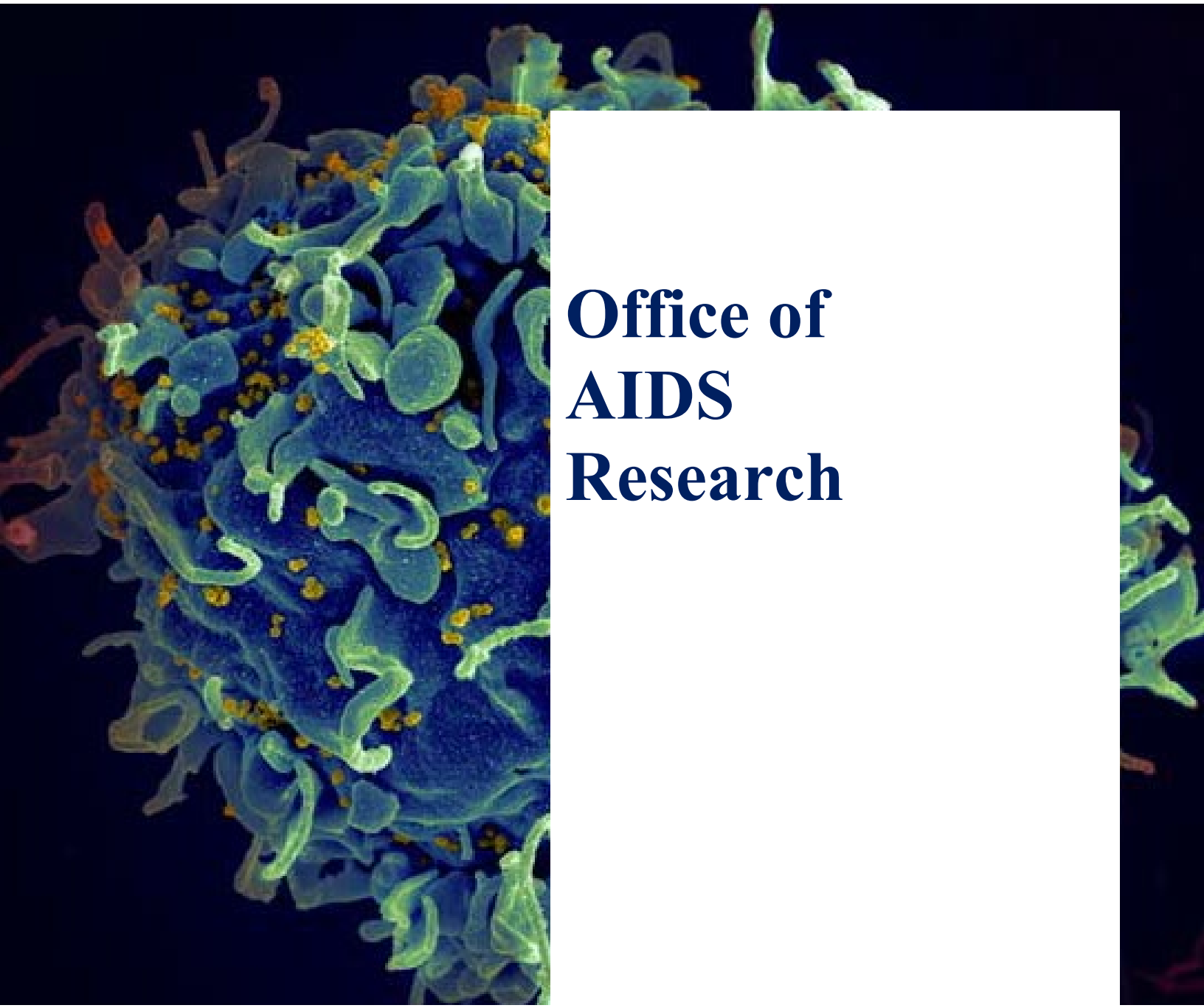

Office of AIDS Research

CONGRESSIONAL JUSTIFICATION
FY 2024

Department of Health and Human Services
National Institutes of Health

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 2024 Budget Table of Contents

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Director's Overview

Figure 1. Maureen M. Goodenow, Ph.D. Associate Director for AIDS Research and Director, Office of AIDS Research

Global health emergencies underscore how public investment in basic, clinical, behavioral, social, and implementation research protects and promotes human health. Over 40 years ago, the discovery of the human immunodeficiency virus (HIV) challenged scientists and policymakers to work together on acquired immunodeficiency syndrome (AIDS), which was then an untreatable, fatal disease. Thanks to the concerted effort of people from every sector of society and sustained U.S. government support, the development and implementation of evidence-based therapeutic, clinical, and behavioral strategies have turned HIV into a manageable chronic condition such that a person with HIV has a near-normal life expectancy.

Through the National Institutes of Health (NIH), investments in HIV/AIDS research have led to groundbreaking advances in our understanding of the virology, immunology, and pathogenesis of HIV. While there has been significant progress, the HIV/AIDS research community continues to face setbacks as a result of the COVID-19 pandemic. In addition, data indicate that persons with or at risk of HIV experienced significant obstacles due to closures, quarantines, and HIV service delivery interruptions.[1] In addition, medical mistrust and supply-chain shortages persist, both domestically and internationally, hindering access to HIV clinical care. Ongoing support for HIV/AIDS research is needed to advance scientific progress, enhance partnerships, and address critical research and implementation opportunities to end the HIV/AIDS pandemic.

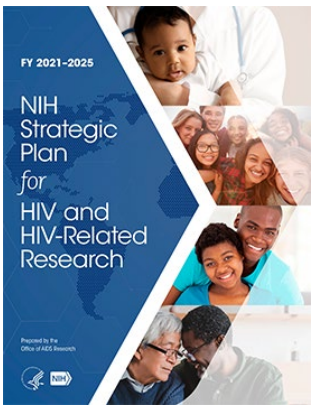
The Office of AIDS Research (OAR) was authorized initially by the Health Omnibus Programs Extension (HOPE) Act of 1988, P.L. 100-607, a statute amending the Public Health Service Act. These amendments legislated the appropriation of federal funding for prevention, testing, research, and fellowship and training programs related to AIDS. Subsequently, the NIH Revitalization Act of 1993, P.L. 103-43, authorized OAR to plan, coordinate, and evaluate AIDS research conducted or supported across NIH. OAR aims to:

- Oversee, coordinate, and manage all NIH HIV/AIDS research.
- Establish HIV-related research priorities and develop the NIH-wide strategic plan for HIV and HIV-related research.
- Identify areas of highest scientific priority for investment.
- Address emerging scientific needs and opportunities.
- Develop and allocate the NIH AIDS research budget and track and report funding.

We operationalize these mandated authorities through four Strategic Goals, outlined in the *Fiscal Year (FY) 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research* (NIH HIV Strategic Plan)[2] to:

[1] UNAIDS. In Danger: UNAIDS Global AIDS Update 2022. July 27, 2022. Accessed October 14, 2022. www.unaids.org/en/resources/documents/2022/in-danger-global-aids-update

[2] National Institutes of Health Office of AIDS Research. FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research. 2020. Accessed October 14, 2022. oar.nih.gov/sites/default/files/NIH_StrategicPlan_FY2021-2025.pdf



- Advance rigorous and innovative research to end the HIV/AIDS pandemic and improve the health of people with, at risk for, or affected by HIV across the lifespan.
- Ensure that the NIH HIV/AIDS research program remains flexible and responsive to emerging scientific opportunities and discoveries.
- Promote dissemination and implementation of research discoveries for public health impact across agencies, departments, and stakeholders within the U.S. government and globally.
- Strengthen human resource and infrastructure capacity to enhance sustainability of HIV/AIDS research discovery and the implementation of findings by a diverse and multidisciplinary workforce.

