HIV Research on Pause

Impacts of US government cuts on HIV R&D

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16 July 2025

IAS 2025 Regional Members' Meeting: United States and Canada



Caveats and Conflict of Interest

- Spoiler Alert: this presentation is depressing
- I am an American citizen, voter and taxpayer who is
 - Deeply sorry
 - Deeply embarrassed
 - Incredibly angry
 - Committed to science, rights and equity
- AVAC receives funding from the US government USAID (when it existed); PEPFAR; NIH via subawards from the I4C, PAVE and REACH Martin Delaney Collaboratories
 - We are the lead plaintiff in AVAC vs. US Dept. of State, which is winding its way through the US courts



What Just Happened?



What Just Happened?

15 July 2025: A small "win", but not a victory

Senate Advances Trump Clawback of Foreign Aid and Public Broadcast Funds

The vote to take up legislation to rescind \$9 billion in congressionally approved funds suggested that Republicans would bow to the president's wishes in the simmering fight over spending powers. The 51-to-50 vote came after Republica

The 51-to-50 vote came after Republican leaders agreed to a handful of concessions to win the votes of holdouts who were uneasy with the proposed rescissions. G.O.P. leaders said on Tuesday they would strip out a \$400 million cut that Mr. Trump requested to the President's Emergency Plan for AIDS Relief, known as PEPFAR, a move that the White House signaled it would not contest.



PrEP Initiations to 2024

https://www.prepwatch.org/pepfar-stop-work/



Number of new PrEP users in 2024 who have lost access to PEPFAR-supported PrEP services



Number of people identifying as **Key Populations who have lost access to HIV prevention** programming under PEPFAR



Off Target: The PEPFAR goal of people initiating CAB for PrEP in 2025 is falling far short – 5k instead of 100k



Research Under Assault

High-level snapshot of cuts to HIV-related research

- Pause on foreign aid and dismantling of USAID, including HIV Research Division
- "Pause"/ban on international research, initial focus on South Africa
- LGBTQ study terminations
- Changes in scientific review processes
- Major staff reductions and forced reassignments
- Cap on indirect rates in grants to US academic institutions, which provide core building, laboratory and training infrastructure
- May 30, 2025: NIH cuts the two Consortia for HIV/AIDS Vaccine Development (CHAVD)

USAID HIV Research Project Terminations

Project	Product(s)	Туре	Country(ries)	# of participants
Advancing BitD of Innovative HV Provention Products for Women	TAF/EVG Fast-dissolving insert	MATRIX-001 Phase 1 safety and acceptability	Kenya, South Africa, USA	60
	 One month dapivirine vaginal film 	MATRIX-002 Safety, acceptability, usability of placebo	Kenya, South Africa, USA, Zimbabwe	100
	Non-ARV nonhormonal contraceptive multipurpose vaginal ring	MATRIX-003 Safety, acceptability, usability of placebo	South Africa, USA, Zimbabwe	100
	Mijectable CAB, Dapivirine Vaginal Ring, Oral TDF/FTC	Cohort study of safety in mothers and babies exposed to ARV-based prevention	Kenya, Lesotho, Zimbabwe	500-800
	One-month dapivirine vaginal film plus levonorgestrel (LNG)	Preclinical study	USA	Preclinical
BRILLI MANT CONSORT&UM	BG505 GT1.1 and 426c.Mod. Core-C4b	B-001 Phase 1 clinical trial	Kenya, South Africa, Uganda	48
	Polyvalent HIV-SET saMRNA vaccine clinical program	Pre-clinical and clinical trials	Multiple African countries	Exploratory
	CAP 256 based mRNA vaccine candidates incl Africa-based mRNA manufacturing	Development program	Multiple African countries	Exploratory
	Multiple founder virus-based vaccines	Exploratory program	Multiple African countries	Exploratory
	Tech-transfer activities in Uganda with SOSIP trimers	Technology transfer	Uganda	Exploratory
ADVANCE	Mosaic Trimers: MOS1SIP, MOS2SIP, M3SIP8 and MPLA	Vaccine	Rwanda, Zambia	40
	Multisite Adolescent Girls and Young Women study	MAGY Epidemiological study	Uganda, Zambia, Kenya, South Africa	1,210
MOSAIC	Injectable CAB, Dapivirine Vaginal Ring, Oral TDF/FTC	CATALYST Implementation Science Study	Kenya, Lesotho, South Africa, Uganda, Zimbabwe	7,500
	Injectable CAB, Dapivirine	Policy and progammatic support, including user-centered research and technical assistance	Bostwana, Eswatini, Kenya, Lesotho, Namibia, South Africa, Uganda, Zambia, Zimbabwe	Community- based
	Dapivirine Vaginal Ring, Oral	Increasing PrEP Options for Women in Eswatini	Eswatini	400
CASPR COALITION TO ACCELERATE & SUPPORT PREVENTION RESEARCH	PrEP, vaccines and multipurpose technologies	Research translation and preparedness, policy support and advocacy to support prevention research	Kenya, Lesot <mark>ho, Malawi, Nige</mark> ria, South Africa, Ug <mark>anda, Zambia</mark> , Zimbabwe	Community- based



