

NIH in a Changing World: Science to Enhance Human Health



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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research (OAR)

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Director's Overview

In June 2021, we commemorated the 40th anniversary of the first published cases of what later became known as AIDS and lauded the remarkable accomplishments in HIV prevention and treatment to date. At the same time, the world faces the ongoing consequences of a new global pandemic—coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)—which has brought unprecedented challenges. The HIV workforce—from infectious disease doctors to basic laboratory researchers to community health advocates—enlisted quickly to fight COVID-19 and to apply knowledge, tools, infrastructure, and practices honed during the response to HIV/AIDS. As COVID-19 spread in the United States and globally, the same kinds of social inequalities and health disparities that characterize the HIV pandemic emerged. Attention to such inequalities was heightened by a resurgent racial justice movement that, along with the immediacy of COVID-19, has forced everyone to think about how to do things differently. Now there is evidence of the cumulative impact of COVID-19 on progress against HIV. Both service provision and research are significantly affected in the United States and globally.^{177,178} This underscores the need to rekindle support for research that will yield novel and nimble tools to address the ongoing challenges of the HIV pandemic and contribute to solutions for other infectious disease pandemics.



**Maureen M.
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Associate Director for
AIDS Research and
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AIDS Research
National Institutes of

The National Institutes of Health (NIH) Office of AIDS Research (OAR) has provided leadership in setting the national and global HIV research agenda since its establishment in 1988 through Section 2353 of the Public Health Service Act. Located within the NIH Office of the Director, the OAR is authorized to—

- Oversee, coordinate, and manage all NIH HIV-related research;
- Establish research priorities and develop the strategic plan for HIV research;
- Ensure that funds are invested in the areas of highest scientific priority and track and report on funding; and
- Address emerging needs and opportunities.

¹⁷⁷ Chenneville T, et al. 2020. The impact of COVID-19 on HIV treatment and research: A call to action. *Int. J Environ Res Public Health* 17(12):4584; doi: 10.3390/ijerph17124548.

¹⁷⁸ Mermelstein E. 2021. At the intersection of two pandemics: The impact of COVID-19 on HIV. *Infectious Disease Advisor*, July 9, 2021. Available at: www.infectiousdiseaseadvisor.com/home/topics/hiv-aids/how-covid-19-affected-the-hiv-pandemic.

OAR operationalizes its authorities through activities related to the following four Strategic Goals outlined in the *Fiscal Year (FY) 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research*.¹⁷⁹



Advance rigorous and innovative research to end the HIV pandemic and improve the health of people with, at risk for, or affected by HIV across the lifespan: OAR catalyzes multidisciplinary and novel approaches in HIV prevention, treatment, cure, and co-morbidities research and supports research to better address underlying HIV-associated health disparities and inequalities related to age, race, ethnicity, sex, gender, economic status, and geographic location.



Ensure that the NIH HIV research program remains flexible and responsive to emerging scientific opportunities and discoveries: OAR works with the NIH Institutes, Centers, and Offices (ICOs) and other partners to develop novel approaches to HIV prevention, treatment, and cure, including long-acting injectables for prevention and treatment, new therapeutic targets, messenger RNA (mRNA) vaccines, and gene therapy. OAR continues to apply lessons learned from the COVID-19 pandemic to HIV science and to monitor the effects of COVID-19 on HIV research.



Promote dissemination and implementation of research discoveries for public health impact across agencies, departments, and stakeholders within the U.S. government and globally: OAR is expanding NIH activities in support of the *Ending the HIV Epidemic* (EHE) initiative;¹⁸⁰ extending its Listening Sessions and other stakeholder outreach and engagement activities;¹⁸¹ and supporting national and international HIV-related conferences to ensure broad access to the latest scientific knowledge.



Strengthen human resource and infrastructure capacity to enhance sustainability of HIV research discovery and the implementation of findings by a diverse and multi-disciplinary workforce: OAR is expanding its initiatives to build and diversify the cadre of early-career HIV investigators and is implementing novel ways to conduct research that are attentive to the needs of diverse communities. OAR is committed to supporting HIV researchers from underrepresented communities and expanding capacity in historically under-resourced academic institutions.

¹⁷⁹ OAR, NIH. 2020. *FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research*. Available at: www.oar.nih.gov/sites/default/files/NIH_StrategicPlan_FY2021-2025.pdf.

¹⁸⁰ HIV.gov. 2021. Overview: What is *Ending the HIV Epidemic in the U.S.*? Available at: www.hiv.gov/federal-response/ending-the-HIV-epidemic/overview.

¹⁸¹ OAR, NIH. 2020. *HIV Stakeholder Outreach and Engagement Report: June 2018–February 2020*. Available at: www.oar.nih.gov/sites/default/files/2020_OAR_Stakeholder_Outreach_Report_12-18-21_508.pdf.

The Strategic Goals provide the framework for how OAR promotes the NIH Director's theme of *NIH in a Changing World: Science to Enhance Human Health*.

Leveraging HIV research and infrastructure to respond to the COVID-19 pandemic: OAR continues to drive scientific progress to protect the health of the American people and the global community at a time of unprecedented challenge.

- ***Pivot HIV research to respond to the COVID-19 pandemic:*** The HIV research and infrastructure that OAR has supported for decades recently resulted in the rapid development of two highly effective mRNA SARS-CoV-2 vaccines within one year of the onset of the COVID-19 pandemic and positioned the United States as a world leader in vaccine research.
- ***Translate tools and technologies to develop COVID-19 treatments:*** OAR promoted the development of monoclonal antibodies for HIV prevention and treatment and supported the repurposing of these technologies to identify and develop monoclonal antibodies to add to the limited toolkit to help improve COVID-19 patient outcomes.
- ***Furnish NIH HIV clinical trials infrastructure for COVID-19 therapeutic development:*** OAR supports the HIV clinical trials infrastructure, including the HIV Prevention Trials Network (HPTN), HIV Vaccine Trials Network (HVTN), AIDS Clinical Trials Group (ACTG), and International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT). These resources were enlisted to address the emergent COVID-19 pandemic and continue to be employed to test the safety and efficacy of COVID-19 vaccines and therapeutics as part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership.
- ***Monitor the impact of COVID-19 on HIV research and services:*** The OAR HIV and COVID-19 Task Force, formed in May 2020, continues to provide recommendations to the NIH OAR on programmatic, scientific, and operational focus areas and action plans that are relevant at the intersection of HIV and COVID-19 and to monitor effects of COVID-19 on HIV research progress.

Focusing on research topics that need additional support: Forty years after the first cases of AIDS were reported, HIV remains a significant domestic and global health challenge. OAR works with stakeholders from academic, community, industry, and public health organizations to identify basic, clinical, behavioral, and implementation research strategies to address those challenges.

- ***End the HIV epidemic in the United States and globally:*** OAR catalyzes the development and implementation of innovative approaches to reaching the EHE goal of reducing new HIV infections in the United States by 75 percent by 2025 and by at least 90 percent by 2030. Working with the NIH ICOs, OAR supports international research and partners with the President's Emergency Plan for AIDS Relief (PEPFAR) to help reach the 2025 global targets for HIV control.¹⁸²

¹⁸² Joint United Nations Programme on HIV/AIDS (UNAIDS). 2021. *2025 Targets: Putting people living with HIV and communities at risk at the centre*. Available at: aids2025.unaids.org/#section-targets.

