Office of AIDS Research

CONGRESSIONAL JUSTIFICATION
FY 2025

Department of Health and Human Services
National Institutes of Health

NIH National Institutes of Health
Office of AIDS Research

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research (OAR)

FY 2025 Budget Table of Contents

General Note

1. FY 2024 funding levels cited in this document are based on the Continuing Resolution in effect at the time of budget preparation (Public Law 118-35) and do not include HIV/AIDS transfers.
2. Detail in this document may not sum to the subtotals and totals due to rounding.

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Director's Overview

The Office of AIDS Research (OAR) was established by the Health Omnibus Program Extension (HOPE) Act of 1988 to coordinate HIV/AIDS research across NIH. Subsequently, the NIH Revitalization Act of 1993 authorized OAR to establish HIV/AIDS research priorities, develop a strategic plan for HIV/AIDS research, and allocate the HIV/AIDS budget across NIH. OAR's mission is to ensure that HIV/AIDS research funding is directed at the highest priority research areas and to facilitate maximal return on the investment. In pursuit of this mission, OAR activities are guided by the *NIH Strategic Plan for HIV and HIV-Related Research (2021–2025)*. Furthermore, OAR works with the White House Office of National AIDS Policy to align NIH and other federal agency goals and to facilitate implementation of the National HIV/AIDS Strategy, 2022-2025.

Diana Finzi, Ph.D., M.P.H.
NIH Acting Associate Director for AIDS Research and Acting Director, Office of AIDS Research

NIH research contributions to life-saving advances in HIV prevention, treatment, and care

At the beginning of the HIV/AIDS pandemic in the 1980s, AIDS was a fatal condition with no effective treatment. In the 1990s, NIH research led to the development of several antiretroviral therapy (ART) regimens to prevent people with HIV from developing AIDS. These breakthrough medical advances changed the course of the pandemic, drastically reducing the number of AIDS-related deaths.

Over the last four decades, sustained investment in HIV/AIDS research at NIH has enabled progressive scientific advances that have led to improved ART with fewer side effects and better adherence which has transformed HIV infection into a manageable chronic condition. Today, people with HIV can anticipate near-normal life expectancy. These advances have also spurred the development and implementation of safe and effective tools to prevent HIV acquisition and transmission. When taken as prescribed, pre-exposure prophylaxis (PrEP), in various formulations, is highly effective at preventing HIV acquisition from anal and vaginal sex, and from injection drug use.[1] By 2018, NIH-supported research had demonstrated that ART taken by people with HIV effectively prevents sexual transmission of HIV to others when the virus reaches undetectable levels in the blood. This research provided the scientific basis for the "Undetectable = Untransmittable," or "U = U," public health campaign.

The benefits of HIV scientific discoveries extend beyond HIV. For example, technologies and resources initially developed in the quest for an HIV vaccine provided a critical platform for the rapid development of mRNA-based COVID-19 vaccines, resulting in major global health impact. In the United States alone, COVID-19 vaccines have helped avert an estimated 120,000 deaths and saved $7.0 billion in preventable hospitalizations.[2]

[1] cdc.gov/hiv/risk/estimates/preventionstrategies.html
[2] pubmed.ncbi.nlm.nih.gov/37098043/

NIH-sponsored HIV/AIDS research had a worldwide impact on public health when ART was introduced globally. Global availability of ART was bolstered by the President's Emergency Plan for AIDS Relief (PEPFAR), launched in 2003. PEPFAR is helping control the global HIV/AIDS pandemic in over 50 countries and has saved over 25 million lives since its launch.[3] Prevention of HIV transmission has averted an estimated 5.5 million infections in babies globally since 2004.[4] The number of new HIV infections worldwide decreased by 38 percent overall between 2010 and 2022.[5]

Responding to evolving HIV/AIDS research needs

Early HIV/AIDS research focused on epidemiologic surveillance to contain the epidemic; later, studies on the mechanisms of HIV pathogenesis were essential for drug discovery. Over time, HIV/AIDS research has developed safe and effective methods of HIV diagnosis, treatment, and prevention for universal implementation, as well as approaches tailored for various populations and settings. Development of a safe and effective HIV vaccine has proven to be more challenging than anticipated because of high rates of viral mutation and variability. Development of a safe, effective and scalable cure for HIV is a global public health priority but is hampered by the unique ability of HIV to persist hidden from the immune system and ART in certain cell types. While substantial progress in HIV vaccine and cure research has been achieved, a safe and effective HIV vaccine and an HIV cure will require continued investment in this critical area.

NIH has increased its attention to addressing the specific needs of different populations, such as sexual and gender minorities, minoritized racial and ethnic groups, and populations with behavioral risks and substance use. Additionally, OAR engages with scientists, clinicians, and members of the community affected by HIV to identify emerging research priorities and unmet scientific needs. Multisectoral outreach aims to ensure that the NIH HIV/AIDS research program is responsive to the needs of the HIV community, while focusing on scientific discoveries needed to prevent, treat, and cure HIV. In response, OAR is expanding its four Signature Programs that foster collaborative and multidisciplinary research initiatives:

- *HIV & Aging:* In 2021, more than half of all people with HIV in the United States were age 50 or older.[6] People with HIV experience age-related comorbidities, some of which are exacerbated by long-term use of ART. They are more likely than their peers without HIV to experience certain age-related conditions—such as frailty, neurocognitive decline, cardiovascular disease, metabolic disorders, and some cancers—and some at younger ages than those without HIV.[7] NIH supports basic, translational, and clinical research to increase understanding, prevention, and management of comorbidities in people aging with HIV. OAR organized two events to increase further research on HIV and Aging in 2023, including a multisectoral panel discussion as part of the U.S. Conference on HIV/AIDS. OAR also is currently working with NIH Institutes, Centers, and Offices (ICOs) to develop a coordinated agency-wide HIV and aging research agenda.

[3] state.gov/pepfar-latest-global-results-factsheet-dec-2023/
[4] state.gov/pepfar-latest-global-results-factsheet-dec-2023/
[5] unaids.org/en/resources/documents/2023/global-aids-update-2023
[6] cdc.gov/hiv/library/reports/hiv-surveillance/vol-34/
[7] clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/hiv-and-older-person

- *HIV & Women:* Women—particularly women of color, young women, and transgender women—remain disproportionately affected by HIV.[8] OAR has partnered with the Office of Research on Women's Health to promote the inclusion of women's health issues throughout the lifespan of all women with or impacted by HIV in the HIV/AIDS research agenda. NIH also supports career development for women in HIV/AIDS research, as described in the program portrait below.

