U.S. Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
Office of AIDS Research (OAR)

Office of AIDS Research Advisory Council (OARAC)
70th Meeting
January 29, 2026

Virtual (VideoCast Link)

Meeting Minutes

Council Members Present:
Dr. Luis J. Montaner (Chairperson)
Dr. Courtney V. Fletcher
Dr. Sonia Flores
Dr. Anne M. Neilan
Dr. Diane M. Santa Maria
Dr. Sara L. Sawyer

***Ex Officio* Members Present:**
Dr. Robert Eisinger
CAPT Melissa Briggs-Hagen
Ms. Heather L. Hauck

OAR Leadership:
Dr. Geri R. Donenberg
Dr. Geetanjali Bansal
CAPT Mary Glenshaw
Dr. Leslie Marshall

Invited Speakers and Guests:
Dr. Susannah Allison
Dr. Gregory D. Kirk
Dr. Matthew J. Memoli
Dr. Jillian Pintye
Dr. Elise Riley
Dr. Dianne Rausch
Dr. Michael Stirratt
Dr. Vasundhara Varthakavi
Dr. Franklin Yates

Welcome and Introductions

CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary,
Associate Director of External Engagement, OAR, NIH
Luis J. Montaner, D.V.M., D.Phil., M.Sc., OARAC Chairperson,
Executive Vice President and Director, HIV Cure and Viral Diseases Center, The Wistar Institute

CAPT Mary Glenshaw and Dr. Luis J. Montaner welcomed participants to the 70th meeting of the NIH OARAC. A quorum was present. Meeting materials provided to Council members included the agenda, a conflict-of-interest form, public comments received prior to the meeting, and minutes from the 69th OARAC meeting, which was held on September 18, 2025. Minutes from the 69th OARAC meeting were approved by notational vote by the Council in advance of the 70th OARAC meeting.

CAPT Glenshaw conducted roll call and Dr. Montaner reviewed the agenda for the 70th meeting, noting the inclusion of time for public comments.

Report: OAR Director

Geri R. Donenberg, Ph.D., Associate Director for AIDS Research and Director, OAR, NIH

Dr. Geri R. Donenberg opened her remarks by recognizing the retirement of OAR Health Scientist Administrator Dr. Paul Gaist. As part of his 40 years of distinguished federal service in HIV research, Dr. Gaist was one of the first staff members of OAR and helped build NIH's HIV-related behavioral and social sciences research portfolio.

Dr. Donenberg acknowledged the support that the HIV clinical practice guidelines have received and explained that NIH leadership has approved OAR's continued management of the guidelines. She also described recent NIH policy changes, some of which directly affect HIV-related research. Following release of an updated NIH Policy on Foreign Subawards, a new parent announcement for NIH Collaborative International Research Projects was published. Investigators working with collaborators at foreign institutions should ensure that they know how to apply for these grants, which are no longer subawards to a U.S.-based investigator.

Efforts across NIH to simplify and streamline the application and funding process include a planned reduction in the number of Notices of Funding Opportunities (NOFOs) in favor of investigator-initiated research applications submitted through parent announcements. Highlighted Topics—specific research areas for which NIH Institutes, Centers, and Offices (ICOs) would like to receive applications—are now listed on a new page for potential applicants. In December, NIH published an OAR-led Highlighted Topic titled "Implementation Science to Optimize HIV Prevention and Treatment"; almost every institute that receives HIV-related funding signed on to it, indicating their interest in this area.

Dr. Donenberg also acknowledged the new grant review criteria outlined in the Unified NIH Funding Strategy, highlighting that peer review and priority scoring will no longer be the main criteria in determining which applications are funded. She commented that the use of additional criteria has the potential to be exciting, particularly for early-stage investigators (ESI). Program staff are now tasked with reading the full review and justifying their funding decisions. The top 30% of applications will be discussed in study section. A middle group of applications whose scores are viewed as meritorious will not be discussed but will be considered for funding. This expands the pool of eligible applications for awards, allowing ICOs to select applications that meet their priorities and recognize ESI.