- ***Expand HIV prevention, treatment, and cure strategies:*** OAR is committed to supporting cutting-edge research to expand the repertoire of long-acting formulations and other novel methods for pre-exposure prophylaxis (PrEP); uncover novel strategies for long-term viral suppression; reduce the emergence of drug-resistant HIV variants; and eliminate HIV viral replication in cellular reservoirs.
- ***Address the consequences of aging with HIV:*** OAR promotes interdisciplinary research to understand comorbidities that are prevalent in people aging with HIV who have had long-term use of antiretroviral therapies. Comorbidities include neurological, cardiovascular, and metabolic diseases and some types of cancers and are influenced by lengthy exposure to chronic inflammation. OAR supports research on the psychosocial aspects of aging with HIV, including such things as survival guilt and trauma.

Learning new ways to conduct research: OAR is engaged in an extensive consultation process with early-stage and established investigators to determine the parameters that will foster the development of a new cadre of HIV investigators representing a range of disciplines, perspectives, and population groups.

- ***Diversify the HIV research workforce:*** OAR prioritizes researcher training and development across the NIH to expand the pool of diverse early career investigators (ECIs)—including early-stage investigators (ESIs) and early established investigators¹⁸³—in HIV research. OAR engages with junior and senior investigators from diverse academic institutions to identify strategies to support, retain, and expand the pool of HIV ECIs and has developed a webpage to provide links to relevant resources. OAR is committed to working with the National Institute on Minority Health and Health Disparities (NIMHD) to support HIV research and research training at institutions serving underrepresented and vulnerable populations.
- ***Capitalize on the use of new technologies and platforms:*** OAR promotes community research to assess the acceptability and effectiveness of technologies, such as the expanded use of telemedicine, to facilitate health care access. OAR supports expansion of virtual research technologies to capitalize on advanced imaging and computer modeling to identify new therapeutic targets that may curtail the emergence of drug-resistant HIV variants.

Critically examining health disparities in research and medicine: OAR is committed to supporting the NIH UNITE initiative¹⁸⁴ to address structural racism in the content and conduct of health research. OAR works with the NIH ICOs to expand social, behavioral, and epidemiological research to mitigate HIV-related health disparities.

- ***Increase attention to social determinants of health:*** OAR supports research to mitigate the negative effects of social factors, including stigma and discrimination, that perpetuate HIV-related health inequalities in different populations and settings.

¹⁸³ NIH. 2017. NOT-OD-17-101. Policy Supporting the Next Generation Researchers Initiative. Available at: grants.nih.gov/grants/guide/notice-files/NOT-OD-17-101.html.

¹⁸⁴ NIH. 2021. UNITE. Available at: www.nih.gov/ending-structural-racism/unite.

Advancing dissemination and implementation research and strategies: OAR regularly works to assess the acceptability and effectiveness of social and technological strategies to deliver effective HIV interventions.

- ***Intensify efforts to optimize effective HIV prevention and treatment strategies:*** OAR supports implementation research to improve uptake, equity, and adherence to HIV prevention and treatment strategies in diverse population groups and settings.
- ***Develop and implement effective community outreach and communication strategies:*** OAR supports behavioral and social research and engages in ongoing outreach activities with community stakeholders to better understand the nuances of delivering appropriate and effective HIV prevention and treatment strategies to different populations.

Returns on Funding Increases for FY 2017–FY 2022

There was no funding increase for HIV research in FY 2017. Between FY 2018 and FY 2021, a cumulative increase of \$86.5 million supported high-priority research in HIV vaccines and neurological and cardiovascular comorbidities, enhancing the number and diversity of ECIs, and renovations of research facilities in Research Centers in Minority Institutions (RCMIs). NIH funding increases of \$16.0 million in FY 2020 and FY 2021 supported NIH EHE research through the Centers for AIDS Research (CFARs) and the AIDS Research Centers (ARCs); in addition, the Minority HIV/AIDS Fund in the U.S. Department of Health & Human Services (HHS) Office of Infectious Disease and HIV/AIDS Policy provided \$2.3 million in FY 2021 to support HIV research at RCMIs.

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OAR History

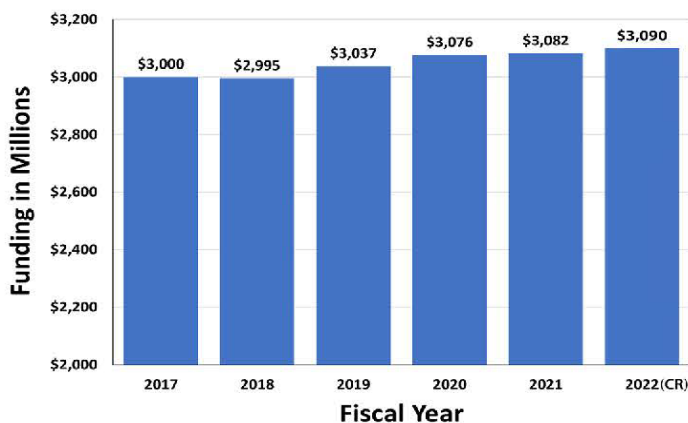
In 1988, the U.S. Congress authorized the establishment of the OAR to oversee, coordinate, and manage NIH HIV/AIDS-related research. Located within the Office of the NIH Director, specifically within the Division of Program Coordination, Planning, and Strategic Initiatives, OAR—

- Establishes NIH HIV/AIDS research priorities;
- Allocates HIV/AIDS research funds in line with scientific priorities;
- Manages HIV/AIDS research across the NIH ICOs; and
- Collaborates across the U.S. government and with scientists, community groups, and organizations globally.

OAR Vision: *Advance research to end the HIV 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.*

NIH HIV/AIDS Funding History FY 2017–2022



The FY 2023 President's Budget request for the NIH-wide HIV/AIDS research program is \$3.10 billion, an increase of \$10.0 million or 0.3 percent compared to the FY 2022 CR level. Funding at this level will expedite NIH efforts to end HIV.

OAR Facts and Figures

- With 33 full-time equivalent employees, OAR coordinates the largest public investment (~\$3.1 billion annually) in HIV/AIDS research globally.
- OAR supports HIV/AIDS-related research administered by a majority of the 27 NIH ICOs.
- The NIH Revitalization Act of 1993 authorized OAR to plan, coordinate, and evaluate HIV/AIDS research; set scientific priorities for the NIH research agenda; and determine budgets for all NIH HIV/AIDS research.
- The NIH AIDS Executive Committee (NAEC) meets monthly and facilitates communication between OAR and all ICOs that administer HIV/AIDS funding.
- The OAR Advisory Council (OARAC) provides advice to the OAR director on the planning, coordination, and evaluation of research and other HIV/AIDS activities conducted or supported by the NIH.



