

Fiscal Year 2020

NIH HIV/AIDS Professional Judgment Budget



Front cover image: 3-dimensional illustration of the HIV virus (purple) and antibodies (tan).

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Building Blocks to End the Epidemic

Scientists around the globe are working hard to develop new HIV prevention and treatment modalities. The advances and breakthroughs we continue to achieve depend on basic research and clinical research studies with participants who seek innovative strategies for themselves and others to prevent and treat HIV. The National Institutes of Health (NIH) is the largest funder of HIV/AIDS research globally and supports much of the research through the Office of AIDS Research (OAR). The OAR coordinates and manages HIV/AIDS research across the NIH Institutes and Centers. The OAR convenes stakeholders and subject-matter experts who help identify emerging areas of science and promising opportunities for further investment to address research gaps.

Although we have made significant progress in the fight against HIV in recent decades, critical work remains to prevent HIV, improve treatment, and find a cure. For example, lifesaving antiretroviral therapies (ART) have been developed, but nearly half of people with HIV (PWH) worldwide do not have access to ART and thus do not benefit from them. Although new HIV infections have declined overall, rates continue to rise in some regions and populations. In 2017, 1.8 million new infections were diagnosed globally.¹ Nearly 40,000 new infections were diagnosed in the United States in 2016. In the United States, new HIV diagnoses are increasing among African American and Hispanic/Latino men who have sex with men (MSM) and women, as well as among people ages 13 to 24 years.^{2,3}

Scientists continue to investigate promising new ART drugs that are less toxic and longer lasting. Making antiretroviral therapies more accessible may increase its uptake and reduce new infections, because PWH who become virally suppressed as a result of regular ART use as prescribed have no risk of sexually transmitting HIV to their HIV-negative partners.

In addition to research to improve treatment, scientists are developing new prevention tools, including HIV vaccines and monoclonal antibodies. Two major preventive HIV vaccine studies currently underway—HVTN 702 and HVTN 705—will produce results in 2020 and 2021, respectively. Although additional research will be needed, even a moderately effective vaccine would have the potential to considerably change the trajectory of the pandemic. There are two prevention studies that involve neutralizing antibodies: HVTN 703 with women in sub-Saharan Africa and HVTN 704 with men who have sex with men in South America and the United States. Both studies have demonstrated a 95 percent retention and high tolerability rates.

As a result of remarkable success in developing effective treatment and prevention strategies, PWH are living longer; nearly half of PWH in the United States are aged 50 years and older.^{2,3} Research to address the many health conditions and complications that PWH experience as they age—as well as the behavioral, social, and environmental factors affecting aging with HIV—will be critical to caring effectively for the growing population of older PWH.

Although we continue to achieve advancements in HIV research, stigma, discrimination, and health disparities persist as significant barriers for reaching people living with, at risk for, and

affected by the virus. In addition, the opioid crisis in the United States—rapid increases in the use of controlled prescription drugs, synthetic opioids, and heroin—has led to a rise in injection drug use, contributing to the spread of infectious diseases, including HIV. The challenges of opioid use have the potential to undermine the progress that has been made to stop HIV and control hepatitis C among people who use drugs.

Collaborations are essential to drive progress and find solutions for complex issues, such as ending new infections in the United States, the intersecting opioid crisis, aging with HIV, and co-occurring health conditions. The NIH supports the President’s strategy to stop the spread of HIV in the United States by 2030 with the goals of reducing infections by 75 percent within five years, then by 90 percent within 10 years.⁴ The OAR will work in a coordinated multi-HHS agency partnership focused on geographic hotspots and disproportionate occurrences of HIV and support the strategies across the federal government as outlined in the *National HIV/AIDS Strategy (NHAS): Updated to 2020*.⁵ The OAR is working with the National Institute on Drug Abuse to address challenges at the intersection of opioid misuse and HIV and is partnering with the National Institute on Aging to fund new research into neurocognitive disorders associated with both HIV/AIDS and aging, including Alzheimer’s disease. We are committed to catalyzing new partnerships for the advancement of scientific research needed to end the HIV pandemic.

The OAR develops an annual fiscal year (FY) HIV/AIDS Professional Judgment Budget proposal that highlights the accomplishments and progress in HIV research during the prior year and points to areas where additional investment will facilitate critical research. For FY 2020, the HIV/AIDS Professional Judgment budget requests \$457 million in additional funds, a 15 percent increase in HIV/AIDS research investment. Funding at this level would allow us to pursue emerging areas of HIV science and fully explore promising new approaches and investigations.