Dr. Donenberg discussed a change in receipt dates for HIV/AIDS applications (NOT-OD-26-029). The final HIV/AIDS-specific application receipt day will be May 7, 2026; applications submitted after this date should follow the general standard application receipt date schedule. This change is expected to reduce administrative challenges. Dr. Donenberg invited Council members to read a blog post she co-authored with Drs. Bruce Reed (Acting CSR Director) and Jon Lorsch (NIH Deputy Director for Extramural Research) for more information.

Dr. Donenberg provided a brief budget update, noting that the Federal government is operating under a continuing resolution and OAR's approximate budget is $3.3 billion. She then provided updates on recent OAR engagements. The Office led three sessions at the 2025 U.S. Conference on HIV/AIDS, covering reproductive aging in women with HIV, viral load monitoring technologies, and lifestyle-based interventions for HIV-associated comorbidity prevention and management. OAR continues to maintain its strong, ongoing commitment to supporting Early Career Investigators (ECI), a priority shared by NIH leadership. In the summer of 2025, several ECI listening sessions were conducted to gather input on needs and challenges in the changing research environment, followed by the 4th Annual NIH Workshop for Early Career Investigators

in HIV in September 2025. The workshop was well attended with 544 participants and addressed issues raised during the summer listening sessions and featured speakers included ECI and mentors. OAR also organized a session focused on ECI at the 16th International Workshop on Aging and HIV.

In December 2025, Dr. Donenberg and CAPT Glenshaw presented OAR updates to the Federal AIDS Policy Partnership, a coalition of approximately 120 organizations across advocacy, civil society, philanthropy, faith-based organizations, and other sectors. Dr. Donenberg also engaged with the Assistant Secretary for Health to outline NIH's interest in expanding implementation science in the HIV research portfolio and to emphasize the need for sustained support for federal implementing partners such as the Health Resources and Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), and Substance Abuse and Mental Health Services Administration (SAMHSA) to translate scientific findings into practice. Following the 18th Annual Conference on the Science of Dissemination and Implementation in December, a seminar was held to reflect on HIV implementation research and regional implementation science hubs. These hubs offer training, capacity building, and consultation opportunities for those interested. Dr. Donenberg also described Her & Now, an education initiative focused on menopause and HIV, an area of increasing national interest. Her & Now was established by an R25 grant funded by OAR, the Office of Research on Women's Health, and National Library of Medicine.

Next, OAR is planning to participate in several sessions at the 2026 Conference on Retroviruses and Opportunistic Infections, and CAPT Glenshaw is participating in the workgroup developing the agenda for the NMAC 2026 Biomedical HIV Prevention Summit.

Update: HIV Clinical Trials Network External Review

Leslie Marshall, Ph.D., Acting Deputy Director, OAR, NIH

Dr. Leslie Marshall provided an update on the external review of the HIV/AIDS Clinical Trials Networks (CTN). OAR commissioned an external review of the networks, which are led by the National Institute of Allergy and Infectious Diseases (NIAID), to help optimize future research priorities—particularly in implementation science and HIV-associated co-occurring conditions—in advance of developing NOFOs for the fiscal year (FY) 2027 network recompete. The review encompasses four networks: Advancing Clinical Therapeutics Globally for HIV/AIDS and Other Infections (formerly ACTG), the HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN), and the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT). The Adolescent Trials Network (ATN) is excluded because it was recompeted and funded in 2023, primarily by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). An *ad hoc* OAR working group will conduct a forward-looking assessment to identify opportunities for strengthening the networks' ability to integrate implementation science and address HIV-related co-occurring conditions. The group includes federal partners (CDC, HRSA, Indian Health Services, U.S. President's Emergency Plan for AIDS Relief), community representatives, and scientific experts—including implementation science specialists—to ensure a diverse and informed evaluation.