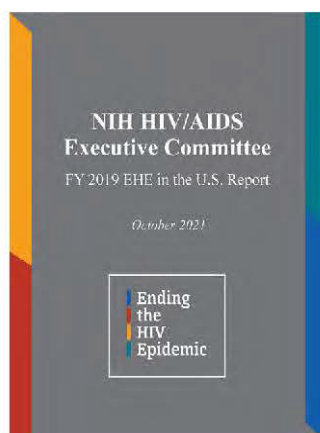
Maureen M. Goodenow, Ph.D.
Associate Director for AIDS Research and Director, Office of AIDS Research National Institutes of Health

Research Highlights

- Two major studies demonstrated the efficacy and superiority of a long-acting injectable drug cabotegravir for the prevention of HIV.
- The Microbicide Trials Network (MTN) 034 study found high levels of adherence among young women to both oral pre-exposure prophylaxis (PrEP) and an intravaginal ring with dapivirine.
- HIV prevention studies using several triple broadly neutralizing antibody combinations are currently in Phase I trials.
- The IMPAACT 2010/VESTED study showed that antiretroviral regimens containing dolutegravir and emtricitabine/tenofovir alafenamide fumarate are the safest and most effective HIV treatment for women during pregnancy.
- Lenacapavir showed potent antiviral activity in heavily treatment-experienced people with multidrug-resistant HIV.
- A rapid enzymatic assay to monitor short- and long-term adherence to HIV drugs was recently developed.
- The first FDA-approved clinical trial of a CRISPR-based gene therapy for HIV cure started in September 2021.

Recent Accomplishments

- Released the *NIH/HIV AIDS Executive Committee FY 2019 EHE in the U.S. Report* (cover at right) establishing a baseline to quantify the initial NIH contribution to EHE and to track future NIH-funded research efforts.
- Coordinated NIH development of HIV research objectives for inclusion in the update to the National HIV/AIDS Strategy.
- Established the NIH OAR Taskforce on COVID-19 and HIV to ensure NIH research priorities reflect the demands of the converging COVID-19 and HIV pandemics.
- Leveraged HIV clinical trials infrastructure to test potential COVID-19 vaccines and therapeutics as part of NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership.
- Accelerated expansion of Research Centers in Minority Institutions (RCMI) research capacity with supplements for laboratory improvements.
- Launched a study to assess the efficacy of mobile, "one-stop" integrated HIV health services for people with opioid use disorder who inject drugs.



Current Activities

- Continuation of OAR's listening sessions (image) and community engagement events to obtain stakeholder input on NIH HIV research priorities and inform future activities.
- Analysis of immune correlates from the Imbokodo (HVTN 705) vaccine trial to better evaluate human immune responses to HIV vaccine models.
- In partnership with NIH ICOs, implementation of a framework to increase the number and diversity of HIV early career investigators, particularly women and those from underrepresented minority groups and under-resourced academic institutions.
- Development of funding initiatives for high-risk, high-reward HIV projects focused on promising new technologies.



Future Initiatives

- Research effective HIV vaccines built on the success of COVID-19 mRNA vaccine models.
- Develop effective antibody-mediated HIV protection strategies.
- Develop new therapies that are safe and effective against multidrug-resistant HIV.
- Explore the effect of HIV and SARS-CoV-2 coinfection on immune dysfunction.
- Improve the quality of life and health outcomes for people aging with HIV.
- Expand basic science research on the viral life cycle to inform HIV cure strategies.
- Develop new methods and delivery of HIV self-testing, point-of-care treatment, PrEP, and post-exposure prophylaxis (PEP).
- Conduct clinical, behavioral, social, translational, and implementation research to address HIV-associated stigma, health disparities, and inequalities.
- Continue focused stakeholder outreach and engagement efforts to identify new research and community partners for local and regional collaborations.

Budget Policy Statement

The FY 2023 President's Budget request for the NIH-wide HIV/AIDS research program is \$3,100.0 million, an increase of \$10.0 million or 0.3 percent compared to the FY 2022 CR 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. The NIH will continue to leverage HIV research and infrastructure to respond to the COVID-19 pandemic, engage with ECIs and 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. The NIH will capitalize on the use of new technologies and platforms and will continue the critical examination of health disparities in research and medicine. The 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 2021 Final¹	FY 2022 CR²	FY 2023 President's Budget	FY 2023 +/- FY 2022
NCI	\$240,513	\$242,285	\$241,238	-\$1,047
NHLBI	84,715	84,823	84,715	-108
NIDCR	18,984	19,008	18,984	-24
NIDDK	34,135	34,179	34,135	-44
NINDS	38,528	41,135	38,655	-2,480
NIAID	1,783,470	1,791,391	1,798,843	7,452
NICHD	147,273	145,081	147,716	2,635
NEI	195	388	195	-193
NIEHS	5,342	5,349	5,342	-7
NIA	23,350	22,651	23,350	699
NIAMS	4,573	4,593	4,587	-6
NIDCD	2,128	2,131	2,128	-3
NIMH	185,868	184,227	186,421	2,194
NIDA	261,336	261,474	262,123	649
NIAAA	31,879	31,920	31,879	-41
NINR	16,350	16,371	16,350	-21
NHGRI	3,538	3,306	3,538	232
NIBIB	1,831	1,841	1,839	-2
NIMHD	23,530	22,809	23,530	721
NCCIH	666	749	666	-83
FIC	24,316	24,420	24,389	-31
NLM	7,685	9,334	7,685	-1,649
OD				
OAR	63,593	62,336	63,593	1,257
ORIP	78,099	78,199	78,099	-100
Subtotal, OD	141,692	140,535	141,692	1,157
TOTAL, NIH	\$3,081,897	\$3,090,000	\$3,100,000	\$10,000

¹ Reflects effects of Secretary's transfers.

² Does not include HIV/AIDS transfers.