The NIH remains dedicated to supporting HIV research in the areas of greatest need and scientific promise—developing building blocks to a world free from HIV.

The OAR is aligned with, and committed to, partners across the federal government in support of the strategies outlined in the National HIV/AIDS Strategy: Updated to 2020.



A handwritten signature in blue ink that reads "Maureen M. Goodenow".

Maureen M. Goodenow, Ph.D.
NIH Associate Director for AIDS Research and
Director, Office of AIDS Research



Snapshot of the Epidemic

The United Nations General Assembly has 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...” According to the joint United Nations Programme on HIV/AIDS (UNAIDS), in 2017—¹

- **Approximately 36.9 million people globally** were living with HIV, including 1.8 million children younger than 15 years of age.
 - **An estimated 35.4 million people** had died from AIDS-related illnesses since the start of the pandemic, including one million in 2017.
 - **1.8 million people** were newly infected with HIV.
 - **About 21.7 million (58 percent) PWH** were using ART, while more than 15 million were not.
- Some populations had higher rates of HIV infection:
 - **Youth ages 13 to 24 years** accounted for 21 percent of all new HIV diagnoses.
 - **Gay and bisexual men**, particularly those who are Black/African American or Hispanic/Latino, remained the group with the most new diagnoses, accounting for 67 percent (26,570) of all HIV diagnoses.
 - **Women accounted for 19 percent** of new HIV diagnoses in the United States.
 - **Approximately 17 percent** of new HIV diagnoses were among people age 50 years and older.

According to the CDC, in 2017—

In the United States, the Centers for Disease Control and Prevention (CDC) reported new HIV diagnoses in every state and higher rates of diagnoses among certain populations in 2016—^{2,3}

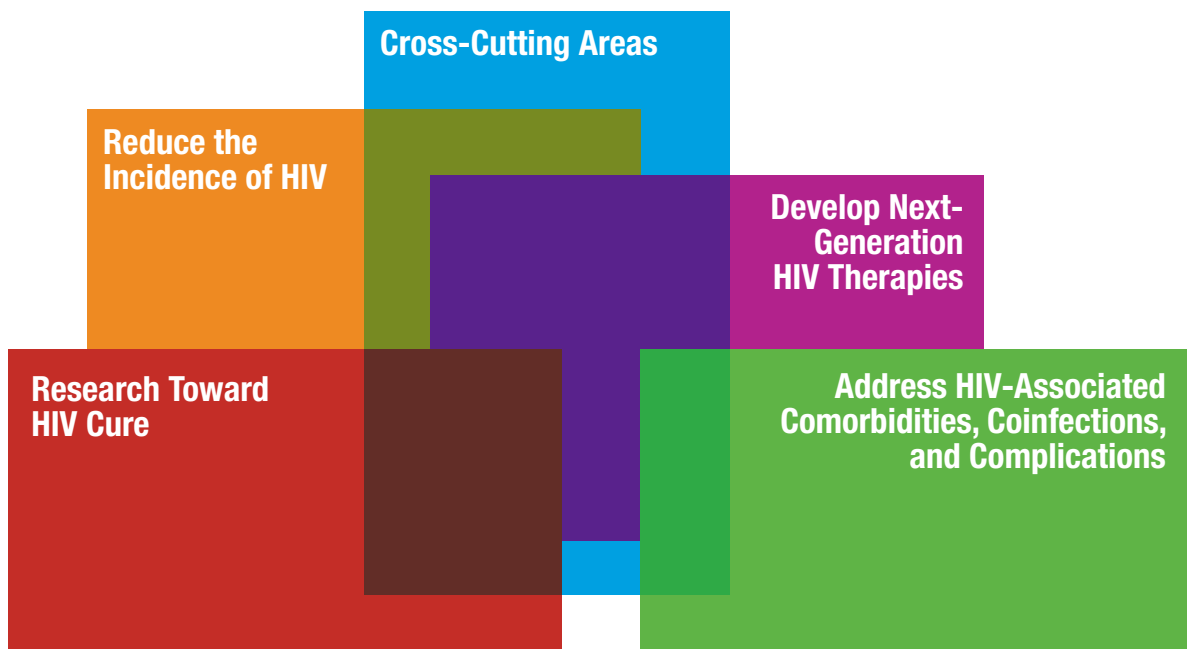
- **More than 1.1 million people** were living with HIV.
 - **Almost 40,000 people** were diagnosed with HIV.
- **More than half of the new diagnoses (52 percent)** occurred in the South.⁶
 - **Approximately six percent of new HIV diagnoses involved injection drug use.** Among all PWH, about three percent reported using injection drugs.⁷
 - **More than 50 percent of new HIV diagnoses occurred in only 48 counties**, Washington, D.C., San Juan, Puerto Rico, and seven states with substantial rural epidemics.⁸