NIH Cuts – Part 1

Trump plans \$18B NIH budget cut, wants 27 centers consolidated into 5

Trump Administration Slashes Research Into L.G.B.T.Q. Health

Nearly half of the N.I.H. grants canceled through early May together worth more than \$800 million — addressed the health of sexual and gender minority groups, The Times found.

Overseas grants could be 'closed down' by NIH under new policy, internal email suggests

Top agency official directs sweeping review of grants with a foreign component

'Borders on the insane': New NIH policy on funding foreign scientists stirs outrage

Agency will make researchers outside United States seek grants of their own rather than "subawards" from U.S. scientists



NIH: Major Retrenchment

Top-line cuts

- Nearly 2500 medical research grants ended or delayed as of May 2025
 - 191 HIV-related grants terminated, worth over ~\$200M
 - Primary topics for NIH grant termination: DEI, "gender ideology", sexual minorities, vaccine hesitancy, mRNA vaccines, and SA/foreign subgranting
- No inclusion of subawards to ANY international partners and awards to be handled directly by NIH – new policy coming Sept 30
 - Temporary reprieves and reinstatements started in July
- NIH's workforce to be cut by 1,200-1,300 staffers
 - Including leaders of NIAID, NIAID's Division of Microbiology and Infectious Diseases, Fogarty International Center, chief bioethicist
- President's "skinny" budget for fiscal year 2026 would codify another 40% reduction, or \$18B in funding, plus \$3.6B for CDC and \$5.2B for NSF



NIH: Cuts to Clinical Trials

Total NIH termination of grants—unprecedented in history of agency

- \$19B lost funding =
 777 terminated grants
- \$643M = 113 active clinical trials terminated
- 56% (\$~360M) of terminated clinical trials related to HIV



Terminated NIH Grants with Active Clinical Trials

Source: Association of American Medical Colleges



NIH: Cuts to Clinical Trials

- EO 14182 ("Enforcing the Hyde Amendment"): Issued Jan 24, 2025: halts federal funding (Medicaid, FEHB, etc.) for elective abortions
- Mexico City Policy reinstated Jan 2025: prohibits foreign NGOs that receive U.S. global health assistance, from using funds from any source (including non-U.S. funds) to "perform or actively promote abortion as a method of family planning" (including advice, information, referral, public campaigns)
- Mar-Apr 2025: funding suspended to 16 grantees (including all Planned Parenthood affiliates), impacting ~30% of Title X patients (~834,000 people)
- HHS 26% agency-wide cut; layoffs impacting programs like Title V, CDC's maternal and child health and fertility surveillance, teenage pregnancy prevention, and the national maternal mental health hotline
- Restricted funding towards transgender populations. Most of this has focused on gender affirming care and HIV



HIV/AIDS Clinical Trials Networks

Details on major clinical trials networks

- 30% of funding withheld from semi-annual Notice of Awards for NIAID's DAIDS-funded trial networks (ACTG, HPTN, HVTN, IMPAACT)
 - ~\$300M per year to networks = ~ \$90M cut for just six months
 - Restricts funding for international research activities, mRNA
- NICHD-funded Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) was halted in March
 - \$18M cut with immediate effect, partially reinstated in May
 - ATN led pioneering work on HIV prevention and treatment interventions for adolescents and young adults



And then it got even worse...