**National Institutes of Health
Office of AIDS Research**

**Budget Mechanism – AIDS¹
(Dollars in Thousands)**

Mechanism	FY 2021 Final ²		FY 2022 CR ³		FY 2023 President's Budget		FY 2023 +/- FY 2022	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects:</u>								
Noncompeting	1,382	\$1,028,454	1,407	\$1,405,627	1,312	\$1,389,496	-95	-\$16,131
Administrative Supplements	(99)	40,762	(78)	34,395	(64)	27,038	(14)	-7,357
Competing	519	724,047	480	319,077	498	343,424	18	24,347
Subtotal, RPGs	1,901	\$1,793,263	1,887	\$1,759,099	1,810	\$1,759,958	-77	\$859
SBIR/STTR	27	14,649	26	18,319	24	17,276	-2	-1,043
Research Project Grants	1,928	\$1,807,912	1,913	\$1,777,418	1,834	\$1,777,234	-79	-\$184
<u>Research Centers:</u>								
Specialized/Comprehensive	62	\$146,798	60	\$144,302	61	\$147,599	1	\$3,297
Clinical Research	0	0	0	0	0	0	0	0
Biotechnology	0	0	0	0	0	0	0	0
Comparative Medicine	16	72,035	15	70,496	15	70,396	0	-100
Research Centers in Minority Institutions	0	0	0	2,522	0	2,602	0	80
Research Centers	78	\$218,833	75	\$217,320	76	\$220,597	1	\$3,277
<u>Other Research:</u>								
Research Careers	270	\$47,528	266	\$47,338	246	\$44,265	-20	-\$3,073
Cancer Education	0	0	0	0	0	0	0	0
Cooperative Clinical Research	0	116	11	4,000	16	9,950	5	5,950
Biomedical Research Support	1	1,838	0	1,600	1	1,600	1	0
Minority Biomedical Research Support	0	0	0	0	0	0	0	0
Other	123	66,433	119	68,020	117	64,703	-2	-3,317
Other Research	394	\$115,915	396	\$120,958	380	\$120,518	-16	-\$440
Total Research Grants	2,400	\$2,142,660	2,384	\$2,115,696	2,290	\$2,118,349	-94	\$2,653
<u>Ruth L. Kirschstein Training Awards:</u>	FTTPs		FTTPs		FTTPs			
Individual Awards	66	\$3,553	75	\$3,497	65	\$3,173	-10	-\$324
Institutional Awards	254	13,309	228	14,823	225	14,786	-3	-37
Total Research Training	320	\$16,862	303	\$18,320	290	\$17,959	-13	-\$361
Research & Develop. Contracts	119	\$344,624	92	\$379,548	98	\$385,705	6	\$6,157
SBIR/STTR (non-add)	(5)	(1,604)	(12)	(5,896)	(12)	(6,104)	(0)	208
Intramural Research		\$348,197		\$345,906		\$342,034		-\$3,872
Res. Management and Support		165,961		168,194		172,360		4,166
SBIR Admin (non-add)		0		0				0
Office of the Director - Appropriation ⁴		141,692		140,535		141,692		1,157
Office of the Director - Other		63,593		62,336		63,593		1,257
ORIP (non-add) ⁴		78,099		78,199		78,099		-100
Total, NIH Discretionary B.A.		\$3,081,897		\$3,090,000		\$3,100,000		\$10,000

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

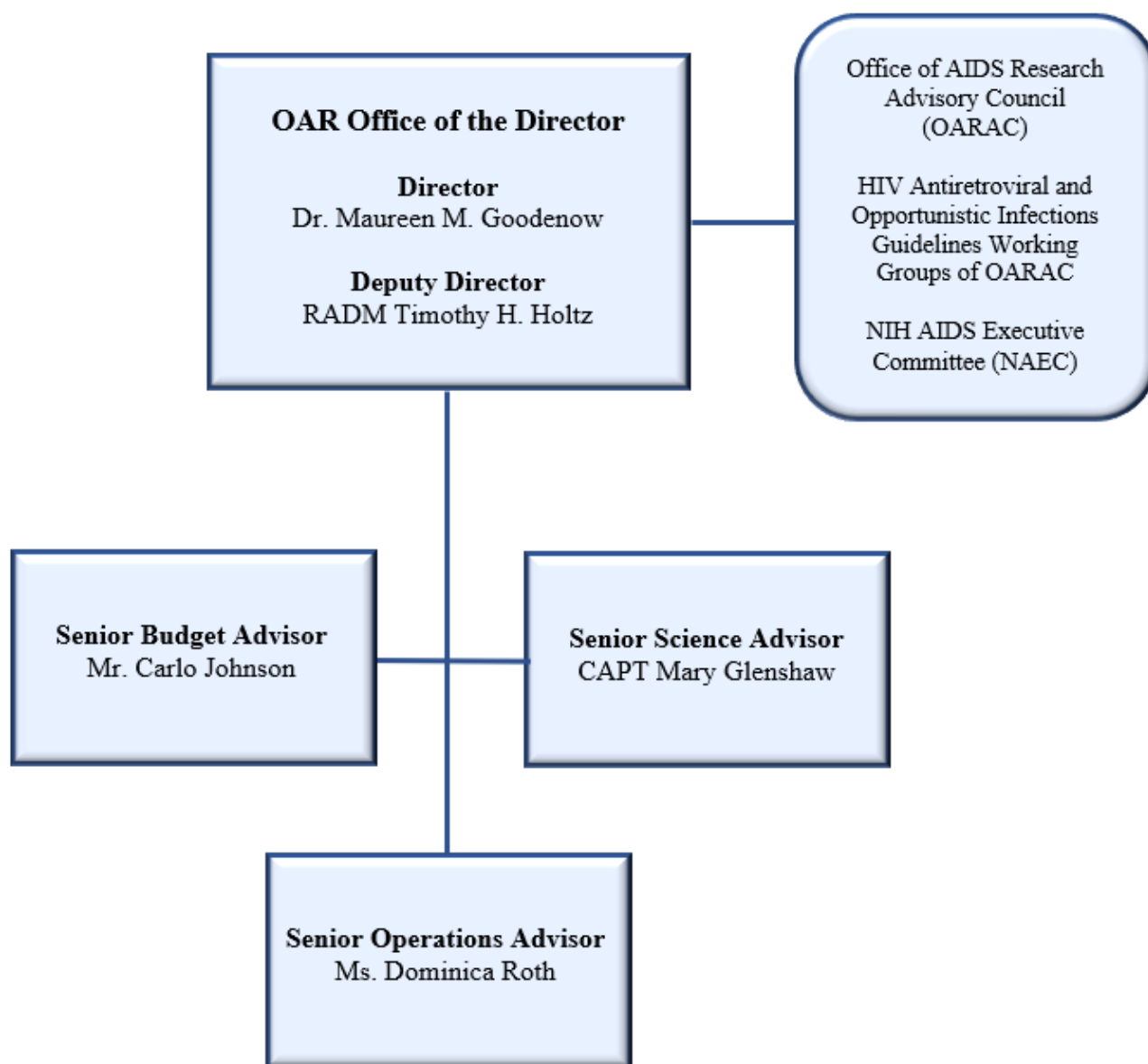
² Reflects effects of Secretary's transfers.

³ Does not include HIV/AIDS transfers.

⁴ 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.

**National Institutes of Health
Office of AIDS Research**

ORGANIZATIONAL CHART



**National Institutes of Health
Office of AIDS Research**

Budget Authority by Activity

(Dollars in Thousands)

Overarching Priorities	FY 2019 Actual¹	FY 2020 Actual	FY 2021 Final¹	FY 2022 CR²	FY 2023 President's Budget	FY 2023 +/- FY 2022
Reduce the Incidence of HIV	\$741,401	\$719,217	\$684,570	\$689,839	\$672,848	-\$16,991
Develop Next-Generation HIV Therapies	368,912	345,378	331,927	341,552	347,969	\$6,417
Research Toward a Cure for HIV	187,777	209,133	224,737	207,147	211,767	\$4,620
Address HIV-Associated Comorbidities, Coinfections, and Complications	531,440	554,452	560,766	561,314	565,872	\$4,558
Cross-Cutting Areas	1,207,770	1,247,881	1,279,897	1,290,148	1,301,544	\$11,396
Total	\$3,037,300	\$3,076,061	\$3,081,897	\$3,090,000	\$3,100,000	\$10,000

¹ Reflects effects of Secretary's transfer.

² Does not include HIV/AIDS transfers.