The Strategic Goals also provide the framework for OAR to promote the NIH Director's theme of *Turning Discovery into Health: Science for Everyone by Everyone.*

To ensure health at all stages of life for all people, we prioritize HIV treatment and prevention for persons of all ages across the lifespan. One significant achievement is the current rate of perinatal HIV transmission of less than two percent in the United States, reflecting, in part, increased routine HIV screening of pregnant persons and uptake of antiretroviral therapy (ART) for treatment and prevention.[3]

Adolescents with HIV infection face unique challenges during the transition from pediatric to adult health care settings, including interruptions in HIV care, changes in socioeconomic status and health insurance, and stigma and disclosure issues. Young adults with HIV often face issues related to cognitive development and mental health; medication adherence; and sexual, reproductive, and gender health concerns. In 2020, more than half of all people with HIV in the United States were age 50 or older, and about 17 percent of new infections occurred in persons older than age 50.[4] Chronic HIV infection and long-term use of ART can contribute to complications, coinfections, and comorbidities in people with HIV, particularly as they age. NIH supports basic, translational, and clinical research across the Institutes, Centers, and Offices (ICOs) to increase understanding of these comorbidities and their prevention and management, as well as their relationship to aging and HIV.

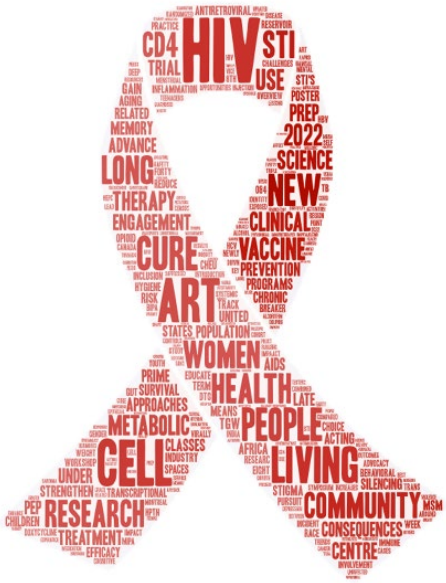
Black/African American and Hispanic/Latino communities are disproportionately affected by HIV compared to other racial/ethnic groups. In 2020, Black/African American persons represented 13.6 percent of the U.S. population, but accounted for 42 percent of people with HIV. Hispanic/Latino persons represented 18.9 percent of the U.S. population, but 27 percent of

[3] Nesheim SR, FitzHarris LF, Mahle Gray K, Lampe MA. Epidemiology of perinatal HIV transmission in the United States in the era of its elimination. *Pediatr Infect Dis J.* 2019;38(6):611-616. doi:10.1097/INF.0000000000002290. pubmed.ncbi.nlm.nih.gov/30724833

[4] Centers for Disease Control and Prevention. HIV Surveillance Report, 2020; vol. 33. May 2022. Accessed October 14, 2022. www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2020-updated-vol-33.pdf

people with HIV.[5,6] NIH supports research to better address underlying HIV-associated health disparities and inequities related to age, race, ethnicity, sex, gender, economic status, and geographic location. NIH is committed to promoting community engagement across the research continuum, with an emphasis on diverse populations, to ensure that community input informs the development of new research concepts and implementation of best practices.

To discover new strategies for prevention and treatment, OAR continues to support cutting-edge research. We were inspired by the advances showcased at the 24th International AIDS Conference (AIDS 2022), held in Montreal, Canada, which presented recent breakthroughs in HIV testing, prevention, and treatment and highlighted scientific gaps and opportunities for continued discovery. Recent NIH studies on long-acting injectable pre-exposure prophylaxis (PrEP) and treatment as prevention, both of which are preventive tools for people at risk of HIV acquisition, were presented at AIDS 2022. Access to and implementation of PrEP and self-testing are growing worldwide. Long-acting injectable PrEP may improve adherence and reduce stigma. Multipurpose prevention technologies for HIV, delivered through modalities such as vaginal rings, implants, or injectables, combine HIV prevention with interventions that prevent other sexually transmitted infections (STIs) and/or unintended pregnancy. Innovative mRNA technology has accelerated initial Phase I trials of HIV vaccine candidates.



To inspire the next generation of scientists, OAR promotes efforts to improve outreach to HIV/AIDS researchers early in their careers, including early stage investigators (ESIs). NIH is committed to developing and implementing a long-term plan to support, sustain, and improve the diversity of the next generation of the HIV/AIDS research workforce.[7] Outreach to ESIs emphasizes diversity, equity, inclusion, and accessibility within the HIV/AIDS research workforce.[8] NIH is committed to supporting HIV/AIDS researchers from underrepresented communities, expanding research capacity in historically under-resourced academic institutions, and ensuring that research is culturally appropriate and attentive to the needs of diverse communities. In spring 2022, OAR convened a listening session to determine how best to support the next generation of HIV/AIDS researchers and address training and capacity-building needs. We subsequently convened a "Workshop for Early Career Investigators in HIV/AIDS" to facilitate interactions between researchers, mentors, and NIH program staff. We plan to make

[5] Centers for Disease Control and Prevention. HIV Surveillance Report, 2020; vol. 33. May 2022. Accessed October 14, 2022. www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2020-updated-vol-33.pdf
[6] U.S. Census Bureau. U.S. Population Data by Race From U.S. Census Bureau. *Quick Facts*. 2020. Accessed October 14, 2022. www.census.gov/quickfacts/fact/table/US/RHI125221
[7] Lauer M, Tabak L, Collins F. Opinion: The Next Generation Researchers Initiative at NIH. *Proc Natl Acad Sci U S A*. 2017;114(45):11801-11803. doi:10.1073/pnas.1716941114. pubmed.ncbi.nlm.nih.gov/29114085
[8] National Institutes of Health. Chief Officer for Scientific Workforce Diversity (COSWD) Strategic Plan for Fiscal Years 2022–2026. April 2022. Accessed October 14, 2022. diversity.nih.gov/sites/coswd/files/images/NIH_COSWD_Strategic_Plan_for_Fiscal_Years_2022-2026_508c.pdf

materials from this workshop available to higher education institutions, including those serving minority and/or underrepresented researchers, as part of regular OAR outreach activities. The ESI initiative includes the launch of a highly visited webpage related to grant opportunities, training, and capacity-building programs.[9]

To promote team-based and interdisciplinary science, OAR convenes the NIH HIV/AIDS Executive Committee (NAEC) across the NIH ICOs to expand implementation, promote community engagement, and disseminate research findings. We will expand research focused on women's health and HIV by ensuring women are represented in HIV/AIDS research in collaboration with the NIH Office of Research on Women's Health (ORWH). NIH will continue to promote interdisciplinary research to better address comorbidities in people aging with HIV, as well as HIV-related psychosocial conditions, in partnership with several ICOs. Another inter-NIH collaboration focuses on reviewing pharmacy-based approaches to increase access to HIV testing, prevention, and care. NIH will continue research partnerships across academia, community, and government.

The omnibus appropriations bills for FY 2022 and FY 2023 provided NIH with the first significant increases for HIV and HIV-related research since FY 2014. OAR allocated this funding to the NIH ICOs to support focused investments in areas aligned with the goals of the NIH HIV Strategic Plan,[10] as well as the objectives of the *National HIV/AIDS Strategy* (NHAS)[11] and the accompanying *NHAS Federal Implementation Plan*,[12] including the *Ending the HIV Epidemic in the U.S.* (EHE) initiative.[13] Specific priorities in FY 2022 and FY 2023 for HIV/AIDS research were related to: direct support to the EHE initiative through the Centers for AIDS Research (CFARs); HIV and aging; vaccines; long-acting antiretroviral formulations; new therapeutic targets and technologies; cellular viral reservoirs; neurologic complications; management of comorbidities; health disparities; stigma; implementation science; social determinants of health; and workforce expansion and diversification.