The primary deliverable will be a high-level summary letter with recommendations to the OAR Director, subsequently presented to OARAC. The review will focus on scientific priorities, protocol development, funding distribution, infrastructure coordination, capacity building, and community engagement. Because of policy-driven and operational constraints (e.g., recent shutdown-related delays), the process is on an expedited timeline, with completion targeted for

March 2026 to align with the development of NOFOs and upcoming NIAID AIDS Research Advisory Committee concept presentations scheduled for April 2026. The working group will hold at least five meetings from January through mid-March, including sessions with network leadership and internal deliberations to finalize recommendations.

Update: HIV and Pharmacy Program

Michael J. Stirratt, Ph.D., Program Officer and Senior Behavioral Scientist, Division of AIDS Research, National Institute of Mental Health, NIH
Geetanjali Bansal, Ph.D., M.Sc., Senior Science Advisor, OAR, NIH

Drs. Michael Stirratt and Geetanjali Bansal provided an update on the HIV and Pharmacy Program. OAR has expanded its multidisciplinary focus areas to include HIV and pharmacies, recognizing their potential to strengthen HIV service delivery. This initiative was catalyzed by the success of Federal Retail Pharmacy Program during the COVID-19 pandemic, underscoring the unparalleled reach, accessibility, and public trust of pharmacies. Pharmacies are widely distributed across both urban and rural communities, offer convenient hours, and may be associated with less stigma compared to traditional HIV clinics—positioning them as critical access points for HIV prevention and care. Geospatial analyses have further revealed that pharmacies are more prevalent than existing pre-exposure prophylaxis (PrEP) delivery sites in communities with high HIV incidence, amplifying their potential to improve access to prevention and treatment. Momentum is also building at the policy level, with more than a dozen U.S. states authorizing pharmacists to prescribe or furnish PrEP.

To assess the current research landscape and identify gaps, OAR and the National Institute of Mental Health (NIMH) conducted a 10-year NIH portfolio analysis, revealing only 15 highly relevant pharmacy- centered HIV projects, demonstrating- a clear need for further research investment. This led to a NIH sponsored public meeting in 2023 and the subsequent development of 2024 Requests for Applications (RFA) signed by nine NIH institutes. The RFAs garnered strong interest across the research community. In FY25, NIH awarded 11 meritorious grants—10 R01 awards and an R21 project—spanning domestic and international settings and addressing the full HIV care continuum, including prevention, treatment, and comorbidities. These awards are distributed across five institutes: NIMH; NIAID; NICHD; National Institute on Drug Abuse (NIDA); and National Heart, Lung, and Blood Institute (NHLBI). These projects include improving HIV training in schools of pharmacy, advancing HIV service delivery through pharmacies, and better integrating pharmacists in HIV clinics. The projects strongly emphasize implementation science, and many awards support first-time R01 principal investigators. The program continues to expand in FY26, with an additional award already issued and others under consideration. OAR and NIMH are convening three virtual planning meetings to support grantee coordination and data harmonization. If funding allows, an in-person meeting will be planned for late 2026 and will include a public component. This growing body of work reflects a collaborative, multi-institute effort and builds on the foundational vision of leaders across NIH who recognized the transformative role that pharmacies can play in advancing HIV prevention and care.

Discussion Highlights

Regarding the NIH policy change for HIV/AIDS applications, Dr. Montaner emphasized that, moving forward, the information should be presented with metrics because grant writers are expecting delays and funding decreases. For example, it should be stressed that there is no change in the budget, so funding should not decrease. Dr. Donenberg reiterated that the timing

of the new cycle is not intended to impact the volume of NIH HIV research and agreed that it is a good idea to track the impact on HIV applications and awards.