NIH Priorities for HIV and HIV-Related Research

The Office of AIDS Research (OAR) oversees, coordinates, and manages NIH HIV-related research. The OAR works across the NIH and with partners and stakeholders including the scientific community, people with HIV, and nongovernmental groups to establish the scientific research priorities for the global fight against HIV. The current research priorities were developed in 2016 for three to five years based on data on the pandemic and the science to prevent, treat, and ultimately cure HIV.

The research priorities outline the NIH's broad HIV/AIDS research agenda, guide decision-making processes related to HIV funding, and inform the development of the NIH Strategic Plan for HIV and HIV-Related Research. The OAR ensures that research funds are invested in the areas of highest scientific priority.

The graphic below provides information on each priority area and illustrates how the research priorities are interrelated.



Reduce the Incidence of HIV

- Vaccines
- Pre-exposure Prophylaxis
- Microbicides and MPTs
- HIV Testing
- Treatment as Prevention
- Monoclonal Antibodies

Research Toward HIV Cure

- Sustained ART-free Viral Remission
- Viral Eradication
- Viral Latency and Sanctuaries
- Cure Ethics and Acceptability

Cross-Cutting Areas

- Basic Virology and Immunology
- Behavioral and Social Sciences Research
- Epidemiology
- Health Disparities
- Information Dissemination
- Implementation Science
- Research Training, Infrastructure, and Capacity Building

Develop Next-Generation HIV Therapies

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

Address HIV-Associated Comorbidities, Coinfections, and Complications

- Coinfections
- Neurologic Complications
- Malignancies
- Cardiovascular Complications
- Mental Illness and Substance Use
- Metabolic Disorders
- Across the Lifespan



Accomplishments of HIV/AIDS Research

Since the discovery more than three decades ago that HIV was the virus causing AIDS, a devastating immune deficiency disease, HIV has been transformed from a rapidly fatal condition to a manageable chronic illness. Such a remarkable achievement is due in large part to NIH's significant investments in scientific research that continues to produce groundbreaking discoveries and advances in our understanding of HIV and has contributed to the prevention, diagnosis, and treatment of HIV.

NIH-funded HIV research successes include—

- Combination ART regimens that enable PWH to achieve undetectable viral loads and allow them to lead longer, healthier lives.
- Triple-drug ART regimens that significantly prevent HIV transmission from mothers with HIV to their infants during pregnancy and breastfeeding.
- Nonvaccine prevention strategies, such as pre-exposure prophylaxis (PrEP) to reduce the risk of HIV transmission or postexposure prophylaxis (PEP) to protect people from acquiring the virus after a one-time exposure to HIV.
- Treatment as prevention with ART, which enables PWH to achieve undetectable viral loads and thereby have no risk of transmitting HIV to their uninfected sexual partners—also known as Undetectable = Untransmittable (U = U).
- Promising vaccine strategies with broadly neutralizing antibodies to prevent or suppress HIV.
- New diagnostic tests to rapidly identify new infections and drug resistance.

To further contribute to scientific advances that benefit PWH in the United States and globally, innovative research is currently underway to prevent, treat, and find a cure for HIV:

- More than 30 clinical trials in various phases are currently in the pipeline to test the effectiveness of potential HIV vaccines. The trials include two large studies in sub-Saharan Africa to test whether experimental vaccine regimens safely prevent HIV infections among adults. Results will be available in 2020 (HVTN 702) and 2021 (HVTN 705–Imbokodo).
- Two prevention studies involve neutralizing antibodies: HVTN 703 with women in sub-Saharan Africa and HVTN 704 with men who have sex with men in South America and the United States. Preliminary results are promising: 35,000 antibody infusions have been given to 4,600 people safely, with 95 percent retention and adherence to the studies.