- *Advancing Technologies to Improve HIV Diagnosis and Care:* There is a significant need for affordable, self-administered, and easy to use U.S. Food and Drug Administration (FDA)-approved diagnostics for HIV testing and monitoring of HIV viral load (level of virus in blood). These products could facilitate earlier diagnosis and lead to faster treatment initiation. They also could allow ongoing monitoring of treatment effectiveness to foster better adherence to ART that would improve the health of people with HIV and help reduce transmission of HIV to others. This signature program, which leverages lessons learned from the COVID-19 pandemic and NIH's Rapid Acceleration of Diagnostics (RADx) initiative,[9] may lead to fast-track development and delivery of diagnostic and self-monitoring tools that ultimately could help increase autonomy, mitigate stigma, reduce costs, improve the health of people with HIV, and save lives. In November 2023, OAR organized a workshop to solicit community, regulatory, academic, and industry input in identifying cutting-edge opportunities to advance the next generation of HIV diagnostic technologies.

- *Early Career HIV Investigators:* NIH is committed to supporting a diverse early career workforce. Since 2022, OAR has collaborated with other ICOs to host an annual professional development workshop for early career investigators interested in HIV/AIDS research. The workshops provide an opportunity to establish mentorship and networking connections and to share information about the NIH HIV/AIDS research program, funding opportunities, and the grant application process. Resources are available on OAR's Early Career Investigator Resources webpage.[10]

Addressing HIV-related health disparities

Disparities by race, ethnicity, gender, and sexual orientation operate in conjunction with other social and structural factors that increase the risk of HIV acquisition and adverse health outcomes for people with HIV. These social determinants of health interact to create syndemics (synergistic epidemics) of HIV, substance use disorder, sexually transmitted infections, viral hepatitis, violence, and mental health issues. A syndemic approach can facilitate the study of co-occurring conditions and the social factors that amplify morbidity and perpetuate health disparities to inform the development of safe, effective, and equitable, combination and multilevel HIV prevention, treatment, and care interventions.

Many new HIV infections in the United States occur in men who have sex with men and bisexual Black or African American and Hispanic or Latino men, particularly those living in high HIV prevalence areas in the U.S. South.[11] In combination, social justice and structural

[8] unaids.org/en/resources/fact-sheet
[9] nih.gov/research-training/medical-research-initiatives/radx
[10] oar.nih.gov/nih-hiv-research-program/hiv-early-career-resources
[11] cdc.gov/hiv/group/index.html

issues, including systemic racism and racialized stigma, create inequities that limit access to care. In Appalachia, the spread of the opioid epidemic during the last two decades has led to an increase in use of injected drugs and in transmission of HIV and hepatitis B and C viruses among people who inject drugs. To improve the health and well-being of all people with HIV and those vulnerable to acquiring it, OAR encourages a combination of biomedical, behavioral, and social sciences research to address the multiple interrelated factors at the individual, relational, community, and societal levels affecting people's ability to prevent, diagnose, and treat HIV.

In the United States, more than half of new HIV diagnoses are concentrated in 50 local areas and jurisdictions (48 counties; Washington, D.C.; and San Juan, Puerto Rico).[12] Focusing on these areas and the 7 states with a substantial rural burden, the *Ending the HIV Epidemic* (EHE) *in the U.S.* initiative was launched in 2019 to reduce new HIV infections by 75 percent by 2025 and 90 percent by 2030.[12] NIH supports the EHE initiative by funding implementation research in geographic areas disproportionately affected by HIV, often focusing on minoritized populations who are at highest risk of HIV acquisition. Specifically, OAR coordinates across NIH to fund new research projects at existing Centers for AIDS Research (CFARs) and AIDS Research Centers (ARCs). Some of these Centers now serve as regional hubs supporting implementation research. These EHE-related projects involve collaborations with local groups and institutions to explore which interventions are most effective. This work at the community level is founded on the four pillars of the EHE strategy—diagnose, treat, prevent, and respond—to end the HIV epidemic in the United States.

For almost four decades, OAR has built strong partnerships with other government agencies, academia, and communities affected by HIV to catalyze, coordinate, and communicate HIV/AIDS research. These vital partnerships have facilitated the translation of biomedical, behavioral, and social sciences research into HIV prevention, treatment, and care strategies and have stimulated innovation in the global fight against the HIV/AIDS pandemic. Although signs of progress are evident, steadfast support will be critical to sustain current gains and continue to save lives globally. Continued investment will be vital for NIH to achieve our aspirational goals to eliminate HIV transmission in areas of high incidence and prevalence, to revolutionize the care of people with HIV—including finding a safe and scalable cure from lifelong infection—and to bring an end to the HIV/AIDS pandemic.

[12] cdc.gov/endhiv/about-ehe/index.html

National Institutes of Health
Office of AIDS Research

Mission: The mission of the Office of AIDS Research (OAR) is to ensure that NIH HIV/AIDS funding is directed at the highest priority research areas and to facilitate maximal return on the investment.

Background and History

NIH provides the largest public investment in HIV/AIDS research in the world. The program spans nearly every area of medicine and scientific investigation. NIH HIV/AIDS research has helped turn HIV from a once-fatal disease into a manageable chronic condition with effective treatment.

In 1988, Congress authorized OAR to oversee, coordinate, and manage the NIH HIV/AIDS research portfolio. A component of the Office of the NIH Director, OAR coordinates NIH funding for HIV research. OAR collaborates across the U.S. government and with researchers, community groups, and global partners to identify priorities for HIV and HIV-related research.

Diana Finzi, Ph.D., M.P.H.
Acting Associate Director for AIDS Research and Acting Director of the Office of AIDS Research, NIH

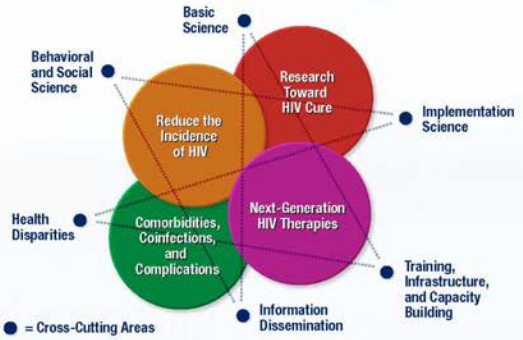
Facts & Figures

- An estimated **1.2 million** people in the United States had HIV at the end of 2021, with more than 50% over the age of 50.
- **6.9%** of the FY 2023 NIH budget was directed at HIV/AIDS funding, supporting around **3,800** HIV/AIDS research projects.
- **23** NIH Institutes, Centers, and Offices received HIV/AIDS funding in FY 2023.
- NIH HIV/AIDS research has informed efforts to reduce the burden of cancer, hepatitis, COVID-19, and many other diseases and conditions.