Dr. Sonia Flores expressed concern about centralizing peer review and no longer basing decisions solely on priority score. She asked whether actual scientific review will be ignored in favor of using alternate criteria. Dr. Donenberg noted that more details are available in the newly published policy: Unified NIH Funding Strategy. Decisions will be made by program staff in accordance with their ICOs' priorities. This policy was developed to align with the administration's priorities. Dr. Anne Neilan suggested that, in the context of additional changes that have occurred, it would be optimal to delay implementing this policy until the guidance has been updated. She noted the example of requirements for PF5 applications, and noted that some NIH staff are not yet trained on how to implement new policies, which she perceives as having a negative impact for HIV applications. Dr. Donenberg replied that guidance is forthcoming as staff determine what implementation will look like. She understands that the updated policy is a challenge; the outcomes from the new activities could be documented and presented to leadership to illustrate how the changes have affected the HIV/AIDS portfolio.

Dr. Elise Riley asked whether study sections that are specific to HIV will remain. Dr. Donenberg responded that of the six current HIV-specific study sections, at least four of them will remain.

Dr. Montaner noted that more clarity about how other criteria will be addressed by programs would be useful. Currently, grant writers are being told to "call their program officers."

Dr. Sara Sawyer commented that some virus-related study sections exclude HIV. She asked whether access to broader study sections will increase. Dr. Donenberg replied that her understanding is that HIV researchers will have access to broader study sections and that the grants may not be reviewed by the same study sections, but there will still be HIV-specific study sections.

Dr. Montaner asked Drs. Stirratt and Bansal about the plan to move the HIV and pharmacy agenda forward by publishing a Highlighted Topic. He asked whether the research agenda will consider online pharmacies, as there is an increased interest in their use. Dr. Stirratt responded that the work on service delivery and pharmacies is more than an RFA; it is a project, and as such, is an area of continued interest. Some of the applications to the RFAs continue to be considered for funding, and some are being resubmitted. The RFA is the initial catalyst of a continued effort. Dr. Stirratt acknowledged that a Highlighted Topic in this area would be beneficial. In terms of online pharmacies, Dr. Stirratt pointed out that different types of pharmacies have different advantages. The current awards focus on community, retail chain, or specialty pharmacies. Dr. Bansal agreed that this is an up-and-coming area and noted that, although these RFAs did not specifically address online pharmacies, future opportunities could. With regard to the OAR HIV and Pharmacy focus area, she added that NIH OAR and other ICOs are exploring future public–private partnerships in this area.

Dr. Courtney Fletcher thanked Drs. Stirratt and Bansal for their work with the pharmacy RFAs. He commented that pharmacists are underused health care professionals and expressed enthusiasm for the program.

Dr. Neilan asked Dr. Marshall to elaborate on the selection criteria for membership on the HIV/AIDS CTN working group and asked whether the roster is publicly available. Dr. Marshall explained that the members were selected for their expertise related to the scope of the review, particularly implementation science and co-occurring conditions. These selections were

balanced with a commitment to community and lack of conflicts of interest that could compromise the integrity of the review process. Most members have extensive NIH experience and no identified conflicts of interest. OAR assembled a group with the expertise necessary to meet the objective and timeline while maintaining objectivity. Dr. Marshall noted that she would discuss sharing the roster with OARAC members when the final report is complete.

HIV Implementation Science Strategy

Matthew J. Memoli, M.D., M.S., Principal Deputy Director, NIH
Geri R. Donenberg, Ph.D., Associate Director for AIDS Research and Director, OAR, NIH

Dr. Matthew Memoli provided perspectives on NIH leadership's vision for the future of NIH-supported HIV research. He noted that incredible progress has been made in a short time, offering people with HIV the ability to lead healthy lives. However, gaps remain that must be addressed, which will require a focused examination of past and current actions to identify next steps. He stated that difficult choices and significant change must be made to reduce the impact of HIV in the United States and hopefully globally. It will be necessary to identify strategies that will benefit people with HIV. He reiterated that NIH is "extraordinarily supportive" of HIV research and supporting people living with HIV.