Accomplishments of HIV/AIDS Research (continued)

- Several promising clinical trials are currently underway to test the effectiveness of a variety of multipurpose prevention technologies, including microbicides and intravaginal rings. Such methods will offer certain advantages for women who may not have other options for protection against acquiring HIV through sex.
- The first round of studies of long-acting injectable and implantable ART will be completed in 2021. Long-acting ART offers the possibility of effective treatment without the need for daily medication and may increase uptake and adherence to treatment by PWH.
- Novel HIV-testing technologies—such as sensitive, rapid point-of-care or self-administered viral load testing—are designed to provide increased ease of monitoring for enhanced prevention of HIV transmission and improved treatment adherence to achieve viral suppression.
- Major breakthroughs are expected in refining gene therapy techniques for more effective nonvaccine treatments.
- Research to develop a tuberculosis (TB) vaccine to benefit both PWH and uninfected individuals is advancing. TB is the most common HIV-related comorbidity globally.
- New immune-based treatment regimens hold promise for suppressing viral replication in PWH who have shown viral resistance to all known antiretroviral drugs.
- Novel HIV latency-reversing agents offer a potential breakthrough in research for a pathway to a cure.

Long-acting ART offers the possibility of effective treatment without the need for daily medication.



Next Frontier of Research Challenges

As the HIV pandemic continues to evolve, the NIH must continue to lead in basic, clinical, and translational research to address the next frontiers of HIV challenges to improve health outcomes of PWH and ultimately find a cure for HIV. Described below are select examples of HIV research challenges.

Ending the HIV Epidemic. The Department of Health and Human Services (HHS) is proposing a once-in-a-generation opportunity to eliminate new HIV infections in our Nation. *Ending the HIV Epidemic: A Plan for America* will work to reduce new infections by 75 percent in the next five years and by 90 percent in the next 10 years, averting more than 250,000 HIV infections in that span. The multiyear program will infuse 48 counties, Washington, D.C., San Juan, Puerto Rico, and seven states that have a substantial rural HIV burden with the additional expertise, technology, and resources needed to end the HIV epidemic in the United States. HHS's four strategies—diagnose, treat, protect, and respond—will be implemented across the entire United States within 10 years. Without this new intervention, new infections will continue and could increase, costing more lives and the U.S. government more than \$200 billion in direct lifetime medical costs for HIV prevention and medication.^{4,8}

Aging with HIV. Effective ARTs have resulted in many PWH living longer and experiencing fewer HIV-associated medical conditions. Nearly half of the PWH in the United States were at least 50 years old in 2016. Approximately one in six HIV diagnoses were among PWH age 50 years or older.^{2,3} The trend is expanding across the developed world and eventually will reach middle- and low-income countries. Because both age and HIV increase the risk for many health conditions, aging with HIV presents special challenges for preventing and treating comorbidities, such as cancers, cardiovascular and lung diseases, and neurocognitive disorders.

HIV and the Brain. Both HIV and its treatment affect the brain. Approximately half of PWH are believed to have an HIV-associated neurocognitive disorder (HAND) affecting attention, language, motor skills, memory, or other cognitive functions. HAND remains prevalent even among PWH treated with ART.⁹ Basic and translational research to understand the mechanisms that contribute to neurodegenerative diseases and neurocognitive disorders in PWH is critical to improving health outcomes. Additionally, although an estimated 1.8 million children globally are living with HIV, little research has examined the effect of HIV and ART on the developing brain. Furthermore, the impact of HIV on cognitive and mental health processes of adolescents who were infected perinatally is not well understood and requires scientific investigation.

HIV and Opioid Co-Epidemics. The growing epidemic of opioid misuse and addiction is one of the most significant public health threats in the United States today. In 2017, an estimated six percent of new HIV diagnoses involved injection drug use. Among all PWH, an estimated three percent reported using injection drugs, including

Next Frontier of Research Challenges (continued)

approximately two percent of PWH who injected methamphetamines and one percent who injected heroin.⁷ Patterns of drug addiction and injection behavior continue to foster HIV transmission and are barriers to HIV prevention and treatment adherence. According to the Center for Drug Use and HIV/HCV Research, the opioid epidemic has the potential to undermine the progress that has been made to end the HIV pandemic and control hepatitis C among people who use drugs.¹⁰ Multidisciplinary research across the NIH is needed to address the intersecting epidemics.

As the HIV pandemic continues to evolve, research must address the next frontiers of the pandemic.

