FY 2019 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 2019 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 and highest priority 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.⁶ The NHAS 2017 Progress Report 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 inequities
- Achieve a more coordinated national response to the HIV epidemic

FY 2019 Trans-NIH HIV/AIDS Professional Judgment Budget (continued)

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 sciences, and translational research on HIV and its associated malignancies; and research relating to comorbidities, complications, and coinfections.

The FY 2019 Professional Judgment Budget estimate for the trans-NIH HIV/AIDS research program is \$3.45 billion, an increase of \$450 million, or 15 percent, above the FY 2018 enacted level. This request reflects the reallocation of resources to address only the highest priority HIV/AIDS research.

FY 2019 AIDS Professional Judgment Budget (Dollars in Thousands)

Research Priority	FY 2017 Actual	FY 2018 Enacted Level	FY 2019 Professional Judgment	FY 2019 +/- FY 2018	Percent Change
Reducing Incidence of HIV/AIDS	\$687,495	\$733,579	\$842,882	\$109,303	14.9%
Next-Generation Therapies	362,820	364,873	368,887	4,014	1.1%
Develop a Cure for HIV/AIDS	170,375	152,450	5,336	5,336	3.5%
Improve Treatments for HIV-Associated Comorbidities and Coinfections	556,608	574,882	676,061	101,179	17.6%
Cross-Cutting Basic Research, Health Disparities, Research Training, and BSSR ^a	1,222,763	1,174,277	1,404,454	230,177	19.6%
TOTAL	\$3,000,061	\$3,000,061	\$3,450,070	\$450,009	15.0%

^a 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 with HIV. The investment has opened the door to scientific discoveries in far ranging scientific fields.

This FY 2019 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 2019 Professional Judgment Budget request provides the resources needed to accelerate the groundbreaking research discoveries that will end the HIV/AIDS pandemic.

**The NIH's leadership and commitment
to build on scientific advances and
strategically allocate funds are essential to
bringing an end to the HIV pandemic.**



References

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- ⁴ UNAIDS. 2017. Fact Sheet. “Latest Statistics on the Status of the AIDS Epidemic.” <http://www.unaids.org/en/resources/fact-sheet>
- ⁵ UNAIDS. 2017. Fact Sheet. “World AIDS Day 2017: 2030—Ending the AIDS Epidemic.” http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf
- ⁶ U.S. Department of Health and Human Services. Office of HIV/AIDS and Infectious Disease Policy, on behalf of the National HIV/AIDS Strategy Federal Interagency Workgroup. 2018. *National HIV/AIDS Strategy for the United States: Updated to 2020—2017 Progress Report*. http://files.hiv.gov/s3fs-public/NHAS_Progress_Report_2017.pdf



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