Dr. Montaner asked how to balance discovery and implementation in the HIV research portfolio, and whether implementation also includes improving current knowledge and practices with novel methods. Dr. Memoli agreed that this is an important point. Implementation has multiple parts, including how to create, test, and improve things so that people have access to—and actually use—them. Dr. Montaner also asked what portion of the budget will be used for implementation science research. Dr. Memoli responded that this is an evolving issue, and no specific amount has been determined. He expressed hope that the science grows and that funding will increase until all problems and challenges are solved. He also noted that this provides an opportunity for new investigators to grow and enter this field.

Dr. Neilan commented that the constraints specific to this field are daunting to ECIs. She asked Dr. Memoli how to keep junior investigators excited despite constraints that do not align with efficient science, such as the new guidance regarding international collaborations. Dr. Memoli explained that the guidelines introduce a new structure in which international collaborators are brought in through subprojects instead of subawards. He commented that this structure helps ensure that funding is properly applied to research through better accountability; the new structure will improve the situation and protect HIV research going forward. Dr. Memoli added that this change is necessary to ensure that international research will be translatable in the United States.

Next, Dr. Donenberg presented on NIH and OAR approaches to accelerate implementation science to end the HIV epidemic. She commented that NIH's HIV research is grounded in activism; the community has ensured that HIV and AIDS were on the research agenda and continues to ensure that NIH focuses on the most important HIV research questions. Over four decades, sustained NIH investment in HIV research has fundamentally reshaped the epidemic's trajectory, transitioning HIV from a uniformly fatal diagnosis to a manageable chronic condition for those with access to care. This transformation reflects breakthroughs across the continuum—from diagnostic innovation and antiretroviral therapy to prevention modalities and models of care—collectively enabling longer, healthier lives and dramatically lowering transmission risk when viral suppression is achieved. The research ecosystem has matured to

include not just discovery and efficacy science but also increasing attention to delivery and access, with an eye toward translating evidence into population-level impacts.

Recent milestones highlight the accelerating promise of long-acting prevention. The U.S. Food and Drug Administration approvals of long acting cabotegravir for PrEP in 2021 and lenacapavir for PrEP in 2025 introduce durable, low-burden options that can address adherence challenges associated with daily oral regimens. These innovations complement a robust array of existing preventive and therapeutic tools, expanding the menu of choices to better match people's diverse needs and circumstances. Together, these tools create a pivotal moment in the epidemic: the science to end the epidemic exists in many forms, but the urgent question is how to get these tools consistently to the people and places where they will have the greatest impact.

Despite scientific advances, however, HIV remains a significant public health challenge in the United States and globally, and modeling indicates that the burden could worsen if prevention and treatment funding declines, especially in heavily affected countries. In the United States, approximately 1.1 million people have HIV, and more than 39,000 were newly diagnosed in 2023. These figures illuminate persistent and emerging vulnerabilities that require targeted, population-informed responses. Without deliberate attention, the benefits of biomedical innovation risk being unevenly realized, leaving gaps that sustain transmission and morbidity.

New U.S. diagnoses also reveal who is being left behind. Among the nearly 40,000 people who were newly diagnosed in 2023, about one in five were adolescents and young adults under 35; 18% were 24 or younger; 19% were women; 24% acquired HIV through heterosexual contact; and a majority resided in the U.S. South. These patterns underscore intersecting structural, geographic, and social drivers—ranging from access barriers and stigma to insurance discontinuations and provider shortages—that affect both susceptibility to HIV and the uptake of HIV services. Epidemiologic trends also emphasize the importance of culturally responsive, locally adaptable approaches that meet communities where they are.