JUSTIFICATION OF BUDGET REQUEST

Office of AIDS Research (OAR)

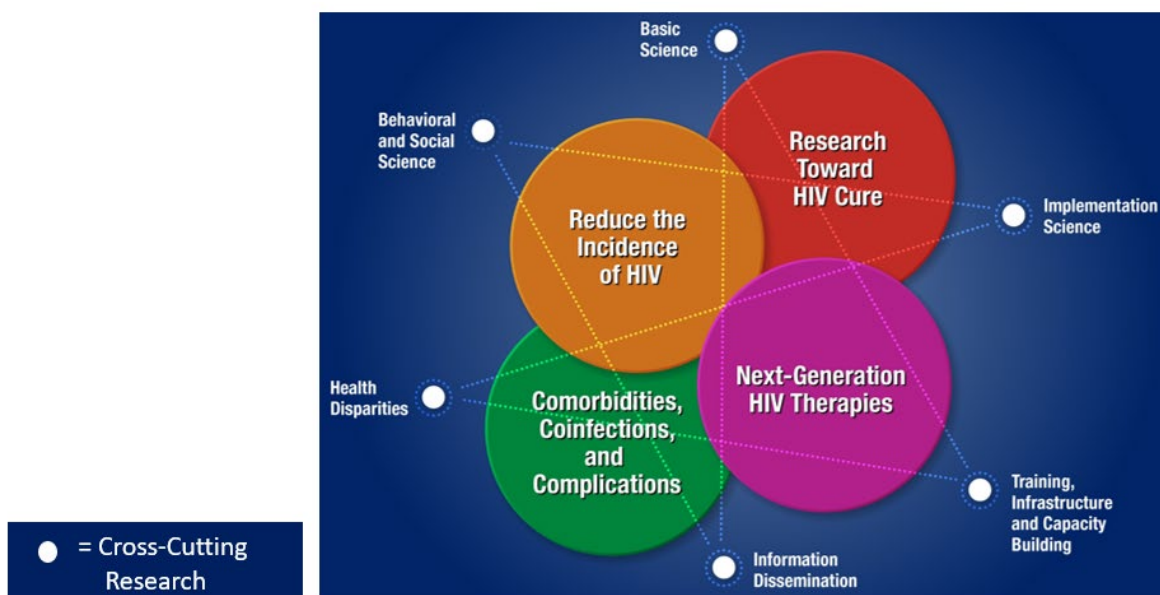
Budget Authority (BA):

	<u>FY 2021 Final</u>	<u>FY 2022 CR</u>	<u>FY 2023 President's Budget</u>	<u>FY 2023 +/- FY 2022</u>
BA	\$3,081,897,000	\$3,090,000,000	\$3,100,000,000	\$10,000,000

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

PROGRAM DESCRIPTIONS, ACCOMPLISHMENTS, AND FUTURE DIRECTIONS

The following selected program areas and activities focus on the highest HIV research priorities as they further the NIH director's theme of *NIH in a Changing World: Science to Enhance Human Health*.

NIH Priorities for HIV and HIV-related Research

Reduce the Incidence of HIV

Each year, approximately 1.5 million people become newly infected with HIV,¹⁸⁵ about 37,000 of whom live in the United States.¹⁸⁶ Globally, HIV incidence disproportionately affects key population groups, including gay men and other men who have sex with men, sex workers and their clients, people who inject drugs, adolescent girls and young women, and transgender people. The special needs of different populations call for differentiated prevention strategies. Much progress has been made in a number of biomedical and behavioral HIV prevention methods—used alone or in combination—that are appropriate for different population groups, although the ultimate strategy—a vaccine—remains elusive.

PrEP: One of the most promising advances in HIV prevention research supported by the NIH is the development and testing of long-acting forms of PrEP. Results from HPTN 083 and 084 Phase 3 studies demonstrated that a long-acting injectable PrEP treatment containing cabotegravir, administered once every eight weeks, is safe, effective, and superior to a daily oral PrEP pill with tenofovir/emtricitabine (Truvada®) across populations.¹⁸⁷⁻¹⁹⁰ Additionally, interim results from the NIH-funded Microbicide Trials Network (MTN) 034 Phase 2a study with young women in Uganda, South Africa, and Zimbabwe found higher levels of adherence than expected both to a vaginal ring containing dapivirine (about 50 percent)



¹⁸⁵ Centers for Disease Control and Prevention (CDC). 2021. HIV: Basic Statistics. Available at: www.cdc.gov/hiv/basics/statistics.html.

¹⁸⁶ UNAIDS. 2021. Global HIV & AIDS statistics—Fact sheet. Available at: www.unaids.org/en/resources/fact-sheet.

¹⁸⁷ National Institute of Allergy and Infectious Diseases (NIAID). 2020. Long-acting injectable drug prevents HIV among men who have sex with men and transgender women. News Release. Available at: www.niaid.nih.gov/news-events/long-acting-injectable-drug-prevents-hiv-among-men-who-have-sex-men-and-transgender.

¹⁸⁸ NIAID. 2020. Long-acting injectable form of HIV prevention outperforms daily pill in NIH study. News Release. Available at: www.niaid.nih.gov/news-events/long-acting-injectable-form-hiv-prevention-outperforms-daily-pill-nih-study.

¹⁸⁹ NIAID. 2020. Statement—NIH study finds long-acting injectable drug prevents HIV acquisition in cisgender women. News Release. Available at: www.niaid.nih.gov/news-events/statement-nih-study-finds-long-acting-injectable-drug-prevents-hiv-acquisition.

¹⁹⁰ Landovitz R, et al. 2021. Cabotegravir for HIV prevention in cisgender men and transgender women. *N Engl J Med* 385:595-608. doi: 10.1056/NEJMoa2101016.

and to oral PrEP (about 59 percent). Both options were well tolerated and rated as highly acceptable by participants.^{191–193}

Measuring adherence to various forms of PrEP is critical to assessing the potential impact of PrEP on HIV incidence. A rapid enzymatic assay for selective detection of HIV drugs to monitor short- and long-term adherence was recently developed. The NIH will continue support for the development and dissemination of technologies that improve both speed and accuracy in measuring PrEP adherence.

Uptake and adherence to various PrEP methods is affected by user preferences, provider attitudes, and accessibility (including cost). The NIH is supporting research that examines user, provider, and health systems stakeholder attitudes and preferences to optimize implementation of long-acting injectable and oral PrEP. The NIH Adolescent Medicine Trials for HIV/AIDS Interventions Network (ATN) 143:P3 study is testing the efficacy of a novel, theory-based mobile app that utilizes game mechanics and social networking features to improve PrEP adherence, retention in PrEP clinical care, and PrEP persistence among young men who have sex with men and young trans women who have sex with men.

Vaccines: Developing safe, effective, and durable preventive vaccines against HIV is a high priority to end the HIV pandemic. This is a formidable scientific challenge that can be met only by multidisciplinary teams of researchers across different fields of basic, translational, and behavioral science from the very beginning of the development process. The scientific complexity and cost of these endeavors has led to the establishment of public-private partnerships to advance the evaluation of vaccine candidates.



NIH partnered with pharmaceutical companies in two large-scale, multinational trials: Imbokodo (HVTN 705) and Mosaico (HVTN 706). The Imbokodo clinical trial, conducted with women in sub-Saharan Africa starting in late 2017, recently was determined to be ineffective in preventing HIV infection.¹⁹⁴ However, the study did provide sufficient data for immunological

¹⁹¹ American Association for the Advancement of Science. 2021. EurekAlert. Study finds adolescent girls and young women in Africa will use HIV prevention products. Available at: www.eurekalert.org/news-releases/612191.