For the past 35 years, OAR has catalyzed, coordinated, convened, and communicated HIV/AIDS research across NIH, alongside other government agencies and academia, with community and non-governmental organizations. Around the world, these partnerships have come together in unique ways to translate research into action, encourage a holistic response to the HIV/AIDS pandemic, and stimulate innovation. Accomplishments in HIV/AIDS research have propelled progress for other public health crises, such as COVID-19 vaccines and treatments. With a clear vision and achievable goals, we can collectively end the HIV/AIDS pandemic. Now is the time.

[9] National Institutes of Health Office of AIDS Research. Early Career Investigator Resources. Accessed October 14, 2022. www.oar.nih.gov/trans-nih-hiv-research-program/hiv-early-career-resources
[10] National Institutes of Health Office of AIDS Research. FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research. 2020. Accessed October 14, 2022. oar.nih.gov/sites/default/files/NIH_StrategicPlan_FY2021-2025.pdf
[11] The White House. National HIV/AIDS Strategy for the United States 2022–2025. December 2021. Accessed October 14, 2022. www.whitehouse.gov/wp-content/uploads/2021/11/National-HIV-AIDS-Strategy.pdf
[12] The White House. National HIV/AIDS Strategy Federal Implementation Plan. August 2022. Accessed October 14, 2022. files.hiv.gov/s3fs-public/2022-09/NHAS_Federal_Implementation_Plan.pdf
[13] What is *Ending the HIV Epidemic in the U.S.?* HIV.gov. Updated July 1, 2022. Accessed October 14, 2022. www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

National Institutes of Health
Office of AIDS Research

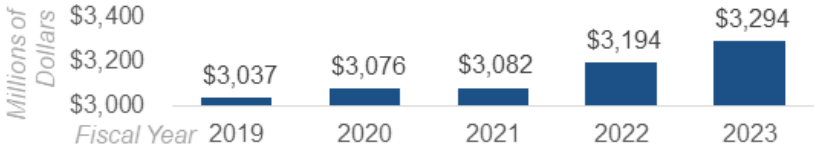
NIH Vision advance research to end the HIV/AIDS pandemic and improve health outcomes for people with HIV

OAR Mission ensure that NIH HIV/AIDS research funding is directed at the highest priority research areas and facilitate maximal return on the investment

The National Institutes of Health (NIH) provides the largest public investment in HIV/AIDS research in the world. HIV 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 the **NIH Office of AIDS Research (OAR)** to oversee, coordinate, and manage the NIH HIV/AIDS research portfolio. OAR is one of the coordinating offices within the Office of the NIH Director, in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). OAR collaborates across the U.S. government and with researchers, community groups, and global partners to identify priorities for HIV and HIV-related research.

NIH HIV/AIDS Funding: FY 2019 to FY 2023



The FY 2024 President's Budget request for the NIH-wide HIV/AIDS research program is $3.294 billion, the same as the FY 2023 Enacted level. Funding at this level will expedite NIH efforts to end the HIV pandemic.

NIH HIV/AIDS Research Highlights: FY 2022

- **New methods for HIV prevention** through preexposure prophylaxis (PrEP) have been approved by the FDA: an injectable drug administered every two months and a daily pill.
- **A clinical trial launched an HIV mRNA vaccine candidate that** utilized technology similar to the vaccine for COVID-19.
- **New reports of HIV remission** were documented in individuals who received a stem cell transplant.
- **Treatment involving bNAbs** (antibodies that can combat multiple HIV variants) could help individuals with HIV suppress the virus without daily pills.
- **Different sugar molecules** on the surface of immune cells affect their vulnerability to HIV infection, which could help discover a cure for HIV.
- **Removing precancerous lesions** in people with HIV could decrease their risk of anal cancer by more than half.

@NIH_OAR
oarinfo@nih.gov

basics and care: **HIVinfo.nih.gov**
clinical guidelines: **clinicalinfo.nih.gov**
research: **oar.nih.gov**

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

Facts & Figures

1.2M	*approximate number of people in the U.S. who have HIV (CDC data, 2019)*
$3.2B	*NIH funding for HIV/AIDS research in FY 2022*
7%	*of overall NIH budget dedicated to HIV/AIDS research in FY 2022*
100%	*of NIH HIV/AIDS research projects align with priorities defined by OAR in the NIH Strategic Plan for HIV and HIV-related Research*
>3,500	*projects in the NIH HIV/AIDS research portfolio, both domestic and international, spanning 96 countries*
22	*NIH institutes, centers, and offices receive funding for HIV/AIDS research through annual allocations managed by OAR*
18	*voting members on OARAC, the federal advisory committee that provides advice and guidance on HIV/AIDS research to OAR, the NIH Director, and HHS Secretary*
1	*The NIH OAR is the only NIH office focused on a single health condition.*

NIH National Institutes of Health
Office of AIDS Research

1981	*First report of the disease that will be named "acquired immune deficiency syndrome" (AIDS)*
1987	*AZT is the first drug approved by the FDA for treatment of people with human immunodeficiency virus (HIV)*
1988	*Congress establishes OAR to coordinate HIV/AIDS research across the NIH*
1996	*Combinations of antiretroviral therapy become widely available.*
1997	*CDC reports 47% decline in AIDS-related deaths in the U.S.*
2003	*U.S. government launches President's Emergency Plan for AIDS Relief (PEPFAR)*
2012	*FDA approves pre-exposure prophylaxis (PrEP) that prevents HIV transmission*
2017	*U = U (Undetectable = Untransmittable) Low viral levels not detectable on tests = no risk of transmitting HIV*
2021	*FDA approves first long-acting HIV treatment and prevention options*
2023	*Congress increases funding to NIH for HIV/AIDS research by an additional $100M*

Future Initiatives

- **Support innovative research** aligned with scientific priorities identified in the NIH Strategic Plan for HIV and HIV-related Research, Professional Judgment Budget for NIH HIV/AIDS Research, National HIV/AIDS Strategy (NHAS), and the *Ending the HIV Epidemic in the U.S. (EHE)* initiative.
- **Improve health outcomes** of people with HIV and comorbid conditions throughout the lifespan through multi-disciplinary and community-responsive research.
- **Understand the pathology and severity of co-infections** affecting the HIV-affected community, such as COVID-19 and mpox.
- **Develop diagnostic, vaccine, and therapeutic technologies** to support HIV/AIDS research, leveraging COVID-19 research platforms.
- **Identify new partners** for academic, governmental, industry, and community HIV/AIDS research collaborations to implement lessons learned, both domestically and globally.
- **Expand professional opportunities** for early career HIV/AIDS researchers.
- **Communicate the impact** of NIH HIV/AIDS research.

Recent Accomplishments

CATALYZE

Developed funding opportunities for HIV/AIDS **research infrastructure** with NIH offices to serve underrepresented or underserved populations

CONVENE

Continued hosting **listening sessions** and community events to gather stakeholder input on NIH HIV/AIDS research priorities

COORDINATE

Coordinated NIH input to strengthen the research components of the NHAS and its Federal Implementation Plan

COMMUNICATE

Authored articles with federal partners in national journals on HIV-related intersectional stigma and discrimination, as well as the NIH role in EHE

Current Activities

CATALYZE

Increase the number and diversity of HIV/AIDS **early career investigators** through workshops, digital resources, mentoring, stakeholder events

CONVENE

Facilitate knowledge exchange on topics related to HIV/AIDS research, such as **HIV and women, aging, diagnostics and clinical monitoring**

COORDINATE

Work across NIH to support cutting-edge methods and technologies, expand implementation, promote community engagement, and disseminate findings

COMMUNICATE

Support panels that provide **clinical guidelines**, developed through the OAR Advisory Council, with websites providing fact sheets and clinical resources