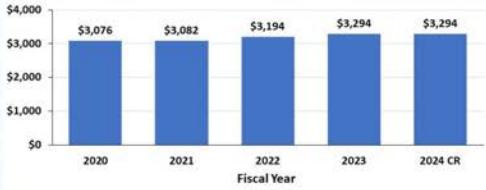
Research Highlights

- Daily statin medication reduces heart disease risk among adults with HIV by 35%.
- Long-acting antiretroviral therapy is safe and effective for people experiencing unstable housing, mental illnesses, substance use disorders, and those who encounter many barriers to treatment.
- Neurocognitive decline in people with HIV is linked to comorbidities, not HIV itself.
- The dapivirine vaginal ring protects women from HIV infection and offers a discreet, long-acting alternative to oral PrEP.
- Newly developed technology identified a profile of cells harboring latent HIV, further enhancing development of HIV cure strategies.

NIH Priorities for HIV and HIV-Related Research



NIH HIV/AIDS Funding: FY 2020–2024



The FY 2025 President's Budget request for the NIH HIV/AIDS research program is $3.294 billion, as was the FY2023 Final Level.

www.oar.nih.gov oarinfo@nih.gov Join the OAR Mailing List

Recent Accomplishments

HIV Clinical Practice Guidelines: OAR coordinates development of federally approved treatment guidelines for HIV and AIDS. Posted on Clinicalinfo.HIV.gov, the guidelines provide current evidence-based standards of care for use by U.S. health care practitioners and inform audiences around the world. An important update this year clarified how to minimize risk from breastfeeding for people with HIV.

Early Career Investigators (ECI) Workshop: As part of OAR's ongoing efforts to increase the number and diversity of young investigators in the field, OAR hosted its second virtual workshop for ECIs with interests in HIV/AIDS research to enhance skills and knowledge for career development and identify funding opportunities in 2023. More than 200 people from 59 institutions across 20 countries attended.

OAR Data Hub: OAR launched the NIH OAR Data Hub, a public resource that leverages and synthesizes publicly available data to promote greater understanding of HIV/AIDS research at NIH and to enable public audiences to identify relevant awards.

Current Activities

HIV & Aging Signature Program: OAR launched a signature program on HIV & Aging to address the unique needs of a population aging with HIV and to catalyze interdisciplinary research and training at the intersection of HIV and aging. Events, resources, and funding opportunities are available on OAR's website.

HIV & Women Signature Program: OAR partnered with the Office of Research on Women's Health to launch the HIV and Women Signature Program. The program will stimulate research to address the disproportionate impact of HIV on women and girls. Events, resources, and funding opportunities are available on OAR's website.

Future Initiatives

Strategic Planning: OAR is preparing to update the *NIH Strategic Plan for HIV and HIV-Related Research* for a release in FY 2026. This update offers the opportunity to review current HIV/AIDS research priorities and ensure that resources are optimized to meet emerging needs.

Advancing Technologies for HIV Diagnosis and Care Signature Program: Affordable and accessible HIV testing and viral load monitoring are critical to prevent, care for, and treat HIV and AIDS. OAR is establishing a new program to accelerate the development of HIV diagnostics and health monitoring technologies. As a first step, OAR organized a workshop in November 2023 to gather public input on the best path forward.

Pharmacy-based HIV Care: The *National HIV/AIDS Strategy for the United States (2022–2025)* recognizes the importance of pharmacies and pharmacists in making HIV care more accessible and improving population health. OAR is exploring opportunities to facilitate effective pharmacy-based delivery and support of HIV-related prevention, testing, and treatment services.

HIVinfo.NIH.gov

OAR manages HIV Info, an online resource offering up-to-date HIV/AIDS information to the general consumer, people with HIV and AIDS, people recently diagnosed and those who care for them.

CLINICAL INFO HIVgov

OAR manages Clinical Info, which offers access to the latest, federally approved HIV/AIDS medical practice guidelines, an HIV drug database, a glossary of HIV-related terms, and resources related to HIV-related research for health care providers, researchers, people affected by HIV/AIDS, and the general public.

Budget Policy Statement

The FY 2025 President's Budget request for the NIH-wide HIV/AIDS research program is $3,294.0 million, equal to the FY 2023 Final level. Funding at this level will expedite NIH efforts to end the HIV epidemic in the United States and globally; expand HIV prevention, treatment and cure strategies; and address the consequences of aging with HIV. NIH will continue to leverage HIV research and infrastructure to respond to public health needs, engage with early-career investigators (ECIs), as well as established investigators, to develop effective approaches for diversifying the HIV research workforce, and prioritize research training and development across the NIH Institutes, Centers, and Offices to expand the pool of ECIs in HIV research. NIH will capitalize on the use of new technologies and platforms and will continue the critical examination of health disparities in research and medicine. NIH will continue to advance dissemination and implementation research and strategies to identify efforts to optimize effective HIV prevention and treatment strategies to develop and implement effective community outreach and communication strategies.

NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Budget Authority by Institute, Center, and Office
(Budget Authority in Thousands of Dollars)

Institute, Center, and Office	FY 2023 Final[1]	FY 2024 Continuing Resolution	FY 2025 President's Budget	FY 2025 +/- FY 2023
NCI	$256,734	$259,652	$256,734	$0
NHLBI	92,953	90,140	92,953	0
NIDCR	20,174	20,199	20,174	0
NIDDK	38,699	36,322	38,699	0
NINDS	41,206	45,713	41,206	0
NIAID	1,911,364	1,911,991	1,911,364	0
NICHD	152,881	154,175	152,881	0
NEI	-	413	-	0
NIEHS	5,512	5,684	5,512	0
NIA	28,538	24,071	28,538	0
NIAMS	4,875	2,701	4,875	0
NIDCD	2,262	2,265	2,262	0
NIMH	199,584	195,774	199,584	0
NIDA	278,533	277,863	278,533	0
NIAAA	35,219	33,921	35,719	500
NINR	17,375	17,397	17,375	0
NHGRI	824	3,514	-	-824
NIBIB	1,954	1,956	1,954	0
NIMHD	24,982	24,239	24,982	0
NCCIH	689	796	796	107
FIC	25,919	25,951	25,919	0
NLM	7,685	9,919	7,685	0
OD	146,038	149,344	146,255	217
OAR	67,589	66,243	67,806	217
ORIP	78,449	83,101	78,449	0
TOTAL, NIH	**$3,294,000**	**$3,294,000**	**$3,294,000**	**$0**

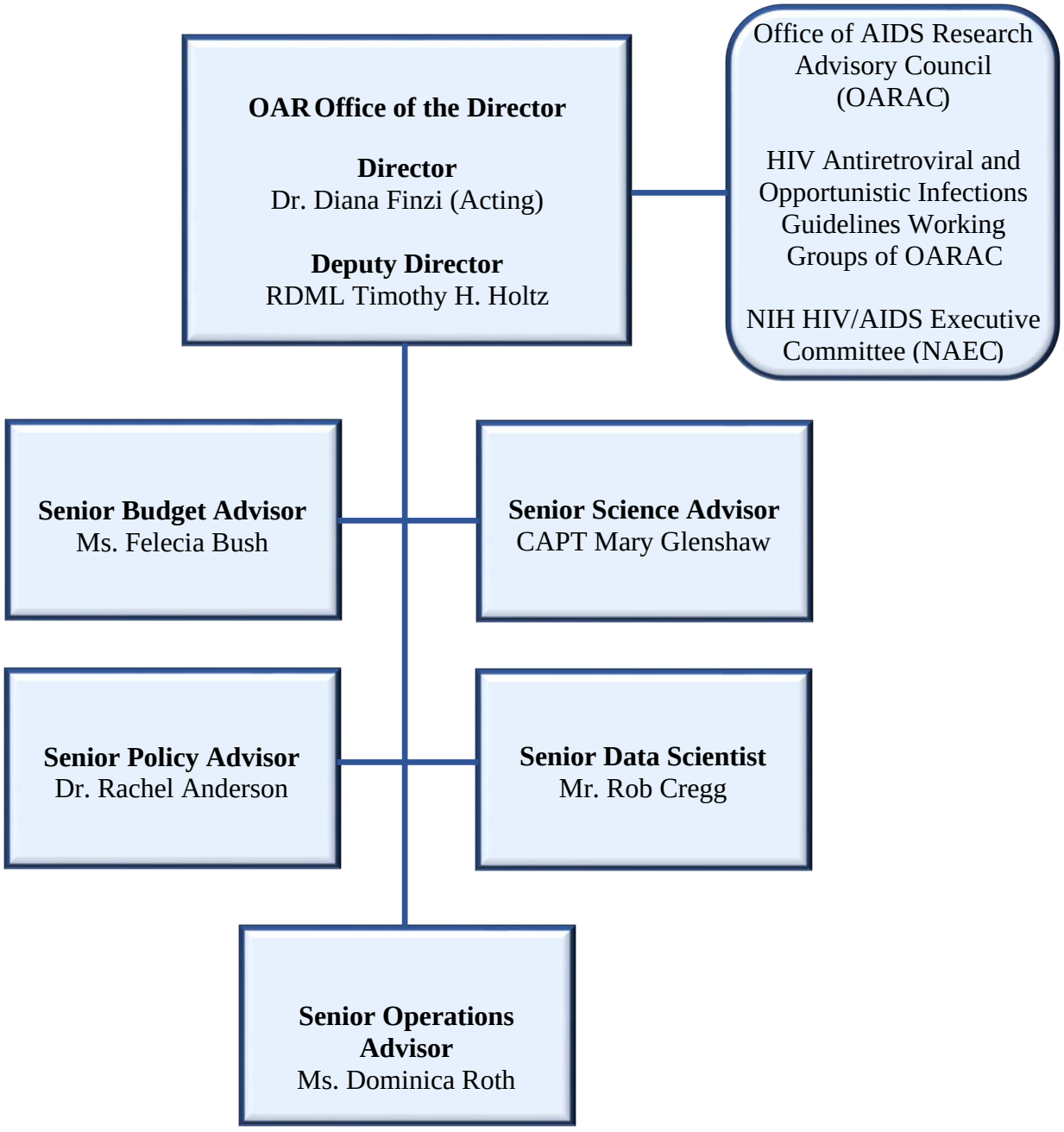
[1]Reflects HIV/AIDS transfers under the authority of Section 213 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2023.

NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Budget Mechanism - AIDS[1]
(Dollars in Thousands)

Mechanism	FY 2023 Final		FY 2024 C.R.		FY 2025 President's Budget		FY 2025 +/- FY 2023	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,403	$1,496,895	1,402	$1,489,520	1,301	$1,405,577	-101	-$91,318
Administrative Supplements	*124*	25,051	*78*	15,678	*88*	17,594	*(10)*	-7,457
Competing	457	296,982	436	287,588	542	364,457	106	67,475
Subtotal, RPGs	1,860	$1,818,928	1,838	$1,792,786	1,843	$1,787,628	5	-$31,300
SBIR/STTR	21	12,650	24	15,018	24	15,173	0	2,523
Research Project Grants	1,881	$1,831,578	1,862	$1,807,804	1,867	$1,802,801	5	-$28,777
Research Centers:								
Specialized/Comprehensive	68	$160,945	65	$160,414	64	$154,416	-1	-$6,529
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	1	1,500	0	0	-1	0
Comparative Medicine	36	70,023	19	72,399	19	70,142	0	119
Research Centers in Minority Institutions	0	0					0	0
Research Centers	104	$230,968	85	$234,313	83	$224,558	-2	-$6,410
Other Research:								
Research Careers	252	$43,499	236	$41,672	237	$41,202	1	-$2,297
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	20	13,443	20	13,283	20	12,802	0	-641
Biomedical Research Support	0	1,904		2,500		2,001	0	97
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	124	62,723	130	61,384	135	65,270	5	2,547
Other Research	396	$121,569	386	$118,839	392	$121,275	6	-$294
Total Research Grants	2,381	$2,184,115	2,333	$2,160,956	2,342	$2,148,634	9	-$35,481
Ruth L. Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs			
Individual Awards	81	$3,588	66	$3,130	77	$3,644	11	$56
Institutional Awards	254	15,251	236	16,144	242	16,680	6	1,429
Total Research Training	335	$18,839	302	$19,274	319	$20,324	17	$1,485
Research & Develop. Contracts	85	$474,713	119	$492,745	119	$498,610	0	$23,897
(SBIR/STTR) (non-add)	*7*	*3,932*	*7*	*4,226*	*7*	*4,226*	*(0)*	*294*
Intramural Research		$362,982		$364,358		$366,113		$3,131
Res. Management and Support		185,762		190,424		192,513		6,751
Res. Management & Support (SBIR Admin) (non-add)		*0*		*0*		*0*		0
Office of the Director - Appropriation[2]		*146,038*		*149,344*		*146,255*		217
Office of the Director - Other		67,589		66,243		*67,806*		217
ORIP (non-add)[2]		*78,449*		*83,101*		*78,449*		0
Total, NIH Discretionary B.A.		**$3,294,000**		**$3,294,000**		**$3,294,000**		**$0**