¹⁹² Wits RHI. 2021. REACH study finds adolescent girls and young women in Africa will use HIV prevention products. Media Release. Available at: www.wrhi.ac.za/media/detail/reach-study-interim-results.

¹⁹³ Nair G., et al. 2021. Adherence to the dapivirine vaginal ring and oral PrEP among adolescent girls and young women in Africa: Interim results from the REACH study. Abstract presentation. 11th IAS Conference on HIV Science. Available at: theprogramme.ias2021.org/Abstract/Abstract/2487.

¹⁹⁴ NIAID. 2021. HIV vaccine candidate does not sufficiently protect women against HIV infection. Press Release. Available at: www.nih.gov/news-events/news-releases/hiv-vaccine-candidate-does-not-sufficiently-protect-women-against-hiv-infection.

correlates research, a stepping stone for basic and clinical research to evaluate the human immune response to HIV vaccine models. The Mosaico Phase 3 trial to prevent HIV-1 infection in cisgender men and transgender individuals who have sex with cisgender men and/or transgender individuals is ongoing.

Development of VIR-1111, a novel cytomegalovirus-based HIV vaccine platform, resulted from a sustained research effort enabled by support from the NIH Office of Research Infrastructure Programs (ORIP), National Institute of Allergy and Infectious Diseases (NIAID), and National Cancer Institute (NCI), as well as the Bill & Melinda Gates Foundation. This model incorporates fragments of HIV virus into a weakened form of human cytomegalovirus capable of triggering potent responses from effector-memory T cells. The first human Phase 1 clinical trial testing this vaccine strategy was initiated in December 2020.



NIH HIV vaccine research supported the development of the mRNA vaccine platform that was deployed to generate highly effective COVID-19 vaccines in record time. Researchers now are capitalizing on this experience to reach an even more ambitious goal: a partnership in the first human trial of mRNA forms of two promising HIV vaccines. The NIH continues to invest in all aspects of translational science, as well as in the strategic expansion of vaccine product manufacturing capabilities to meet future supply demands.

Concomitant to vaccine-based prevention strategies, antibody-mediated protection using passive immunity is being tested as an alternative way to prevent HIV infection. A triple broadly neutralizing antibody (bNAb) combination is predicted to afford high levels of protection for 4 to 6 months. Several of these bNAb concepts are currently being tested in Phase I trials.

Budget Policy: The FY 2023 President's Budget request to reduce the incidence of HIV is \$672.8 million, a decrease of \$17.0 million or 2.5 percent compared to the FY 2022 CR level.

Develop Next-Generation HIV Therapies

Decades of NIH-supported research have produced highly effective antiretroviral therapies that have helped people with HIV live long and healthy lives. An ongoing goal of HIV treatment research is to find ways to minimize the pill-taking burden on individuals with HIV while maintaining their viral suppression and other good health outcomes. One approach is to reduce the number of drugs one takes on a daily basis. A recent clinical trial demonstrated that among virally suppressed adults, switching to the two-drug regimen of dolutegravir/lamivudine (DTG/3TC) fixed-dose combination is as effective as continuing a three-drug regimen through 24 weeks.¹⁹⁵

¹⁹⁵ Llibre JM, et al. 2021. Switching to the 2-drug regimen of dolutegravir/lamivudine (DTG/3TC) fixed-dose combination (FDC) is non-inferior to continuing a 3-drug regimen through 24 weeks in a randomized clinical trial (SALSA). Abstract presentation. Available at: <https://theprogramme.ias2021.org/Abstract/Abstract/1457>.

The development of long-acting and injectable formulations of antiretrovirals is another approach to optimizing HIV treatment (as it is to HIV prevention). The once-monthly long-acting regimen of cabotegravir and rilpivirine (brand name Cabenuva) was recently approved by the U.S. Food and Drug Administration (FDA) as a complete treatment regimen for HIV-1-infected adults.¹⁹⁶ Lenacapavir (LEN), a long-acting first-in-class inhibitor of HIV-1 capsid function, also is showing promise. LEN showed potent antiviral activity in heavily treatment-experienced people with HIV who had multidrug resistance, as well as in people with HIV who were treatment-naïve, when used subcutaneously or orally in combination with tenofovir alafenamide fumarate (F/TAF).¹⁹⁷ LEN was well tolerated, and its pharmacokinetics support its use every 6 months, which will be a significant reduction in daily pill burden.



A number of new antiretroviral treatment (ART) classes and drugs are in various stages of preclinical and clinical development and target different parts of the HIV life cycle. These include entry inhibitors, nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, integrase strand transfer inhibitors, capsid inhibitors, and maturation inhibitors. Additionally, different novel delivery systems (subcutaneous, intravenous, topical, implantable, long-acting oral) for these new drugs and classes, as well as newer drug delivery platforms and technologies (microarray patches, implants, reduced volume injections) are currently being developed and tested in clinical trials. By providing a wider array of choices and options for individuals, these new delivery systems and technologies likely will improve adherence to drug regimens and reduce the burden on health systems.

It is essential to determine the best HIV treatment regimens for different populations. The NIH-funded IMPAACT 2010/VESTED study recently showed that antiretroviral drug regimens containing dolutegravir and emtricitabine/tenofovir alafenamide fumarate (DTG+FTC/TAF) are the safest and most effective HIV treatment regimen for women during pregnancy.¹⁹⁸ This Phase III study, which enrolled more than 640 pregnant women with HIV across four continents, affirms updated World Health Organization recommendations for HIV treatment during pregnancy.

¹⁹⁶ FDA. 2021. FDA approves Cabenuva and Vocabria for the treatment of HIV-1 infection. Available at: www.fda.gov/drugs/human-immunodeficiency-virus-hiv/fda-approves-cabenuva-and-vocabria-treatment-hiv-1-infection.

¹⁹⁷ Gilead. 2021. Gilead submits New Drug Application to U.S. Food and Drug Administration for Lenacapavir, an investigational, long-acting capsid inhibitor for the treatment of HIV-1 people with limited therapy options. Press Release. Available at: www.gilead.com/news-and-press/press-room/press-releases/2021/6/gilead-submits-new-drug-application-to-us-food-and-drug-administration-for-lenacapavir-an-investigational-longacting-capsid-inhibitor-for-the-tre.

¹⁹⁸ NIAID. 2020. Newer anti-HIV drugs safest, most effective during pregnancy. News Release. Available at: www.niaid.nih.gov/news-events/newer-anti-hiv-drugs-safest-most-effective-during-pregnancy.

Budget Policy: The FY 2023 President’s Budget request to develop next-generation HIV therapies is \$348.0 million, an increase of \$6.4 million or 1.9 percent compared to the FY 2022 CR level.

Address HIV-Associated Comorbidities, Coinfections, and Complications

Although ART increases the life expectancy of persons living with HIV, many challenges and opportunities persist for the treatment of HIV and HIV-associated comorbidities, coinfections, and complications across the lifespan.