Geographic Disparities. The U.S. South—defined as the District of Columbia and 16 states—now has the greatest burden of HIV infection, illness, and deaths of any region in the Nation. In 2017, the southern states accounted for more than half of new diagnoses. In the South, 23 percent of new HIV diagnoses are in suburban and rural areas. Likewise, in the Midwest, 21 percent of new HIV diagnoses are in suburban or rural areas. The large and more geographically dispersed populations living with HIV pose new prevention and treatment challenges. African Americans are most affected by HIV in the South.⁶ Gay, bisexual, and other MSM account for 59 percent of all HIV diagnoses among African Americans in the South, while African American women account for 69 percent of all HIV diagnoses among women in the South.¹¹

Such factors as income inequality and poverty are more widespread in the South overall. Inadequate and underfunded prevention and care services contribute to worse health outcomes. Cultural factors and issues—such as homophobia, transphobia, and racism—can lead to higher levels of stigma, which may affect people’s willingness to access HIV testing or care. Sustained investments in behavioral and social sciences research and implementation research are needed to help address disparities.

Opportunities for Scientific Advancement

To meet the challenges of the future, accelerated basic, clinical, and translational research is required to address both current knowledge gaps and emerging opportunities in the scientific response to the pandemic. NIH investment in research is necessary to advance scientific discoveries and—

- Understand the underlying mechanisms that drive HIV acquisition.
- Define the mechanisms that prevent immune clearance of the virus.
- Understand the structure and dynamics of HIV proteins to prevent ART drug resistance.
- Identify the cause of residual inflammation in PWH who have undetectable viral loads with treatment.
- Develop sensitive assays, biomarkers, and imaging technologies to detect the viral reservoir and HIV persistence in different tissues and organs, coupled with cutting-edge studies of biology, pharmacology, and immunology.
- Understand the pathophysiology and epidemiology of HIV-associated comorbidities, such as neurocognitive disorders and cardiovascular disease; chronic lung disease and infectious lung complications; and platelet dysfunction, endothelial activation, and hypercoagulation.
- Address health disparities in treatment and outcomes through behavioral and social sciences research.
- Develop an effective vaccine to prevent HIV.

The NIH research portfolio addresses critical emerging issues, as well as the full range of HIV/AIDS research priorities, and promises to advance scientific knowledge to end the pandemic and improve management of HIV-related conditions.



FY 2020 NIH HIV/AIDS Professional Judgment Budget Request

The OAR is legislatively mandated to develop an annual NIH-wide Full-Funding Budget Estimate or Professional Judgment Budget for NIH HIV research. The budget estimate is based on current research opportunities and scientific gaps as determined by internal and external stakeholders. The budget estimate supports a comprehensive research program that includes research addressing basic, clinical, translational, implementation, and behavioral and social sciences.

The FY 2020 NIH HIV/AIDS Professional Judgment Budget request—

- Focuses on the President's goal to end the HIV epidemic in the United States within 10 years
- 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
- Enhances the research foundation needed to implement the major goals of the *National HIV/AIDS Strategy for the United States: Updated to 2020* and the accompanying Federal Action Plan and
- Addresses both intramural and extramural HIV/AIDS research, as well as funding for research facilities and infrastructure, research training, and program evaluation.

Coordination with Other Federal HIV/AIDS Efforts

The ***National HIV/AIDS Strategy for the United States (NHAS): Updated to 2020*** is a plan to guide the collective federal response to the HIV epidemic.⁵ The NHAS 2017 Progress Report charts a course of action across the federal government and nation 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 align closely 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 2020 Trans-NIH HIV/AIDS Professional Judgment Budget (continued)

The FY 2020 Professional Judgment Budget estimate for the NIH-wide HIV/AIDS research program is \$3,502 million, an increase of \$457 million or 15 percent over the FY 2019 Estimate. The budget estimates the resources needed to support the highest priority HIV/AIDS research across the NIH and addresses critical scientific opportunities to develop safe, effective, practical, and affordable HIV vaccines; identify effective socio-behavioral interventions to achieve uptake of HIV prevention and treatment strategies; discover new therapeutic targets to inhibit HIV replication for safer and more effective ways to treat and prevent HIV infection; explore innovative novel technologies, such as genetic engineering, to develop durable and scalable cure approaches for people with HIV; and define long-term HIV treatment in the development of coinfections and comorbid conditions across the lifespan. The Professional Judgment Budget provides expanded investment to accelerate ending the HIV pandemic and improving the health and health outcomes of people with HIV.