[1] All items in italics and brackets are non-add entries.

[2] Number of grants and dollars for the ORIP component of OD are distributed by mechanism and are noted here as a non-add. Office of the Director - Appropriation is the non-add total of these amounts and the funds accounted for under OD - Other.


OAR Office of the Director
Director
Dr. Diana Finzi (Acting)
Deputy Director
RDML Timothy H. Holtz
Office of AIDS Research Advisory Council (OARAC)
HIV Antiretroviral and Opportunistic Infections Guidelines Working Groups of OARAC
NIH HIV/AIDS Executive Committee (NAEC)
Senior Budget Advisor
Ms. Felecia Bush
Senior Science Advisor
CAPT Mary Glenshaw
Senior Policy Advisor
Dr. Rachel Anderson
Senior Data Scientist
Mr. Rob Cregg
Senior Operations Advisor
Ms. Dominica Roth

NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Budget Authority by Activity
(Dollars in Thousands)

Research Priorities	FY 2021 Actual [1]	FY 2022 Final	FY 2023 Enacted	FY 2024 C.R.	FY 2025 President's Budget	FY 2025 +/- FY 2023
Reduce the Incidence of HIV	$684,570	$689,324	$690,815	$674,410	$674,410	-$16,405
Develop Next-Generation HIV Therapies	331,927	348,034	355,904	363,467	363,467	$7,563
Research Toward a Cure for HIV	224,737	223,450	229,925	230,732	230,732	$807
Address HIV-Associated Comorbidities, Coinfections, and Complications	560,766	630,948	664,765	665,668	665,668	$903
Cross-Cutting Areas	1,279,897	1,302,244	1,352,591	1,359,723	1,359,723	$7,132
Total	**$3,081,897**	**$3,194,000**	**$3,294,000**	**$3,294,000**	**$3,294,000**	**$0**

[1] Reflects effects of Secretary's transfer.

Office of AIDS Research

Budget Authority (BA):

	FY 2023 Final	FY 2024 CR	FY 2025 President's Budget	FY 2025 +/- FY 2023
BA	$3,294,000,000	$3,294,000,000	$3,294,000,000	$0

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

Overall Budget Policy: The FY 2025 President's Budget request for the Office of AIDS Research (OAR) is $3.294 billion, which is equal to the FY 2023 Final level. This level of funding will support the priorities of the NIH HIV research agenda, as described below, namely to reduce the incidence of HIV; develop next-generation HIV therapies; support research toward a cure; address HIV-associated comorbidities, coinfections, and complications; and advance cross-cutting areas of research in the basic sciences, behavioral and social sciences, epidemiology, implementation science, information dissemination, and research training.

Program Descriptions

Reduce the Incidence of HIV

Despite the available tools to prevent HIV transmission, more than one million people acquire HIV each year worldwide. In the United States and its dependent areas, 36,136 people received an HIV diagnosis in 2021.[13] Individuals from sexual and gender minority communities have the highest rates of infection. Both access and adherence to a daily medication for pre-exposure prophylaxis (PrEP) remains an issue for many in the United States and globally. To address these challenges, NIH is supporting research to develop more convenient HIV prevention approaches that can be long-acting or used intermittently when needed.

Using a syndemic framework is crucial to develop better prevention approaches adapted to the needs of each community. Ongoing research continues to investigate novel antiretroviral formulations and to identify barriers to successful implementation of HIV prevention and treatment in communities that urgently need these tools. For example, a vaginal ring that releases the antiretroviral drug dapivirine for 28 days can protect women from HIV acquisition. It offers a discreet, long-acting alternative to oral PrEP. Recent NIH-supported research showed

[13] cdc.gov/hiv/basics/statistics.html

the ring is safe and effective during late pregnancy and breastfeeding.[14] The HIV Prevention Trials Network is studying the long-acting injectable PrEP formulation containing the antiretroviral cabotegravir, which reduces the risk of sexually acquired HIV with injections every other month.[15] The recent Food and Drug Administration (FDA) approval of this long-acting PrEP is critical to address the global HIV/AIDS pandemic, protecting people for whom access or adherence to a daily medication is a major challenge.

NIH supports research to better understand the barriers to HIV prevention uptake in various communities. The NIH-supported International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) and the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) evaluate interventions to prevent and treat HIV in infants, children, adolescents, and pregnant/postpartum people, including the elimination of perinatal transmission. They conduct independent and collaborative research exploring promising prophylactic, behavioral, microbicidal, and vaccine modalities. The Prevention And Treatment through a Comprehensive Care Continuum for HIV-affected Adolescents in Resource Constrained Settings ($PATC^3H$) consortium was expanded to strengthen the scientific innovation that will yield effective public health interventions for adolescents and young adults in low-to-middle income countries. To address the disproportionate burden of HIV infection on sexual and gender minority populations, NIH is launching a new initiative[16] to support epidemiologic, intervention, and implementation research to identify focused approaches to reduce the number of new HIV infections among these groups. NIH continues to encourage research to develop innovative multipurpose prevention technologies (MPT) that simultaneously prevent HIV and pregnancy or sexually transmitted infections in cis and trans men and women of all ages.[17] To optimize uptake, MPT will have to be convenient and as safe and effective as each of its component medicines.