Recent Publications by OAR Staff
https://pubmed.ncbi.nlm.nih.gov/35703750/
https://pubmed.ncbi.nlm.nih.gov/35763747/
https://pubmed.ncbi.nlm.nih.gov/35763741/
https://pubmed.ncbi.nlm.nih.gov/33886010/

basics and care: **HIVinfo.nih.gov**
clinical guidelines: **clinicalinfo.nih.gov**
research: **oar.nih.gov**
contact: **OARinfo@nih.gov**

Budget Policy Statement

The FY 2024 President's Budget request for the NIH-wide HIV/AIDS research program is $3.294 billion, equal to the FY 2023 Enacted 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 ICOs 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
(Dollars in Thousands)

Institute, Center, and Office	FY 22 Final	FY 2023 Enacted [1]	FY 2024 President's Budget	FY 2024 +/- FY 2023
NCI	$248,940	$256,734	$256,734	$0
NHLBI	89,280	92,953	92,953	0
NIDCR	19,562	20,174	20,174	0
NIDDK	37,524	38,699	38,699	0
NINDS	40,206	41,206	41,206	0
NIAID	1,853,338	1,911,364	1,911,364	0
NICHD	147,716	152,881	152,881	0
NEI	234	-	-	0
NIEHS	5,505	5,512	5,512	0
NIA	26,038	28,538	28,538	0
NIAMS	4,727	4,875	4,875	0
NIDCD	2,193	2,262	2,262	0
NIMH	193,525	199,584	199,584	0
NIDA	270,077	278,533	278,533	0
NIAAA	34,150	35,219	35,219	0
NINR	16,848	17,375	17,375	0
NHGRI	824	824	824	0
NIBIB	1,895	1,954	1,954	0
NIMHD	24,224	24,982	24,982	0
NCCIH	689	689	689	0
FIC	25,132	25,919	25,919	0
NLM	7,685	7,685	7,685	0
OD	143,688	146,038	146,038	0
OAR	65,489	67,589	67,589	0
ORIP	78,199	78,449	78,449	0
Subtotal, OD	143,688	146,038	146,038	0
TOTAL, NIH	**$3,194,000**	**$3,294,000**	**$3,294,000**	**$0**

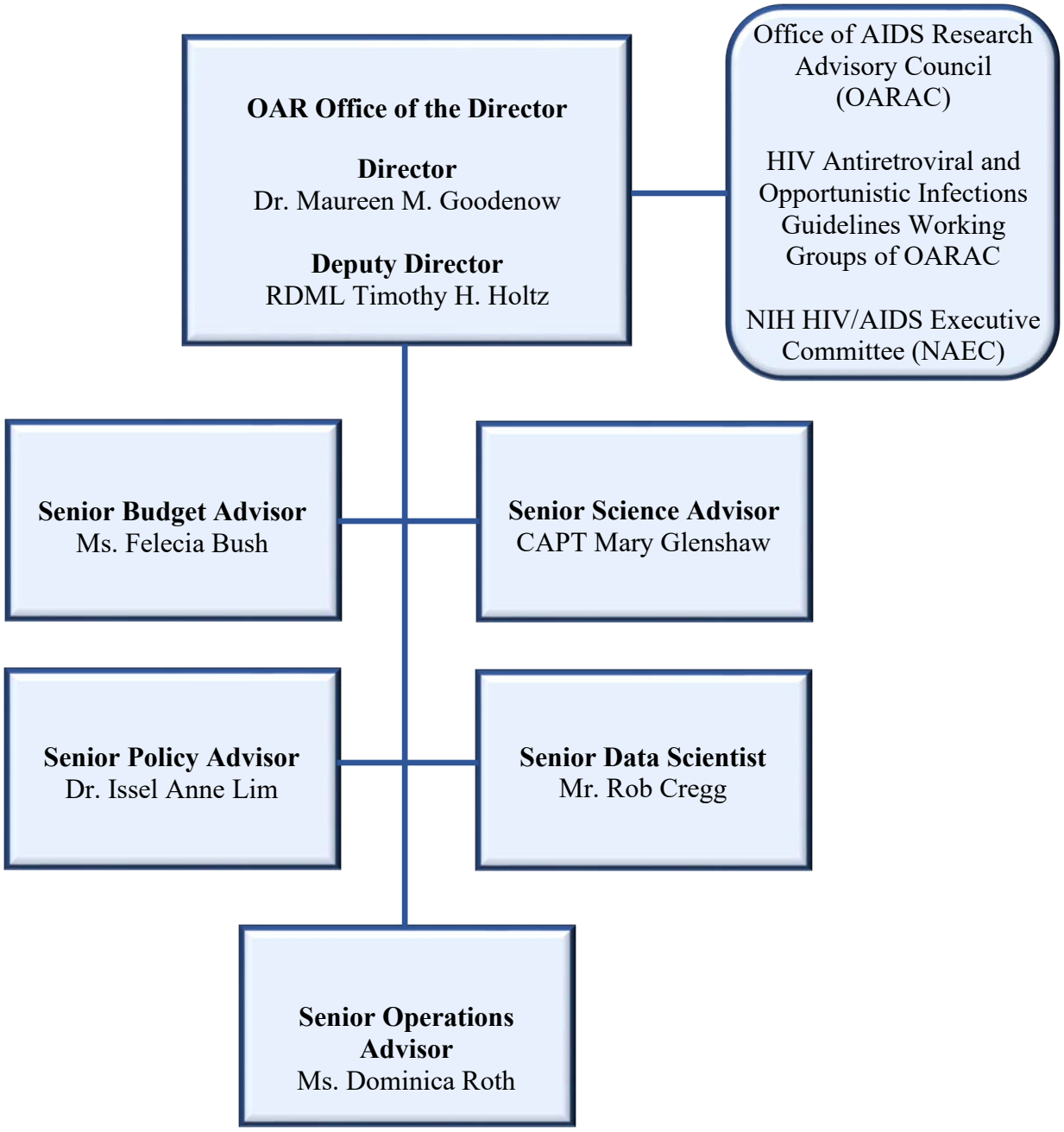
[1]Reflects HIV/AIDS transfers under the authority of Section 213 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2023.

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

Mechanism	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 +/- FY 2023	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Research Projects:								
Noncompeting	1,406	$1,463,353	1,412	$1,566,421	1,442	$1,549,307	30	-$17,114
Administrative Supplements	*(114)*	43,008	*(66)*	14,241	*(64)*	17,199	*(2)*	2,958
Competing	468	307,444	448	294,030	460	310,077	12	16,047
Subtotal, RPGs	1,874	$1,813,805	1,860	$1,874,692	1,902	$1,876,583	42	$1,891
SBIR/STTR	30	18,769	29	18,458	27	17,321	-2	-1,137
Research Project Grants	1,904	$1,832,574	1,889	$1,893,150	1,929	$1,893,904	40	$754
Research Centers:								
Specialized/Comprehensive	58	$149,683	63	$156,657	59	$153,376	-4	-$3,281
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	19	73,213	19	70,626	19	70,956	0	330
Research Centers in Minority Institutions	1	4,413	5	5,040	5	5,040	0	0
Research Centers	78	$227,309	87	$232,323	83	$229,372	-4	-$2,951
Other Research:								
Research Careers	265	$46,840	242	$42,595	244	$40,533	2	-$2,062
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	6	2,721	18	12,167	18	14,164	0	1,997
Biomedical Research Support	18	1,605	18	1,600	18	1,648	0	48
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	116	64,739	108	61,225	99	56,311	-9	-4,914
Other Research	405	$115,905	386	$117,587	379	$112,656	-7	-$4,931
Total Research Grants	2,387	$2,175,788	2,362	$2,243,060	2,391	$2,235,932	29	-$7,128
Ruth L. Kirschstein Training Awards:	FTTPs		FTTPs		FTTPs			
Individual Awards	85	$3,879	80	$3,716	69	$3,479	-11	-$237
Institutional Awards	240	14,726	245	15,891	241	15,745	-4	-146
Total Research Training	325	$18,605	325	$19,607	310	$19,224	-15	-$383
Research & Develop. Contracts	91	$408,648	97	$419,048	93	$422,980	-4	$3,932
(SBIR/STTR) (non-add)	*(7)*	*(3,898)*	*(5)*	*(3,898)*	*(5)*	*(3,898)*	*(0)*	*0*
Intramural Research		$356,467		$366,817		$368,511		$1,694
Res. Management and Support		169,003		177,879		179,764		1,885
Res. Management & Support (SBIR Admin) (non-add)		*0*		*0*		*0*		*0*
Office of the Director - Appropriation [2]		*143,688*		*146,038*		*146,038*		*0*
Office of the Director - Other		65,489		67,589		67,589		0
ORIP (non-add) [2]		*78,199*		*78,449*		*78,449*		*0*
Total, NIH Discretionary B.A.		**$3,194,000**		**$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. Maureen M. Goodenow
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. Issel Anne Lim
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 2020 Actual [1]	FY 2021 Actual [1]	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Reduce the Incidence of HIV	$719,217	$684,570	$689,324	$704,951	$698,941	-$6,010
Develop Next-Generation HIV Therapies	345,378	331,927	348,034	356,093	362,406	$6,313
Research Toward a Cure for HIV	209,133	224,737	223,450	227,310	226,463	-$847
Address HIV-Associated Comorbidities, Coinfections, and Complications	554,452	560,766	630,948	653,705	664,581	$10,876
Cross-Cutting Areas	1,247,881	1,279,897	1,302,244	1,351,941	1,341,609	-$10,332
Total	**$3,076,061**	**$3,081,897**	**$3,194,000**	**$3,294,000**	**$3,294,000**	**$0**