Similarly, among the 1.1 million people with HIV in the United States more than half are now older than 50 years, reflecting both treatment success and the need to plan for aging-related comorbidities and services. Persistent racial and ethnic inequities remain stark, with Black/African American and Hispanic/Latino men who have sex with men disproportionately affected. Addressing these inequities requires multilevel strategies that integrate biomedical tools with attention to social determinants of health, including housing, transportation, mental health, substance use services, and trusted points of care.

Care continuum data further highlight implementation gaps. In 2022, for every 100 people with HIV in the United States, 13% did not know their status, 34% did not receive HIV care, and 43% were not virally suppressed. These figures point to missed opportunities across testing, linkage, retention, and reengagement in care—precisely the domains where implementation science can accelerate progress. They also reinforce that improving outcomes is not simply a matter of proving efficacy; it depends on removing barriers, adapting delivery, and ensuring sustained access in real-world settings.

Implementation science provides the toolkit to close the gap between discovery and impact by rigorously studying how to deliver, scale, and sustain effective interventions. Dr. Donenberg explained that, distinct from efficacy/effectiveness research that asks whether "the thing" works, implementation science examines how best to do "the thing" in routine care (e.g., who should deliver it, which strategies improve uptake and fidelity). Frameworks that parse the audiences,

implementers, strategies, and implementation outcomes help ensure that interventions are not only effective but also adopted and maintained at scale.

Portfolio analyses using NIH's Research, Condition, and Disease Categorization (RCDC) system indicate encouraging growth but also clear room for expansion. Awards coded as both HIV/AIDS and Dissemination & Implementation Research increased steadily from 2021 to 2024, rising to $216 million across 470 awards in 2024, or 7% of the HIV research portfolio overall. The distribution spans multiple ICOs, with some (e.g., NIMH) allocating a larger share of HIV funds to implementation science. Cross cutting RCDC categories often accompany HIV research and implementation science—such as health disparities, mental health, substance use, and women's health—mirroring the real-world complexity that implementation efforts must address to be effective and equitable.

To accelerate translation, OAR is advancing a multilayered program—ARISE (Advancing Research in Implementation Science to End HIV)—to catalyze implementation science within the HIV portfolio. No specific funds have been set aside for ARISE. ARISE consists of a coordinated set of activities designed to grow the HIV and implementation science research agenda: research symposia and seminars; cross-NIH Highlighted Topics; collaboratively developed NOFOs; challenge competitions to spur innovation; and publications that synthesize gaps and opportunities. The proposed program management structure includes a steering committee of implementation experts across HHS (including outside HIV), an OAR working group/coordinating core, an NIH-wide working group of program staff, and engagement with NIH senior leadership. This ensures methodological rigor and alignment with downstream implementers.

The *FY 2026-2030 NIH Strategic Plan for HIV and HIV-Related Research* is currently under review by NIH leadership. The plan reflects three foundational principles. First, NIH supports a comprehensive, multidisciplinary research portfolio. Second, research and implementation must center the populations and geographies most affected by HIV. Third, multisector partnerships are critical: NIH's role spans discovery, efficacy, and implementation research, but durable impact requires collaboration with federal, state, local, and private partners to embed and sustain proven approaches.

Looking ahead, NIH plans to continue investing across the spectrum—from basic discovery and preclinical work to clinical trials and implementation—to ensure a steady pipeline of improved products and delivery models. Opportunities include advancing new biomedical tools; tailoring interventions to diverse user needs; addressing such emerging challenges as viral resistance; and building training and capacity in implementation science so that the workforce can design, test, and scale solutions efficiently. The overarching aim is a landscape in which people can select prevention and treatment options that align with their lives, supported by delivery systems capable of making those choices accessible, acceptable, and sustainable.

Ultimately, ending HIV as a public health threat depends on collaborative execution. Researchers, clinicians, federal partners, policymakers, payers, private sector innovators, and people with lived experience each hold essential pieces of the solution. With highly effective tools now available—including game-changing long-acting options—the imperative is to close the distance between clinical promise and population impact. By expanding implementation science, focusing on equity, and deepening cross-sector partnerships, NIH and OAR aim to ensure that what works in trials becomes what works in people's lives—consistently, at scale, and where the need is greatest.