Much progress has been achieved in preventing perinatal transmission of HIV in the United States; only 65 HIV infections were attributed to perinatal transmission in 2018.¹⁹⁹ Limited ART formulations for infants and children make HIV management in these age groups challenging. Questions remain about the impact of HIV and ART exposure *in utero*, as well as HIV infection and long-term antiretroviral therapy on the growing and developing child. Although early treatment reduces morbidity and mortality from HIV, whether very early ART can ameliorate complications of HIV and preserve neurodevelopment, optimal cognitive functioning, and mental health in children living with HIV is unclear.

In 2019, young people aged 13–24 years represented 21 percent of all new HIV infections in the United States. Although improved routine HIV testing has reduced undiagnosed HIV infection overall in the United States, up to 80 percent of young



people still are unaware of their infection. Durable linkage to care, which is associated with improved outcomes, remains an elusive goal for young persons. Regulatory approvals for the use of novel treatment strategies in adolescents lag behind approvals for adults. Adolescents with perinatally or behaviorally acquired HIV face unique challenges during the transition from pediatric to adult health care settings, including interruptions in HIV care, changing socioeconomic and health insurance status, and new stigma and disclosure issues. Cognitive development and mental health issues, medication adherence, and sexual, reproductive, and gender health concerns are paramount in young adults with HIV.

Over half of Americans currently living with HIV in the United States are 50 years or older, and about 20 percent of new infections occur in older individuals. This group is projected to expand with increased use of effective ART among those newly diagnosed with HIV. However, individuals aging with HIV are also more likely to suffer from the effects of accelerated aging, higher rates of neurocognitive and cardiovascular complications, some malignancies, and metabolic and bone disorders, most likely caused by chronic low-level activation of the immune system.²⁰⁰ An increase in the risk of experiencing cardiovascular diseases and increased arterial “age” are some examples of health problems affecting people aging with HIV.

¹⁹⁹ CDC. 2020. HIV and Pregnant Women, Infants, and Children. Available at: www.cdc.gov/hiv/pdf/group/gender/pregnantwomen/cdc-hiv-pregnant-women.pdf.

²⁰⁰ Szanjawski MA and Spivak AM. 2020. Senotherapeutics for HIV and aging. *Curr Opin HIV AIDS*. 15(2):83-93. doi: 10.1097/COH.0000000000000609.

An interdisciplinary approach that includes geroscience²⁰¹—the study of the intersection between basic aging biology and chronic disease—and the social sciences is required to address the growing health concerns and improve health outcomes in people living and aging with HIV, given that most comorbidities are multifactorial and include lifestyle factors.

At a population level, COVID-19 is threatening gains achieved by four decades of HIV research.^{202,203} The intersection of two global pandemics is a continuously evolving situation that requires careful analysis of emerging data and creative interventions to mitigate regressive outcomes for HIV research objectives.

Many details are unknown about the impact of COVID-19 among people with HIV, particularly considering preexisting health inequalities and adverse social determinants of health.^{204,205} A recent analysis of data from the NIH-funded U.S. National COVID Cohort Collaborative (N3C) found that, after adjusting for covariates, people with HIV had higher odds of COVID-19 death than people without HIV; older, male, Black, African American, Hispanic, and Latinx adults with HIV had elevated odds of death; and a lower CD4 cell count was associated with all the adverse COVID-19 outcomes, while viral suppression was associated only with reduced hospitalization.²⁰⁶

Although COVID-19 is an acute crisis, tuberculosis constitutes the most significant cause of mortality for people with HIV globally. Hepatitis viruses, some viral-associated cancers, and other concomitant sexually transmitted infections (STIs) are also significant challenges for people with HIV.

Additionally, behavioral health issues—including alcohol and tobacco use, substance abuse disorders, and mental health disorders—co-occur with HIV infection and frequently are associated with violence, marginalization, social discrimination, stigma, and other behavioral and

²⁰¹ Justice J. 2021. Translational science and the application of geroscience approach in understanding the mechanisms of aging in HIV. Invited Presentation. 11th IAS Conference on HIV Science. Available at: theprogramme.ias2021.org/Programme/Session/230.

²⁰² Chebbeville T et al. The Impact of COVID-19 on HIV Treatment and Research: A Call to Action. *Int J Environ Res Public Health*. 2020 Jun;17(12):4548.

²⁰³ The Global Fund. 2021. Global Fund results report reveals COVID-19 devastating impact on HIV, TB, and malaria programs. News Release. Available at: www.theglobalfund.org/en/news/2021-09-08-global-fund-results-report-reveals-covid-19-devastating-impact-on-hiv-tb-and-malaria-programs.

²⁰⁴ Mandavilli A. 2021. COVID is especially risky for people with HIV, large study finds. *New York Times*, July 15, 2021. Updated September 7, 2021. Available at: www.nytimes.com/2021/07/15/health/covid-hiv-risk-study.html.

²⁰⁵ Mirzaei H et al. 2020. COVID-19 among people living with HIV: A systematic review. *AIDS Behav*, July 30:1-8. doi: 10.1007/s10461-020-02983-2 (Epub ahead of print).

²⁰⁶ Yang X et al. 2021. Associations between HIV infection and clinical spectrum of COVID-19: A population level analysis based on US National COVID Cohort Collaborative (N3C) data. *Lancet HIV*. Published online October 13, 2021. doi.org/10.1016/S2352-3018(21)00239-3.

psychosocial challenges. These complex, intersecting conditions need to be better recognized, understood, and addressed to make lasting improvements in the health and well-being of people living and aging with HIV.

Budget Policy: The FY 2023 President’s Budget request to address HIV-associated comorbidities, coinfections, and complications (CCC) is \$565.9 million, an increase of \$4.6 million or 0.8 percent compared to the FY 2022 CR level.

Research Toward a Cure for HIV

The persistence of HIV reservoirs in people after ART is discontinued is a formidable obstacle to achieving sustained virologic remission or cure. Spontaneous remission is extremely rare and HIV cure using medical technologies, such as complex bone marrow transplantation, is costly and impractical to use in large groups of people with HIV. The rare examples of HIV cure—only three cases worldwide—provide a glimpse into the areas of research that need to be addressed to understand the dynamics of viral reactivation and the nature of cellular reservoirs.

NIH investment in HIV virology will continue to advance the understanding of the viral reservoir composition and localization and its relationship with viral replication and long-term viral suppression; the host genetic factors that may influence the size and composition of latent reservoirs in people with HIV on ART regimes; virus/host cell interactions; and how to ward off the development of drug resistance. A range of techniques, including single-cell imaging technologies, is being used to identify and describe the HIV reservoir and discover mechanisms of viral reactivation from latently infected cells.

Experimental treatments under development include latency reversing agents that make the HIV virus visible to the immune system so that the virus can be cleared; cure-inducing immunotherapies using bNAbs and 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 longer.

The recent discovery of a bacterial gene editing mechanism called CRISPR-Cas led to the immediate testing of this new research tool to excise viral HIV from the genomic DNA of people with HIV. The first clinical trial investigating CRISPR-based gene therapy as a possible means to achieve HIV cure was approved for initiation by the FDA in September 2021.²⁰⁷

The NIH is supporting behavioral and social science research to ascertain what kind of cure strategies are desirable among different groups of people with HIV. In the end, the goal of integrated HIV cure research is to develop safe, scalable, and sustainable strategies that will be available to all people with HIV globally.