1/ Reflects effects of Secretary's transfer

Office of AIDS Research (OAR)

Budget Authority (BA):

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
BA	$3,194,000,000	$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 2024 President's Budget request for OAR is $3.294 billion, which is equal to the FY 2023 Enacted 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

At the end of 2020, an estimated 1.1 million persons in the United States and 6 dependent areas were living with diagnosed HIV infection, approximately 87 percent of whom were aware of their positive HIV status. During 2020, over 18,400 people with HIV died (due to any cause) and nearly 30,700 persons acquired a new HIV infection, with the highest rate occurring among young persons ages 25–34 years.[14] According to the U.S. Centers for Disease Control and Prevention (CDC), these numbers should be interpreted with caution, given disruptions in health care services due to the COVID-19 pandemic; therefore, these statistics may be an underestimate.

Despite the persistence of the HIV/AIDS pandemic, decades of public investment and the steadfast efforts of the scientific community have led to discoveries with the potential to radically change these statistics. The effective utilization of those treatment and prevention resources is essential to reduce HIV incidence and end the HIV/AIDS pandemic.

[14] Centers for Disease Control and Prevention. HIV Surveillance Report, 2020; vol. 33. May 2022. Accessed October 14, 2022. www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2020-updated-vol-33.pdf

Recently developed exciting new therapeutics have the potential to be used for more than one purpose. For example, long-acting antiretroviral formulations developed for HIV treatment also provide an effective prophylactic tool for HIV prevention. The HIV Prevention Trials Network studies of HPTN 083,[15] which studied cisgender men who have sex with men (MSM) and transgender women, and HPTN 084,[16] which studied cisgender women, demonstrated the safety and efficacy of long-acting injectable cabotegravir (CAB-LA) for PrEP, compared to daily oral PrEP. Long-acting injectable PrEP expands HIV prevention options and is now incorporated into regulatory requirements and World Health Organization (WHO) HIV guidelines.[17] NIH will continue support of research aiming to optimize use of injectable PrEP, as well as to understand the physiological consequences of long-term PrEP use. In addition, HIV vaccine research is a top funding priority in order to achieve an end of the HIV/AIDS pandemic.

Budget Policy: The FY 2024 President's Budget request to promote research to reduce HIV incidence is $699.0 million, a decrease of $6.0 million or -0.9 percent compared to the FY 2023 Enacted level.

***Ending the HIV Epidemic in the U.S.* (EHE) Initiative**

Launched in 2019, the EHE initiative aims to reduce new HIV infections in the United States by 75 percent in 2025 and by 90 percent in 2030. To achieve maximum impact, Phase I of EHE efforts focused on 57 jurisdictions, including 48 counties where more than 50 percent of new HIV diagnoses occurred in 2016 to 2017, as well as 7 states with a disproportionate occurrence of HIV in rural areas. These hotspots included Washington, DC, and San Juan, Puerto Rico.

NIH's primary role in the EHE initiative is to develop, test, and disseminate best practices based on state-of-the-art biomedical and social/behavioral research findings. Initiated from FY 2019 to FY 2022, NIH EHE projects address the four EHE pillars: diagnose, prevent, treat, and respond. In total, NIH EHE funding has been awarded to 201 highly meritorious projects. Focal areas include priority populations, communications strategies, and minority-serving institutions. In FY 2022, NIH funded 66 EHE projects that use data science, health equity strategies, behavioral economics, and status-neutral approaches with a focus on strategic partnerships across jurisdictions. There are 26 Centers for AIDS Research (CFARs), administered by the National Institute of Allergy and Infectious Diseases (NIAID), and AIDS Research Centers (ARCs), administered by the National Institute of Mental Health (NIMH), participating in the EHE initiative, with 10 CFARs serving as regional hubs for implementation science support. Over 50 state, local, and territorial public health departments and over 275 community organizations have participated in implementing NIH EHE research.

Develop Next-Generation HIV Therapies

Promising new technologies, such as 3D printing, microfluidics, and nanotechnology, could revolutionize HIV treatment and prevention strategies. New product delivery platforms and devices are being tested in specific populations, such as pediatric, adolescent, pregnant, and postpartum persons. NIH-funded researchers are studying early, intensive administration of ART in newborns to gauge the

[15] A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men. HIV Prevention Trials Network protocol number: HPTN 083 (20725). Accessed October 17, 2022. www.hptn.org/research/studies/hptn083

[16] A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women. HIV Prevention Trials Network protocol number: HPTN 084 (38070). Accessed October 17, 2022. www.hptn.org/research/studies/hptn084

[17] World Health Organization. Consolidated Guidelines on HIV, Viral Hepatitis and STI Prevention, Diagnosis, Treatment and Care for Key Populations. July 29, 2022. Accessed October 14, 2022. www.who.int/publications/i/item/9789240052390

possibility of early HIV remission, as well as the pharmacokinetics and safety of early ART in this population.[18]

Innovative technologies for viral load testing (measuring the amount of virus in the body) that are sufficiently sensitive and simple to use could help determine effectiveness of and adherence to emerging HIV therapies. Real-time rapid viral load monitoring could enable careful integration of analytical treatment interruption; specifically, when study participants stop using their usual ART to determine if a new investigational HIV drug can be as effective in delaying or preventing viral rebound. New combinations of modalities for HIV treatment, based on broadly neutralizing antibodies (bNAbs), are also being tested for prevention.

Multipurpose prevention technologies (MPTs) could allow the combination of HIV prevention and treatment with interventions for other health conditions or indications, such as contraception, prevention of STIs, and hormone replacement therapy for postmenopausal women. These MPTs can be delivered through different modalities, such as vaginal rings, implants, or injectables. This is a crucial next step in the development of behaviorally congruent products that fit into people's lifestyles to improve HIV prevention and treatment uptake and adherence.

In the wake of scientific advancement and successes in HIV self-testing during the COVID-19 pandemic, communities are expressing interest in self-administered, affordable, and accessible products to monitor and maintain their health. Several studies are investigating person-centered, holistic, and integrated intervention approaches for groups disproportionately affected by the HIV/AIDS epidemic in the United States, including transgender people (HPTN 091),[19] people who inject drugs (HPTN 094),[20] and Black MSM in the South (HPTN 096).[21] NIH will continue to expand its support of multidisciplinary research designed to advance the development, future use, and equitable delivery of long-acting and extended delivery regimens for HIV prevention and treatment, as well as self-testing and monitoring technologies.