Breaking News, May 30, 2025

Trump Administration Ends Program Critical to Search for an H.I.V. Vaccine

The termination is the latest in a series of cuts to H.I.V. research

and programs to prevent the disease.

'Devastating': NIH cancels future funding plans for HIV vaccine consortia

May 30, 2025

Researchers decry agency's decision just as new leads reinvigorate search for long-sought vaccine

The Trump administration has dealt a sharp blow to work on H.I.V.

vaccines, terminating a \$258 million program whose work was

instrumental to the search for a vaccine.

Trump administration ending multiple HIV vaccine studies, scientists and officials say



The Cost of Cutting HIV Research

NIH terminated 191 HIV-specific grants in 2025, slashing over \$200 million from key HIV prevention research grants¹



¹Grants may cover more than one research area, so total across categories shown here exceeds \$200 million in total funding lost

Not included: estimated \$300M funding to CHAVDs to begin in 2026



Glimmer of Hope:

Breaking News: June 15 – Federal judge rules hundreds of grant terminations illegal; July 3 – some SA grants restored

Trump's Cuts to N.I.H. Grants Focused on Minority Groups Are Illegal, Judge Rules

The judge accused the Trump administration of discriminating against racial minorities and L.G.B.T.Q. people and ordered the government to restore much of the funding.

NIH restores grants to South Africa scientists, adds funding option for other halted foreign projects

A policy tweak to the ban on foreign "subawards" should allow clinical trials worldwide to continue



• We are not going back to 19 January 2025...



"SIX WEEKS ON THE JOB! HAS IT BEEN THAT LONG ALREADY?"



...must build for the future



SCIENCEINSIDER | HEALTH

Trump has blown a massive hole in global health funding—and no one can fill it

Other countries, foundations, international groups are unable to replace billions lost in U.S. cuts

8 APR 2025 • 4:18 PM ET • BY IDA JOOSTE

"We are in the middle of a massive earthquake. When buildings fall, we can't just build back what we had before. We need a whole new global health funding architecture, but we won't be able to build it fast enough to avoid significant harm."

<u>https://www.science.org/content/article/trump-has-blown-massive-hole-global-health-</u> <u>funding-and-no-one-can-fill-it</u>



Some guiding principles (and/or random thoughts)

- Prioritize, Prioritize like we've never prioritized before
- Don't miss out on innovation
- Think health systems not disease- or product-specific
- Think differently
- And collaborate differently in new ways and with different stakeholders
- Re-define sustainability and make sure it is not just about money
- Local ownership & leadership



...must build for the future

The New York Times Trump Administration Dialing Back Support for H.I.V. Prevention

The move follows cuts to prevention and treatment efforts worldwide with the shuttering of U.S.A.I.D.

"We've got to snap out of any paralysis or any disbelief or shock, and we've really got to look at what needs to be built in the future. "One of the biggest tragedies in all of this would be if we let this narrative be written entirely by people who don't understand science or health care or research or foreign assistance,"



Further resources

- AVAC Impact Trackers
- Weekly <u>Global Health Watch</u>, AVAC
- <u>Science in the Crosshairs: Research Advocacy in a Time of Crisis</u>, Choice Agenda webinar recording, slides and resources
- The Best Investment You Didn't Know You Made: How NIH Funding Fuels Innovation and Economic Growth, amfAR
- Quick Take: HIV Research Matters for America, amfAR & O'Neill Institute
- Impact of NIH Grant Terminations, Association of American Medical Colleges
- Research Matters Advocacy Toolkit, AVAC, TAG, HIVMA
- <u>NIH halts more collaborations with South Africa on HIV/AIDS trials</u>, Science
- We do the sums: The NIH funds \$350-million (R6.65-billion) of research in SA, Bhekisisa
- Inside the Bloodbath at the NIH, The Nation