Budget Policy: The FY 2023 President’s Budget request to promote research toward a HIV cure is \$211.8 million, an increase of \$4.6 million or 2.2 percent compared to the FY 2022 CR level.

²⁰⁷ Parkins K. 2021. FDA approves first trial investigating CRISPR gene editing as HIV cure. Clinical Trials Arena. Available at: www.clinicaltrialsarena.com/news/crispr-gene-editing-hiv-cure.

Cross-Cutting Areas

Basic Science: Continued basic biomedical research is indispensable to advance discovery in HIV virology, immunology, and pathogenesis. The unusual characteristics of the viral life cycle present significant challenges to the development of effective vaccine and cure strategies.

A significant breakthrough in understanding fundamental aspects of HIV-1 structure and viral life cycle within host cells was achieved recently by novel imaging technologies. NIH intramural researchers developed a method to label infectious viral complexes with a green fluorescent protein.²⁰⁸ Using the imaging technology, the scientists showed that HIV-1 capsids remain intact until minutes before uncoating in the nucleus to achieve viral integration into the host cell genome. Novel imaging work further demonstrated that nuclear pores are larger than previously estimated. This characteristic allows HIV-1 capsids to enter the nucleus in an intact form and to release HIV genomic complexes inside the nucleus, not in the cytoplasm, as previously thought.²⁰⁹

The NIH will continue to approach HIV research from a systems biology perspective to achieve an HIV cure. Of particular importance is the gap in our understanding of fundamental aspects of innate immunity, viral reservoir composition and localization, cell type contribution to the HIV reservoir, and host genetic factors that may influence the size and composition of latent reservoirs in people with HIV on ART.

Behavioral and Social Science: Progress in HIV prevention and treatment, even with the best biomedical advances, is affected by numerous social factors that influence knowledge, attitudes, availability, uptake, and adherence among individuals and groups. Also referred to as social determinants of health, these factors shape the environment in which individuals interact with health systems and interventions²¹⁰ and include, for example, stigma, discrimination, racism, sexism, food security/insecurity, housing stability/instability, and economic inequality. Although the importance of social factors for HIV-related outcomes was recognized from the beginning of the pandemic, the ability to rigorously model, map, and measure nuanced social dynamics persists as a challenge. The NIH supports studies of a range of innovative methodologies appropriate for analyzing social factors in diverse settings.

The COVID-19 pandemic highlights the need for better understanding of health communications, particularly in the context of uncertainty and rapidly evolving health

²⁰⁸ Burdick RC et al. 2020. HIV-1 uncoats in the nucleus near sites of integration. *Proc Natl Acad Sci USA*, 117(10):5486-5493. doi: 10.1073/pnas.1920631117.

²⁰⁹ Zila V et al. 2021. Cone-shaped HIV-1 capsids are transported through intact nuclear pores. *Cell*, 184(4):1032-1046.e18. doi: 10.1016/j.cell.2021.01.025.

²¹⁰ Office of the Assistant Secretary for Health. Healthy People 2030. Social Determinants of Health. Available at: health.gov/healthypeople/objectives-and-data/social-determinants-health.

information.²¹¹ The NIH will enhance support for behavioral and social research on effective ways to communicate complex and dynamic evidence-based health information and to mitigate misinformation campaigns that undermine public health practice.

Epidemiology: Persistent monitoring of the global HIV pandemic, including how it is affected by the COVID-19 pandemic, is critical. The NIH supports research using advanced technology for surveillance, big data mining, advanced bioinformatics, phylodynamics, epigenetics, and other epidemiological analyses.

Health Disparities: HIV incidence and prevalence are not distributed evenly across population groups and settings. In the United States, Black/African American and Hispanic/Latino gay and other men who have sex with men, Black/African American women, and people residing in the South have the highest rates of new HIV infections.^{212,213} The NIH supports research to better understand and address HIV and associated health disparities that stem from social inequalities related to sex, gender, race, ethnicity, socioeconomic status, age, substance use behavior, and geographic location.

Implementation Science: The NIH supports research on the optimal provision and uptake of effective HIV prevention, care, and treatment strategies, particularly as these further the goals of the *National HIV/AIDS Strategy for the United States* (NHAS) and the EHE initiative.

Information Dissemination: OAR will continue its series of listening sessions and community engagement meetings in various locales to obtain stakeholder input on recent research findings, research priorities, and optimal translation and dissemination strategies.

Training, Infrastructure, and Capacity-Building: The NIH remains committed to supporting and nurturing the next generation of HIV researchers and to ensuring that the HIV research workforce is diverse and representative of historically underrepresented groups.

Budget Policy: The FY 2023 President's Budget request to advance the critical framework of cross-cutting areas of research is \$1,301.5 million, an increase of \$11.4 million or 0.9 percent compared to the FY 2022 CR level. This includes a \$10.0 million increase above the FY 2022 CR level to expand implementation research activities under the Ending the HIV Epidemic in the U.S. (EHE) initiative conducted by the Centers for AIDS Research (CFARs) and AIDS Research Centers (ARCs).

NIH- and HHS-Wide Initiatives

²¹¹ Han PK et al. 2021. Communicating scientific uncertainty about the COVID-19 pandemic: Online experimental study of an uncertainty-normalizing strategy. *J Med Internet Res*, 23(4):e27832. doi: 10.2196/27832.

²¹² CDC. 2021. Estimated HIV Incidence and Prevalence in the United States, 2015–2019. HIV Surveillance Supplemental Report 26(No.1). Available at www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-26-1.pdf.

²¹³ Bosh, K.A., et al. 2021. Estimated Annual Number of HIV Infections – United States, 1981–2019. *Morbidity and Mortality Weekly Report* 70(22):801-806. Available at www.cdc.gov/mmwr/volumes/70/wr/mm7022a1.htm?s_cid=mm7022a1_w.

Ending the HIV Epidemic in the U.S. (EHE): OAR continues to collaborate with NIH and HHS partners to advance the EHE goals of reducing new HIV infections in the United States by 75 percent by 2025 and by at least 90 percent by 2030. EHE focuses on four key strategies or pillars: Diagnose, Treat, Prevent, and Respond to Outbreaks. OAR is responsible for monitoring, tracking, and reporting EHE investments across all NIH ICOs for this initiative.

OAR collaborated with the NIH HIV/AIDS Executive Committee (NAEC) EHE Working Group to develop the NIH *FY 2019 EHE in the U.S. Report*, released in 2021. This report establishes a baseline to quantify the initial NIH contribution to EHE and to track future NIH-funded research efforts.

National HIV/AIDS Strategy for the U.S. (NHAS) Update: OAR partnered with the White House Office of National HIV/AIDS Policy (ONAP) in the update of the NHAS for 2022–2025, released on World AIDS Day, December 1, 2021. As the NIH representative on the Steering Committee for the NHAS, OAR coordinated NIH-wide input for comments related to strengthening the research component of the document. OAR provided revised language for the NHAS goals and objectives, based on the consolidated NIH input. OAR continues to work with ONAP to highlight the critical role of research in achieving the goals of the NHAS.