Dr. Sawyer agreed that implementation science is important but reminded participants that lenacapavir is monotherapy, and resistance arises with monotherapies. Removing individuals from triple-drug PrEP and placing them on monotherapy could result in HIV acquisition despite being on PrEP. She cautioned against conveying that Lenacapavir is a solution to HIV prevention. She reinforced that we cannot change the HIV response based solely on lenacapavir given that drug resistance is an ongoing concern that should not be ignored.

Dr. Flores commented that it appears that population-focused research will be emphasized. She recommended that guidance be provided to researchers—particularly young investigators who are interested in HIV research—so that research is not flagged in terms of language used to describe the populations that are disproportionately affected by HIV. Dr. Donenberg responded that NIH still funds research to address health disparities. She has discussed health disparity populations with NIH leadership, who agree that all Americans deserve to benefit from treatments and research. Research framed as health disparities (e.g., health disparity in access to care by race or men who have sex with men) is acceptable. When framing this research, investigators should work with their program officers and identify population factors that are relevant to the health disparities that the population in question experiences.

Dr. Fletcher asked about the appropriate budget for HIV implementation research. Increasing implementation research means that clinical or basic research—or both—must decrease. He asked about the larger NIH plan for increasing spending on implementation research in its overall budget. Dr. Donenberg explained that no amount has been set, and budget decisions will evolve as a process, echoing Dr. Memoli's prior statement.

Dr. Gregory Kirk noted that, for peer review, it is common for experts to advocate for more representation from their own disciplines (e.g., behavioral scientists, biostatisticians). Increasingly, implementation scientists insist that peer review be led by "card-carrying" implementation scientists. He commented that there are not enough formally trained specialists to lead all emerging projects, much as many clinician-scientists successfully conduct epidemiologic studies without being trained epidemiologists. This creates both a training gap and a review-process challenge. He asked what training approaches could be developed to train researchers who are already conducting implementation-focused work but lack deep grounding in formal implementation science theory and how peer review expectations might be adapted to recognize and support this broader pathway into the field. Dr. Donenberg replied that there are a growing number of training programs to build capacity, as well as NIH efforts to fund implementation science hubs and cores that can provide consultation to investigators. CSR has invited peer reviewers with different expertise. She strongly urged Dr. Kirk to share any recommendations that he has with program staff and noted that there is an opportunity to incorporate this new expertise to train peer reviewers. Dr. Kirk agreed that a pivot with focused training is a real opportunity; a new degree is not needed. Dr. Donenberg noted that much of implementation science is rooted in behavioral science.

Dr. Montaner commented that one of the issues raised by multiple investigators during the listening sessions is that when they propose strategies for implementation in their communities, study sections reject them as non-generalizable for national uptake and impact. This disconnect speaks to study section construction that may favor research proposals with national level impact only. He encouraged OAR to collaborate with CSR to establish a dedicated implementation science study section that includes a balanced mix of expertise—biostatistics, social science, and implementation science—and is intentionally structured to support these applications. Dr. Donenberg responded that two study sections specifically focus on dissemination and implementation research but do not necessarily have expertise on other

topics. She added that what Dr. Montaner is suggesting is challenging to accomplish. She suggested that Dr. Montaner present this issue to the recently convened HIV implementation science working groups so that they can develop recommendations. Secondly, some researchers are hesitant to frame their work as health disparities research because they fear it will be rejected or flagged during review. To address this, it may be helpful to showcase the current portfolio of funded health disparities projects to clarify the types of questions and approaches that are actually being supported. This could be instructive and encourage more investigators to engage in disparities-focused research rather than assume it will be dismissed.