Budget Policy: The FY 2024 President's Budget request to support research to develop next-generation HIV therapies is $362.4 million, an increase of $6.3 million or 1.8 percent compared to the FY 2023 Enacted level.

[18] Very Early Intensive Treatment of HIV-Infected Infants to Achieve HIV Remission. ClinicalTrials.gov identifier: NCT02140255. Updated November 4, 2021. Accessed October 14, 2022. clinicaltrials.gov/ct2/show/NCT02140255

[19] Integrating HIV Prevention, Gender-Affirmative Medical Care, and Peer Health Navigation to Prevent HIV Acquisition and HIV Transmission for Transgender Women in the Americas: A Vanguard Feasibility and Acceptability Study. HIV Prevention Trials Network protocol number: HPTN 091 (38695). Accessed October 17, 2022. www.hptn.org/research/studies/hptn091

[20] INTEGRA: A Vanguard Study of Health Service Delivery in a Mobile Health Delivery Unit to Link Persons who Inject Drugs to Integrated Care and Prevention for Addiction, HIV, HCV and Primary Care. HIV Prevention Trials Network protocol number: HPTN 094 (38715). Accessed October 17, 2022. www.hptn.org/research/studies/hptn094

[21] Getting to Zero Among Black MSM in the American South: Testing the Efficacy of an Integrated Intervention Strategy. HIV Prevention Trials Network protocol number: HPTN 096 (38561). Accessed October 17, 2022. www.hptn.org/research/studies/hptn096

Research Toward HIV Cure

Groundbreaking research advances in HIV treatment have helped turn HIV into a manageable, chronic condition—but current treatments do not cure HIV. HIV cure research is focused on two broad aims: sustained viral remission and, in the longer term, viral eradication.

HIV is a complex virus that can hide from the immune system, but NIH investment in HIV virology will continue to advance the current understanding of viral reservoirs and long-term viral suppression. Latent HIV viral reservoirs are groups of cells that are infected with HIV, but are not actively producing new virus. These small amounts of latent HIV persist even in people taking ART, presenting a significant challenge for an HIV cure because the virus can reactivate at any time. Additionally, HIV reservoirs can be found in certain "sanctuary" sites in the body; that is, cells where the virus is protected from both the person's immune system and ART, such as in the central nervous system (CNS) and other tissues. To work towards a cure for HIV, NIH supports studies to develop novel approaches and treatments that target these HIV reservoirs. 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 cure for HIV.

Methods using a combination of donated cord blood stem cells and cells from a related donor hold major promise for a potential HIV cure.[22] There are a few, rare examples of having achieved an HIV cure (currently, only four cases worldwide) that provide a glimpse into the areas of research needed to better understand the dynamics of viral reactivation (the process by which the virus becomes active from its latent state).

NIH also supports research on the host's genetic factors that may influence the size and composition of latent viral reservoirs in people with HIV on ART regimens, interactions between the virus and immune cells, and strategies to prevent the development of drug resistance. Several experimental techniques, including single-cell imaging technologies, gene assays, and testing new molecular treatments, are being used to better understand how HIV can reactivate from latently infected cells. Latency-reversing agents can make HIV visible to the immune system so it can be eliminated. Other experimental treatments include genetically engineered immune cells that are resistant to HIV infection, therapeutic vaccines, and long-acting antiretrovirals that can suppress virus for a few months or even longer. Another strategy is gene editing using CRISPR-Cas9 that potentially could cut and remove viral HIV integrated into the genomic DNA of people with HIV. In September 2021, the U.S. Food and Drug Administration (FDA) approved the initiation of the first clinical trial investigating CRISPR-based gene therapy

[22] Marley G, Tan RKJ, Tang W. Stem cell research finds possible HIV cure with cord blood transplant. *Innovation (Camb)*. 2022;3(3):100238. doi:10.1016/j.xinn.2022.100238. pubmed.ncbi.nlm.nih.gov/35601216

as a possible approach to achieve an HIV cure.[23] Additional NIH-funded studies are planned in this area.

Research focused on prevention also can help drive discovery toward an HIV cure. An NIH-funded study found that individuals with HIV who began taking ART in the early stages of infection, then stopped ART and received two infusions of bNAbs, achieved a lengthy period of HIV suppression.[24,25] Since bNAbs can be engineered to recognize a broad array of HIV variants, they could help remove viral variants and induce remission.

NIH will expand support for multidisciplinary research teams to analyze processes to establish and maintain latent HIV reservoirs in various tissues (e.g., gastrointestinal, male genital tract, kidney, and adipose tissues). NIH will advance nanotechnology approaches to target reservoirs and promote new research models to replicate viral-host cell interactions, especially for privileged sanctuary sites like the brain. NIH will also advance behavioral and social science research to ascertain which cure strategies would be most effective in different populations with HIV. The ultimate goal of integrating behavioral, biomedical, and implementation science approaches in cure research is to develop safe, effective, scalable, and sustainable strategies that will be available to all people with HIV around the globe, thus maximizing the impact of this research.

Budget Policy: The FY 2024 President's Budget request to promote research toward an HIV cure is $226.5 million, a decrease of $0.8 million or -0.4 percent compared to the FY 2023 Enacted level.

Address HIV-Associated Comorbidities, Coinfections, and Complications

People with HIV who adhere to ART regimens have a near-normal life expectancy. However, comorbidities, coinfections, and other complications can affect the health and well-being of persons with HIV at all ages. The aggregate of multiple concomitant conditions, known as multimorbidity, can significantly jeopardize the quality of life of persons with HIV. Common HIV-associated coinfections, including tuberculosis, hepatitis, malaria, and STIs, have posed long-standing challenges worldwide. New emerging infectious diseases bring additional challenges and require critical attention to improving the health and well-being of persons with HIV. In recent years, two emerging infectious diseases, COVID-19 and mpox (formerly monkeypox), have significantly affected people with or at risk of HIV acquisition.

Biospecimens and clinical data from ongoing, large NIH-funded cohort studies, such as the Multicenter AIDS Cohort Study (MACS)/Women's Interagency HIV Study (WIHS) Combined Cohort Study (also known as MWCCS), are being leveraged to better understand the impact of the COVID-19 pandemic among men and women in the United States with or at risk of HIV

[23] Study of EBT-101 in Aviremic HIV-1 Infected Adults on Stable ART. ClinicalTrials.gov identifier: NCT05144386. Updated October 19, 2022. Accessed October 25, 2022. clinicaltrials.gov/ct2/show/NCT05144386

[24] Combination anti-HIV antibody infusions suppress virus for prolonged period. Media Advisory. National Institutes of Health. June 1, 2022. Accessed October 14, 2022. www.nih.gov/news-events/news-releases/combination-anti-hiv-antibody-infusions-suppress-virus-prolonged-period

[25] Sneller MC, Blazkova J, Justement JS, et al. Combination anti-HIV antibodies provide sustained virological suppression. *Nature.* 2022;606(7913):375-381. doi:10.1038/s41586-022-04797-9. pubmed.ncbi.nlm.nih.gov/35650437

infection and to evaluate host factors that contribute to disease acquisition, expression, severity, and recovery.[26,27] Recent MWCCS survey data show that, despite similar testing rates and COVID-19 mitigation efforts, persons with HIV were more likely to have a positive SARS-CoV-2 test and report more symptoms than persons who are not infected with HIV.[28] Additionally, investigators are documenting the psychosocial health effects related to the COVID-19 pandemic in people with HIV and proposing structural and social interventions.[29] NIH's clinical guidelines panels, under the auspices of the OAR Advisory Council (OARAC), published guidance for COVID-19 and people with HIV.[30] Expanded research efforts will focus on investigating the challenges and barriers that account for these health disparities.