FY 2020 AIDS Professional Judgment Budget Request (Dollars in Thousands)

Research Priority	FY 2018 Actual	FY 2019 Estimate	FY 2020 Professional Judgment	FY 2020 +/- FY 2019	Percent Change
Reduce the Incidence of HIV	\$714,553	\$741,203	\$957,221	\$216,018	29.1%
Develop Next-Generation Therapies	364,484	369,680	370,965	1,285	0.3%
Research Toward a Cure	175,757	190,735	190,867	132	0.1%
Address HIV-Associated Comorbidities, Coinfections, and Complications	517,884	537,435	587,483	50,048	9.3%
Cross-Cutting Areas [†]	1,222,703	1,206,008	1,395,284	189,276	15.7%
TOTAL	\$2,995,381	\$3,045,061	\$3,501,820	\$456,759	15.0%

[†] Cross-cutting areas include basic sciences, behavioral and social sciences, epidemiology, health disparities, implementation science, information dissemination, and research training.



Conclusion and Looking Forward

The NIH's investment in HIV/AIDS research continues to produce significant scientific discoveries benefiting millions of people affected by, at risk of, or living with HIV. The investment has opened the door to scientific discoveries in far-ranging scientific fields. NIH-funded research has supported development of science and tools that make the ambitious goals to end the HIV epidemic in the U.S. achievable.

The FY 2020 HIV/AIDS Professional Judgment Budget represents collaborative expertise among diverse stakeholders regarding the research priorities and investment of NIH HIV/AIDS resources. The OAR is confident that the FY 2020 Professional Judgment Budget request provides the resources needed to accelerate the groundbreaking research discoveries that will end the HIV/AIDS pandemic and improve the health of people with HIV. We look forward to sharing scientific progress on HIV with stakeholders in research, medicine, policy, industry, and—most important—the people and communities living with and affected by HIV.

The OAR is confident that the FY 2020 Professional Judgment Budget request provides the resources needed to accelerate the groundbreaking research discoveries that will end the HIV/AIDS pandemic and improve the health of people with HIV.



References

- ¹ United Nations Programme on HIV/AIDS. 2018 Fact Sheet. Global HIV & AIDS Statistics—2018 Fact Sheet. Available at www.unaids.org/en/resources/fact-sheet. Accessed March 22, 2019.
- ² Centers for Disease Control and Prevention (CDC). HIV/AIDS Basic Statistics. Available at www.cdc.gov/hiv/basics/statistics.html. Accessed March 22, 2019.
- ³ CDC. November 2017. Diagnoses of HIV Infection in the United States and Dependent Areas, 2016. HIV Surveillance Report; vol. 28. Available at www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2016-vol-28.pdf.
- ⁴ Fauci AS, Redfield RR, Sigournas G, Weaklee MD, Giroir BP. 2019. “Ending the HIV Epidemic. A Plan for the United States.” *JAMA* Published Online February 7, 2019. doi:10.1001/jama.2019.1343
- ⁵ *National HIV/AIDS Strategy for the United States: Updated to 2020*. July 2015. Available at files.hiv.gov/s3fs-public/nhas-update.pdf.
- ⁶ CDC. June 2018. HIV in the United States by Region. Available at www.cdc.gov/hiv/statistics/overview/geographicdistribution.html. Accessed March 22, 2019.
- ⁷ CDC. May 2018. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States, 2015 Cycle (June 2015–May 2016). HIV Surveillance Special Report; no. 20. Available at www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-20.pdf.
- ⁸ *Ending the HIV Epidemic: A Plan for America*. Available at www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview
- ⁹ Department of Health and Human Services. Funding Opportunity Announcement. “Pathogenesis of Age-Related HIV Neurodegeneration.” Available at grants.nih.gov/grants/guide/rfa-files/RFA-AG-18-023.html. Accessed March 22, 2019.
- ¹⁰ Center for Drug Use and HIV/HCV Research. November 2015. Prescription Opioid Misuse: Addressing a Potential Threat to Progress in Ending the HIV and HCV Epidemics. Available at www.cduhr.org/implementation_brief/prescription-opioid-misuse-addressing-potential-threat-progress-ending-hiv-hcv-epidemics/#.W9H4gGhKiUI. Accessed March 22, 2019.
- ¹¹ CDC. Issue Brief. June 2018. HIV in the Southern United States. Available at www.cdc.gov/hiv/pdf/policies/cdc-hiv-in-the-south-issue-brief.pdf.



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Office of AIDS Research