Ultimately, ending the global HIV/AIDS pandemic likely will require a safe and effective HIV vaccine. Vaccines work by inducing the immune system to make antibodies that can neutralize (kill) a particular pathogen. The ability of HIV to mutate rapidly has been challenging, and the immune system only rarely makes broadly neutralizing antibodies (bNAbs) that are effective in protecting against a wide range of HIV variants. Recent studies[18] have established the safety of an experimental HIV vaccine candidate that stimulates a rare type of immune B cell that is capable of producing bNAbs. This vaccine is intended to be the first part of a multistep vaccination regimen. A different vaccine candidate, called VIR-1388, is being tested in one of the NIH-supported clinical trial networks. This Phase 1 trial[19] will examine the safety of VIR-1388 and its ability to induce an immune response against HIV in people in the United States and South Africa. In addition, NIH is interested in projects that examine how to develop immunity to HIV early in life to harness young children's more adaptable and efficient immune systems.

[14] pubmed.ncbi.nlm.nih.gov/37432541/
[15] pubmed.ncbi.nlm.nih.gov/34379922/; pubmed.ncbi.nlm.nih.gov/35378077/
[16] grants.nih.gov/grants/guide/rfa-files/RFA-DA-25-002.html
[17] grants.nih.gov/grants/guide/pa-files/PAR-22-222.html
[18] hiv.gov/blog/encouraging-first-in-human-results-for-a-promising-hiv-vaccine/; nih.gov/news-events/nih-research-matters/progress-toward-eventual-hiv-vaccine
[19] nih.gov/news-events/news-releases/clinical-trial-hiv-vaccine-begins-united-states-south-africa

Advancing Research on HIV and Women

Notwithstanding tremendous advances in HIV research over the last 40 years, women—particularly women of color, young women, and transgender women—remain disproportionately affected by HIV. Focused research initiatives are critical to better understanding optimal ways to prevent, treat, and cure HIV and associated comorbidities across women's lifespans.

In February 2023, OAR, and the Office of Research on Women's Health (ORWH) launched the HIV and Women Signature Program to advance research on HIV and women's health. The program contributes to achieving the NIH vision of a world in which all women—including cisgender, transgender, and gender-diverse women, as well as people assigned female at birth—receive evidence-based prevention, and treatment tailored to their unique needs, circumstances, and goals.

OAR and ORWH organized multiple research and community engagement events in FY 2023. A research symposium highlighted innovative, multidisciplinary research to address the health of women with or affected by HIV to identify the highest research priorities and the most impactful ways for NIH to advance women-centered HIV/AIDS research. To gather additional feedback from community members and federal partners, OAR and ORWH organized a workshop on HIV and Women at the 2023 U.S. Conference on HIV/AIDS. A recent funding opportunity announcement encourages research to improve uptake and equitable implementation of HIV prevention for women.

Ongoing activities of the Signature Program will inform women-centered HIV/AIDS research and be incorporated in the next NIH Strategic Plan for HIV and HIV-Related Research to ensure that research will improve the lives of all women and girls with or affected by HIV worldwide.

Budget Policy: The FY 2025 President's Budget request to promote research to reduce HIV incidence is $674.4 million, a decrease of $16.4 million or -2.4 percent compared to the FY 2023 Final level.

Develop Next Generation HIV Therapies

NIH continues to support research on new long-acting HIV treatments with fewer side effects, as well as novel formulations and delivery methods to improve efficacy of and support adherence to HIV medications. Innovative biological products, such as bNAbs engineered to destroy HIV-infected cells, could revolutionize HIV treatment and prevention strategies. Clinical trials have established that bNAbs are safe and can prevent infection and maintain viral suppression in people with different strains of HIV that are sensitive to these bNAbs.[20] NIH is supporting projects to design and evaluate bNAbs or similar antibody-like agents that could treat a broad range of HIV strains.

Injections of two existing antivirals, cabotegravir and rilpivirine, are the only long-acting antiretroviral therapy (ART) FDA-approved for people with HIV. NIH-supported research showed[21] that these novel therapeutics can be helpful to engage adults with HIV with high rates of unstable housing, mental illness, and substance use—people who historically have had challenges accessing effective treatment. Overall, nearly 98 percent of individuals in the study achieved viral suppression, a rate similar to that in more controlled clinical trials.

New products and delivery platforms are being tested to facilitate use in specific populations, such as children, adolescents, or pregnant and postpartum people. A recent study demonstrated the promise of dissolving

[20] pubmed.ncbi.nlm.nih.gov/33730454/; pubmed.ncbi.nlm.nih.gov/35650437/; pubmed.ncbi.nlm.nih.gov/35418681/
[21] pubmed.ncbi.nlm.nih.gov/37399555/

patches[22] for intradermal delivery of long-acting ART for pediatric HIV. This approach would be less painful and safer than intramuscular injections, enabling the use of long-acting ART in children. A new type of antiretroviral, lenacapavir, is in development as a long-acting agent to treat or prevent HIV. As lenacapavir acts via a different mechanism from existing ART, a trial[23] demonstrated that adding lencapavir to an optimized ART regimen was safe and effectively treated people with multidrug-resistant HIV.

Budget Policy: The FY 2025 President's Budget request to support research to develop next-generation HIV therapies is $363.5 million, an increase of $7.6 million or 2.1 percent compared to the FY 2023 Final level.

Research Toward HIV Cure

Groundbreaking research advances in HIV treatment have helped turn HIV into a manageable condition. These advances, however, do not obviate the need for a cure, which, while theoretically feasible, is not yet available. To work towards a cure for HIV, NIH supports studies to develop novel approaches and treatments that target HIV reservoirs. HIV can hide from the immune system by staying dormant in certain cells to constitute a latent viral reservoir. These cells, infected with HIV but not actively producing new virus, are usually located in areas such as the nervous system, which are protected from the immune system and ART.

The initiation of ART within the first few weeks of HIV infection has been associated with the development of a smaller latent reservoir. Accordingly, NIH is encouraging research to explore novel strategies designed to limit the establishment of the HIV reservoir around the time of ART initiation.[24] NIH-supported research continues to investigate the nature of HIV reservoirs and viral remission. For example, NIH is aiming to stimulate research[25] into more efficient bNAbs and other products that can seek out and destroy sufficient numbers of HIV-infected cells to reduce the existing HIV reservoir. This approach could enable people to maintain viral suppression without ongoing treatment, leading to a functional cure.