HIV and Aging

According to CDC, over half of persons with HIV in the United States are age 50 years or older, and nearly 17 percent of new infections in 2020 occurred in this age group. With expanded ART use, the number of people aging with HIV is increasing rapidly. Individuals aging with HIV are more likely to experience the effects of accelerated aging, higher rates of neurocognitive and cardiovascular complications, some malignancies, and metabolic and bone disorders. These conditions are most likely caused by chronic low-level activation of the immune system. Older people with HIV have higher levels of comorbidities compared to people of similar age without HIV. Furthermore, people aging with HIV face both age-related and HIV-related stigma.

An interdisciplinary approach that includes geroscience (the study of the intersection between basic aging biology and chronic disease) and the social sciences is required to address the increasing health concerns and improve health outcomes in people aging with HIV. OAR collaborates with the National Institute on Aging (NIA) to support research on HIV and aging.

Preliminary CDC data from May to July 2022 suggest that MSM comprised a high proportion of mpox cases in the United States early in the mpox outbreak, and nearly 40 percent of those occurred in persons with HIV. In addition, people with HIV experience more severe symptoms of mpox infection. Significant racial disparities exist among people who have both HIV and mpox, with higher rates in Black and Hispanic individuals compared to White individuals and other populations.[31] NIH is screening novel therapeutic compounds and planning more extensive clinical testing of drug candidates, since a specific treatment is not approved for mpox virus infection. The NIH-funded AIDS Clinical Trials Group (ACTG) network is conducting a clinical trial to test the drug tecovirimat (TPOXX) for treatment of mpox

[26] D'Souza G, Bhondoekhan F, Benning L, et al. Characteristics of the MACS/WIHS Combined Cohort Study: Opportunities for Research on Aging With HIV in the Longest U.S. Observational Study of HIV. *Am J Epidemiol*. 2021;190(8):1457-1475. doi:10.1093/aje/kwab050. pubmed.ncbi.nlm.nih.gov/33675224

[27] MACS/WIHS Combined Cohort Study. Accessed October 25, 2022. statepi.jhsph.edu/mwccs

[28] D'Souza G, Tong W, Gustafson D, et al. SARS-CoV-2 infection among people living with HIV compared with people without HIV: Survey results from the MACS-WIHS Combined Cohort Study. *J Acquir Immune Defic Syndr*. 2022;89(1):1-8. doi:10.1097/QAI.0000000000002822. pubmed.ncbi.nlm.nih.gov/34878431

[29] Friedman MR, Kempf MC, Benning L, et al. Prevalence of COVID-19-related social disruptions and effects on psychosocial health in a mixed-serostatus cohort of men and women. *J Acquir Immune Defic Syndr*. 2021;88(5):426-438. doi:10.1097/QAI.0000000000002799. pubmed.ncbi.nlm.nih.gov/34757972

[30] Guidelines Working Groups of the NIH Office of AIDS Research Advisory Council. Guidance for COVID-19 and People with HIV. Updated February 22, 2022. Accessed October 14, 2022. clinicalinfo.hiv.gov/en/guidelines/guidance-covid-19-and-people-hiv/whatsnew-covid-19-and-hiv-guidance

[31] Centers for Disease Control and Prevention. Severe Manifestations of Monkeypox Among People Who Are Immunocompromised Due to HIV or Other Conditions. September 29, 2022. Accessed October 14, 2022. emergency.cdc.gov/han/2022/han00475.asp

virus in individuals with underlying immunodeficiency, including persons with HIV.[32] Additional research will continue to investigate the high rate of mpox co-occurrence with HIV, with investments in diagnostics and vaccine efficacy in this population.

Other Comorbidities Across the Lifespan

Common comorbidities in people with HIV, which continue to persist despite effective ART, include neurological complications, cardiovascular disease, diabetes, some cancers, kidney and liver disease, bone loss, and complications due to long-term ART.[33,34] The risk of fracture is higher and increases about 10 years earlier in people with HIV, compared to the general population.[35] People with HIV are also at a high risk of developing mental health, cognitive, and/or substance use disorders.[36] Optimizing approaches to integrated service delivery are needed to address comorbidities, frailty, polypharmacy, social and mental health, and sexual health.

Immune dysfunction and chronic immune activation are thought to be the primary drivers of CNS comorbidities in people with HIV on ART. These CNS comorbidities include neurologic, neurocognitive, and mental health problems; however, considerable gaps exist in understanding these HIV-associated comorbidities. Recent studies show that HIV specifically alters the immune system and the microbiome in the gut, resulting in immune dysfunction, as well as higher levels of systemic inflammation, which may alter brain development, neurotransmitter systems, signaling pathways, and other CNS functions.[37] Current NIH research in the neuro-HIV field is focused on studying the mechanisms underlying microbiome-immune-neuronal interactions, how these mechanisms are affected by HIV even with individuals receiving ART, and how these disruptions impact neuronal function.[38,39] OAR and NIA are partnering to support cross-disciplinary studies on the similarities and differences between the mental and physical declines in Alzheimer's disease and HIV-associated neurocognitive disorder (HAND).[40] In 2022, NIA released a Notice of Special Interest (NOSI) to accelerate new knowledge related to

[32] National Institute of Allergy and Infectious Diseases. Monkeypox Treatment. Reviewed October 13, 2022. Accessed October 14, 2022. www.niaid.nih.gov/diseases-conditions/monkeypox-treatment
[33] Go AS, Reynolds K, Avula HR, et al. Human immunodeficiency virus infection and variation in heart failure risk by age, sex, and ethnicity: The HIV HEART Study. *Mayo Clin Proc*. 2022;97(3):465-479. doi:10.1016/j.mayocp.2021.10.004. pubmed.ncbi.nlm.nih.gov/34916054
[34] HIV linked to increased risk for heart failure. News release. National Heart, Lung, and Blood Institute. January 21, 2022. Accessed October 14, 2022. www.nhlbi.nih.gov/news/2022/hiv-linked-increased-risk-heart-failure
[35] Biver E. Osteoporosis and HIV infection. *Calcif Tissue Int.* 2022;110(5):624-640. doi:10.1007/s00223-022-00946-4. pubmed.ncbi.nlm.nih.gov/35098324
[36] National Institute of Mental Health. HIV/AIDS and Mental Health. Accessed October 14, 2022. www.nimh.nih.gov/health/topics/hiv-aids
[37] Le LT, Price RW, Gisslén M, et al. Correlation between CD4/CD8 ratio and neurocognitive performance during early HIV infection. HIV Med. 2022; online ahead of print. doi: 10.1111/hiv.13411. https://pubmed.ncbi.nlm.nih.gov/36134890/
[38] National Institutes of Health. RFA-MH-21-250. Deciphering Immune-CNS interactions in people living with HIV on Anti-Retroviral therapy. August 19, 2022. Accessed October 14, 2022. grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-250.html
[39] National Institutes of Health. RFA-MH-22-230. Understanding the role of Gut Immune dysfunction and Gut Microbiome in pathogenesis of Central Nervous System co-morbidities in people living with HIV. April 25, 2022. Accessed October 14, 2022. grants.nih.gov/grants/guide/rfa-files/RFA-MH-22-230.html
[40] National Institutes of Health Office of AIDS Research. Office of AIDS Research and National Institute on Aging Launch Collaboration. Reviewed June 8, 2020. Accessed October 14, 2022. www.oar.nih.gov/trans-nih-hiv-research-program/project-spotlightnational-institute-on-aging-collaboration

the science of HIV and aging and to expand the pool of researchers conducting studies at the intersection of HIV and aging.[41]

People with HIV who are aging experience significant metabolic complications; however, the mechanisms by which these complications occur are not fully understood. Studies have shown that long-term ART may contribute to potentially detrimental lipid storage in multiple tissues, which in turn may lead to chronic inflammation and metabolic dysfunction, resulting in comorbidities such as diabetes and cardiovascular disease.[42] NIH is supporting research to investigate the mechanisms by which the immune system contributes to this abnormal lipid distribution to advance diagnostic and therapeutic interventions to improve the metabolic health of people with HIV.