Current scientific findings suggest that the first step toward a potential HIV cure may require viral remission (a state in which the virus is suppressed without ART), also known as a functional cure. Potential cure-inducing treatments must be as safe, effective, and available for widespread use as today's ART regimens. Viral eradication, or elimination of the virus entirely, is a more challenging, longer-term goal. Integration of real-time, rapid viral load monitoring with analytical treatment interruption may also enable clinical evaluation of promising new approaches to achieving a functional cure for HIV.

NIH also supports studies that investigate the social, behavioral, and bioethical issues associated with HIV cure research. Current studies focus on topics such as study participant representation and diversity in HIV cure research, attitudes toward analytical treatment interruption, partner protection from HIV acquisition in cure trials, and other ethical considerations.

[22] pubmed.ncbi.nlm.nih.gov/36224503/
[23] pubmed.ncbi.nlm.nih.gov/37451297/
[24] grants.nih.gov/grants/guide/pa-files/PAR-23-296.html
[25] niaid.nih.gov/grants-contracts/june-2023-daids-council-approved-concepts#engineering

Budget Policy: The FY 2025 President's Budget request to promote research toward an HIV cure is $230.7 million, an increase of $0.8 million or 0.4 percent compared to the FY 2023 Final level.

Address HIV-Associated Comorbidities, Coinfections, and Complications

People with HIV are more likely to experience comorbidities, coinfections, and other complications across their lifespan that affect their health, well-being, and quality of life. NIH supports multiple longitudinal research cohorts that provide crucial sources of data and facilitate the long-term investigation of health conditions that impact people with HIV. For example, the Multicenter AIDS Cohort Study/Women's Interagency HIV Study Combined Cohort Study (MACS/WIHS-CSS)[26] is a collaborative research effort that focuses on the chronic health conditions—including heart, lung, blood, and sleep disorders—that affect people with HIV. The Veterans Aging Cohort Study[27] similarly examines the overall impact of HIV, HIV treatment, and comorbid conditions on morbidity and mortality. The central nervous system (CNS) HIV Anti-Retroviral Therapy Effects Research (CHARTER) cohort studies have produced a key repository containing data on neuro-medical conditions, neuropsychological assessments, psychiatric and drug use variables, treatment, neuroimaging, and viral and host genetics.

Comorbidities

People with HIV experience accelerated aging, altered metabolism, and chronic immune activation that converge and contribute to the development of several comorbidities. Comorbid conditions that disproportionately affect people with HIV include cardiovascular disease, chronic kidney disease, liver disease, frailty and reduced bone density, and cancers. Neuropsychiatric conditions, such as depression and neurocognitive disorders, also are significantly more prevalent among people with HIV than those without HIV and are associated with poor ART adherence. NIH supports multidisciplinary research to better understand and identify targets for intervention to mitigate multiple HIV-associated comorbidities.[28] For example, NIH currently is funding research projects that investigate the role of chronic immune activation and the gut microbiome in cardiovascular conditions and HIV.

The median age of people with HIV has increased in recent decades as a result of advances in HIV treatment. The increasing number of older adults with HIV poses challenges and opportunities for the treatment of HIV and HIV-associated comorbidities, coinfections, and complications across the lifespan. Similarly, people born with HIV have unique needs and challenges as they age with the virus.

Research on HIV and aging represents an active area of collaboration across NIH. NIH currently supports a number of projects through a research program for multidisciplinary studies of HIV and aging.[29] In FY 2023, increases in HIV/AIDS funding enabled expanded support for supplements for research on HIV and aging.[30] As a result, 14 awards from 6 NIH ICs were funded to expand emphasis on HIV and aging, including studies on co-occurring conditions such

[26] statepi.jhsph.edu/mwccs/about-mwccs/
[27] medicine.yale.edu/intmed/vacs/cohorts/vacsresources/
[28] grants.nih.gov/grants/guide/pa-files/PAR-21-027.html
[29] grants.nih.gov/grants/guide/pa-files/par-21-068.html
[30] grants.nih.gov/grants/guide/notice-files/NOT-AG-23-008.html

as neuroinflammation, cardiovascular disease, alcohol and substance use, and cognitive impairment.

Recent advances highlight progress in addressing comorbidities in people with HIV. An NIH-supported clinical trial found that statins, a class of cholesterol-lowering medications, may offset the high risk of cardiovascular disease in people with HIV by more than a third, potentially preventing one in five major cardiovascular events or premature deaths in this population. Notably, the study population included people with low-to-moderate risk of cardiovascular disease who typically would not be prescribed statins.[31] These results will inform clinical care guidelines for people with HIV.

Results from another NIH-supported study indicated that neurocognitive decline in people with HIV may be unrelated to HIV infection, but significantly linked to comorbidities such as diabetes, hypertension, chronic pulmonary disease, frailty, and others. These findings demonstrate exacerbating indirect effects of multiple comorbidities that disproportionately affect people with HIV and underscore the importance of managing these (often treatable) conditions.[32]

Coinfections

Tuberculosis (TB), hepatitis, and sexually transmitted infections are common coinfections that affect the health and well-being of people with HIV of all ages.[33] Globally, TB is the leading cause of death for people with HIV.[34] In the United States, an estimated 10 percent of people with HIV have hepatitis B, and approximately 21 percent have hepatitis C. Hepatitis B and C progress faster and cause higher rates of mortality in people with HIV than in those without HIV.[35]

To improve the health of people with HIV and coinfections, NIH continues to support research on the mechanisms of and interventions for HIV-associated coinfections. NIH is soliciting research proposals to develop safe and effective treatments for TB specifically for people with HIV, as well as proposals to address the unique challenge of curing hepatitis B in people with HIV.[36] NIH is also encouraging research to develop and evaluate new models of care that integrate HIV, hepatitis B and C, addiction, and primary care services.[37]

Among people with HIV who also have TB and/or hepatitis, successful completion of prolonged multidrug regimens for each condition is significantly linked to improved health. Accordingly, NIH supports research to develop sustained release/long-acting drug delivery systems that require less frequent administration, potentially supporting improved adherence to the treatment regimens.[38]

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[31] nhlbi.nih.gov/news/2023/daily-statin-reduces-heart-disease-risk-among-adults-living-hiv
[32] pubmed.ncbi.nlm.nih.gov/36477867/
[33] aidsinfo.unaids.org/
[34] pubmed.ncbi.nlm.nih.gov/30897077/
[35] hiv.gov/hiv-basics/staying-in-hiv-care/other-related-health-issues/hepatitis-b-and-c/
[36] grants.nih.gov/grants/guide/notice-files/NOT-AI-22-043.html
[37] grants.nih.gov/grants/guide/rfa-files/RFA-DA-25-020.html
[38] grants.nih.gov/grants/guide/notice-files/NOT-AI-22-042.html

Understanding how comorbidities and coinfections that are prevalent in people with HIV interact with HIV viral reservoirs represents another area for future investigation. Due to emerging evidence that co-occurring conditions impact the HIV reservoir in ways that may interact with potential cure strategies,[39] future research on HIV reservoirs will need to investigate the impact of inflammation, altered metabolism, or other biological processes associated with prevalent comorbidities or coinfections.