NIH will continue to foster basic and translational research, focusing on how HIV infection and HIV treatment impacts systemic disease progression and pathogenesis, resulting in HIV-associated comorbidities. Additional research will focus on identifying and developing etiological targets and biomarkers for diagnosis and therapeutic interventions. In addition, NIH will expand support for multidisciplinary approaches to better understand the underlying mechanisms of long-term HIV comorbidities.

Budget Policy: The FY 2024 President's Budget request to support research to address HIV-associated comorbidities, coinfections, and complications is $664.6 million, an increase of $10.9 million or 1.7 percent compared to the FY 2023 Enacted level.

Cross-Cutting Areas

Basic Science: Expanding the basic biomedical research portfolio is critical to advance discovery in HIV virology, immunology, and pathogenesis. The unique characteristics of the viral life cycle, including the ability of HIV to become part of the host cell genome, present significant challenges to the development of effective vaccine and cure strategies. Another challenge is the diversity of immune cells the virus can infect. Recently, an NIH-funded team found that patterns of sugars at the surface of human immune cells affect their vulnerability to HIV infection. These data suggest that infected immune cells harboring HIV could be located by identifying the sugar profiles on the surface of these cells.[43,44]

Behavioral and Social Sciences Research: NIH continues to support research at the intersection of HIV, mental health, and substance use to accelerate testing of effective prevention interventions and address underlying social determinants of health. Several ongoing and recent studies focus on key populations, including MSM, Black/African American women, people who use alcohol and other drugs, and other priority populations in geographic hotspots such as in the

[41] National Institutes of Health. NOT-AG-22-014. Notice of Special Interest: Administrative Supplements for HIV/AIDS and Aging Research. February 22, 2022. Accessed October 14, 2022. grants.nih.gov/grants/guide/notice-files/NOT-AG-22-014.html
[42] Bailin SS, Gabriel CL, Fan R, et al. Relationship of Subcutaneous Adipose Tissue Inflammation-Related Gene Expression With Ectopic Lipid Deposition in Persons With HIV. *J Acquir Immune Defic Syndr.* 2022; 90(2):175-183. doi: 10.1097/QAI.0000000000002926.pubmed.ncbi.nlm.nih.gov/35125474/
[43] Tabak, L. Finding HIV's 'Sweet Spot.' *NIH Director's Blog*. July 19, 2022. Accessed October 14, 2022. directorsblog.nih.gov/2022/07/19/finding-hivs-sweet-spot
[44] Ma T, McGregor M, Giron L, et al. Single-cell glycomics analysis by CyTOF-Lec reveals glycan features defining cells differentially susceptible to HIV. *Elife*. 2022;11:e78870. doi:10.7554/eLife.78870. pubmed.ncbi.nlm.nih.gov/35787792

Southern United States. Initiatives aimed at developing and testing novel behavioral and social science interventions along the HIV continuum of care, such as multilevel, combination prevention approaches, and the deployment of digital tools for HIV testing and clinical monitoring show promising outcomes, particularly in youth. Advancing similar strategies in diagnostics and distribution approaches has the potential to facilitate HIV self-testing, expand access to health care, and reduce stigma for persons with and risk for HIV acquisition. NIH plans to expand research to better understand the causal pathways between core psychosocial factors and HIV outcomes, including health disparities and inequalities, to inform development of sociostructural interventions and develop appropriate metrics and methodologies for assessing health systems, organizational contexts, and implementation processes and outcomes in diverse settings.

Information Dissemination and Health Communications: The health communications landscape has been radically transformed by the widespread use of social media, mobile app-based services, and other new communication technologies that enable users to access real-time information, which then can be rapidly disseminated and amplified. Accurate and fact-based scientific information can be a powerful public health tool, whereby the channels and content of health communications reflect the needs and concerns of diverse communities. An example of a highly successful HIV-related health communications campaign has been promotion of the message that undetectable (HIV) is untransmittable, or U=U. The NIH Advancing Health Communication Practice and Science program will investigate new ways to engage with diverse HIV communities and capitalize on the benefits of more than 40 years of public investment in HIV science.[45] Future research will develop and test novel health communication strategies to improve the introduction, explanation, and rollout of new HIV scientific tools and discoveries, such as those to inform and support acceptance and uptake of future vaccine candidates that would protect against HIV acquisition, a key NIH priority. Another priority is research on the prevention, mitigation, and/or counteraction of HIV-related misinformation and deliberate disinformation campaigns. OAR will continue its series of listening sessions and community engagement meetings in various locations to obtain stakeholder input on recent research findings, research priorities, and optimal translation and dissemination strategies.

Implementation Science: NIH supports research to identify effective HIV interventions and strategies to optimize provision and uptake of HIV prevention, care, and treatment, particularly as these further the goals of the NHAS, the *NHAS Federal Implementation Plan*, and the EHE initiative. NIH-wide input strengthened the NHAS research component in FY 2022, noting gaps in knowledge and implementation practices. The NHAS research-focused objectives cover a broad range of basic, clinical, behavioral/social sciences, implementation, and communications science. Planned activities include strengthening interventions and implementation strategies that target social and structural determinants of health and ultimately improve HIV outcomes (including retention in care and adherence to treatment) and reduce health inequities. NIH also

[45] National Institutes of Health Office of Strategic Coordination – The Common Fund. Advancing Health Communication Science and Practice. Reviewed September 13, 2022. Accessed October 14, 2022. commonfund.nih.gov/healthcommresearch

Promoting a Diverse Workforce

The NIH HIV Strategic Plan highlights a goal to "build human resource and infrastructure capacity to enhance sustainability of HIV research discovery and the implementation of findings by a diverse and multidisciplinary workforce." Researchers who are starting to build their careers are critical to the long-term stability of all scientific research. OAR works with NIH ICOs to develop and support HIV-focused initiatives that will support HIV/AIDS researchers who are early in their careers.

OAR conducted multiple stakeholder events and gathered comprehensive input on how to improve outreach to this group of HIV/AIDS researchers. OAR improved access to training in grant writing and peer review, offering consultations with HIV/AIDS senior scientists and mentors. OAR also developed online resources to centralize all relevant information for HIV/AIDS researchers and provide easy access to relevant grant opportunities, training, and capacity-building programs. OAR convened a successful workshop in April 2022 to stimulate scientific collaborations among the next generation of HIV/AIDS researchers and enhance career development skills. An additional workshop is planned for FY 2023.

supports implementation research on the development of health care strategies tailored for older people with HIV.[46,47]

Training, Infrastructure, and Capacity-Building: NIH is committed to supporting the next generation of HIV/AIDS researchers and ensuring the HIV/AIDS research workforce is diverse and representative of historically underrepresented groups through support of virtual workshops and other focused outreach activities. Multidisciplinary training also provides innovative perspectives on HIV and geriatrics research, which could inform responses to the health care needs of a growing population of people who are aging with HIV. NIH will increase its support for research infrastructure by funding alterations, renovation, equipment, and resources for facilities conducting HIV/AIDS research.

Budget Policy: The FY 2024 President's Budget request to support research to address HIV/AIDS research in cross-cutting areas is $1,341.6 million, a decrease of $10.3 million or -0.8 percent compared to the FY 2023 Enacted level.

[46] National Institutes of Health. U24HL15442. Implementation Research Strategies for Heart, Lung, and Blood Co-morbidities in People Living with HIV - Research Coordinating Center. September 15, 2022. Accessed October 14, 2022. reporter.nih.gov/project-details/10477320

[47] National Institutes of Health. K76AG064545. Tailored Geriatric Assessment and Management for HIV Care Settings. May 4, 2022. Accessed October 14, 2022. reporter.nih.gov/project-details/10361518