Health conditions that co-occur with HIV interact with behavioral, economic, and environmental factors that influence the HIV/AIDS pandemic. Current NIH-supported projects are investigating interactions between HIV, co-occurring conditions, and other mitigating factors including substance use, polypharmacy, violence, sleep disruptions, and several social and structural determinants of health related to HIV prevention and treatment. Continued investment is needed to advance HIV/AIDS research on co-occurring conditions using a syndemic approach.[40]

Budget Policy: The FY 2025 President's Budget request to support research to address HIV-associated comorbidities, coinfections, and complications is $665.7 million, an increase of $0.9 million or 0.1 percent compared to the FY 2023 Final level.

Cross-Cutting Areas

NIH supports basic, foundational science to drive the discovery, development, and evaluation of novel HIV prevention, treatment, and cure strategies. The HIV/AIDS basic research agenda promotes advances in virology, immunology, and mechanisms of viral persistence. Basic research on the structural biology of the HIV capsid protein core provided the foundation for development of lenacapavir, the first capsid inhibitor approved by the FDA for treatment of HIV infection. A recent preclinical study showed that blocking an enzyme involved in forming HIV particles stopped the virus from becoming infectious, suggesting a possible new target for treating HIV infection.[41]

NIH supports behavioral and social sciences research to better understand and address the behavioral factors and social contexts that have an impact on HIV prevention, care, treatment, and cure. A recent study conducted in young adults with perinatally acquired HIV found that individuals who reported average or high levels of social support were more likely to maintain viral suppression than those with limited social support.[42] Behavioral and social sciences research also investigates the social determinants of health that influence well-being and quality of life. Recent research demonstrated that intersectional stigma and discrimination are factors that can discourage HIV testing, reduce engagement and retention in HIV prevention and care services, and result in worse health outcomes for women with HIV.[43] NIH continues to support research that investigates the mechanisms and pathways by which intersectional stigma and

[39] niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/concept-clearances/may-2023/impact-comorbidities-co-infections-hiv-reservoirs
[40] grants.nih.gov/grants/guide/rfa-files/RFA-HL-21-018.html; grants.nih.gov/grants/guide/rfa-files/RFA-DA-25-002.html; grants.nih.gov/grants/guide/pa-files/PAS-23-172.html
[41] nimh.nih.gov/news/science-news/2023/blocking-hiv-enzyme-reduces-infectivity-and-slows-viral-rebound
[42] nichd.nih.gov/newsroom/news/071723-HIV-social-support
[43] pubmed.ncbi.nlm.nih.gov/35876640/

discrimination, or other social and structural determinants of health interact to affect HIV prevention and treatment outcomes.

To optimize the public health impact of HIV/AIDS research, scientific findings must be implemented in clinical and community practice and disseminated to people affected by HIV. NIH encourages research on information dissemination and health communication strategies to promote public understanding, acceptance, and uptake of effective HIV-related interventions. NIH also supports research to identify and address HIV service gaps, reduce HIV-related health disparities, and contain HIV outbreaks in defined populations or geographic regions. Implementation science can identify strategies to increase real-world adoption of evidence-based interventions to close the science-to-service gap. A recent NIH-funded study found that mobile integrated harm reduction services (i.e., provision of PrEP, medications for opioid use disorder, and syringe exchange within a mobile unit) represent an acceptable venue to deliver HIV prevention services to African American/Black people who inject drugs.[44]

NIH is currently developing a new implementation science network to build on the success of the PATC^{3}H research program.[45] The Network will expand the achievements of PATC^{3}H to new geographic settings, stimulating implementation science research to prevent HIV acquisition among at-risk adolescent populations, and to promote long-term viral suppression among youth with HIV in low-to-middle income countries. The first group of awards for this network were funded in FY 2023.

NIH also addresses HIV health care service gaps through a new initiative to stimulate research on decentralizing these services to increase access to and capacity for routine delivery of HIV testing, prevention, and care services through pharmacies. Pharmacies are often seen as places where people can go for health care without feeling judged or stigmatized, and they offer more convenient access through longer hours and more locations in communities affected by HIV. NIH convened a meeting in July 2023 to identify barriers to delivering HIV-related services in pharmacies to generate research questions, and efforts are underway to develop new implementation science funding opportunities in this research area.

Capacity-building and strengthening activities represent another cross-cutting area within the HIV/AIDS research portfolio. NIH supports the development, recruitment, and retention of a diverse, multidisciplinary HIV research workforce. OAR works with Institutes, Centers, and Offices (ICOs) to support initiatives for HIV researchers who are early in their careers, including those from underrepresented groups, through a variety of funding mechanisms. The NIH-funded Visiting Professors program, a career development program for scientists conducting research to reduce health disparities in HIV and sexually transmitted infections, reports that program alumni have been awarded nearly $300 million in grant funding since the program's inception in 1997.[46]

NIH also supports research infrastructure by funding renovation, equipment, and resources for facilities conducting HIV/AIDS research. OAR collaborates with ICOs to offer funding opportunities for institutions to support development or renovation of HIV/AIDS research

[44] pubmed.ncbi.nlm.nih.gov/36463183/
[45] nichd.nih.gov/research/supported/PATC3H
[46] prevention.ucsf.edu/education/visiting-professor-program/accomplishments

facilities that serve underrepresented and underserved populations or are in states with historically low levels of NIH funding. These awards expand the diversity of researchers contributing to scientific discoveries and ensure significant long-term institution-wide support for HIV/AIDS research.

Budget Policy: The FY 2025 President's Budget request to support research to address HIV/AIDS research in cross-cutting areas is $1,359.7 million, an increase of $7.1 million or 0.5 percent compared to the FY 2023 Final level.