Addressing Needs and Expanding Opportunities in HIV Early-Career Investigator Mentorship

NIH Program Perspectives to Support HIV Research Mentorship: Highlights from NIMH and NIDA

Vasundhara Varthakavi, D.V.M., Ph.D., Acting Director, HIV Research Program, NIDA, NIH
Susannah Allison, Ph.D., Program Officer and Training Director, NIMH, NIH

Drs. Susannah Allison and Vasundhara Varthakavi provided an overview of the NIH training and career development mechanisms supported by NIMH and NIDA. These mechanisms span from predoctoral fellowships to mentored career development awards, all designed to support the progression toward independent research careers. They noted that program staff are eager to help potential applicants determine which mechanisms best fit their backgrounds and goals.

The major NIH fellowship mechanisms that support pre- and postdoctoral trainees include F30 awards for dual-degree students, F31 awards for predoctoral trainees, and F32 awards for postdoctoral researchers. The K-series career development awards include both mentored and independent mechanisms for early- to mid-career faculty, postdoctoral researchers, and established independent investigators. In FY25, NIMH supported nearly 50 K01 and K23 awards and 18 institutional training programs; NIDA's portfolio showed similar patterns, with the exception of a notable increase in K24 awards. NIDA analyzed the low numbers of F31 and F32 awards and determined that fellowship recipients are more likely than T32 trainees to apply for and receive subsequent K awards. As a result, NIDA has prioritized individual fellowships since 2020 and has encouraged T32 directors to guide trainees toward applying for F and K mechanisms.

Drs. Allison and Varthakavi highlighted examples of successful awardees. One NIDA K23 recipient used his mentored award as a springboard to secure multiple independent grants. Another K24 recipient uses the award to support both his research and his extensive mentoring of emerging investigators, many of whom have gone on to secure their own NIH funding. Word clouds describing the research areas of active K awards granted by both institutes were presented to demonstrate how their training portfolios align with HIV research priorities.

The NIMH R25 program is a flexible mechanism that varies across NIH institutes. At NIMH, R25 programs must include both research experiences and mentoring activities and may support trainees from the undergraduate level through early career stages. For example, the Sustained Training on Aging and HIV Research (known as STAHR) program at the University of California, San Diego, offers a 3-year program that includes training activities and an annual workshop with a focus on grant and paper writing.

Discussion With OARAC and Invited Guests

Gregory D. Kirk, M.D., Ph.D., M.P.H., Vice Dean for Research and Professor of Epidemiology, Medicine, and Oncology, Johns Hopkins Bloomberg School of Public Health
Jillian Pintye, Ph.D., M.P.H., RN, Associate Professor, Global Health, and Associate Professor, Biobehavioral Nursing and Health Informatics, Department of Global Health, University of Washington
Elise Riley, Ph.D., M.P.H., Professor in Residence, Division of HIV, Infectious Disease and Global Medicine, Department of Medicine, University of California, San Francisco

Dr. Montaner initiated the discussion session, asking participants to focus on three questions: (1) What initiative(s) (e.g., R25, other existing awards) should be used to foster mentorship? (2) What are the best features of the K awards? (3) What features of K awards can be improved and made more effective?

Dr. Kirk commented that when considering the return on investments, it is important to examine guiding principles and difficulties. Mentorship requires time, energy, and infrastructure. The research cohorts, Centers for AIDS Research (CFARs), and other structures that blend with specific K or F proposals should not be forgotten. Investment is limited if infrastructure is not available. Investigators mentor because they enjoy mentoring, not because it is incentivized. However, faculty are extremely busy, and so a K24 award that provides mentoring time is valuable. Awards should emphasize integration and collaboration. K12 and R25 awards require a great deal of work for training a relatively finite number of individuals with no sustained funding. Dr. Kirk advocated for longer-term funding that allows faculty to collaborate and integrate.

Dr. Jillian Pintye agreed and suggested creating career development supplements to existing investigator-initiated grants—similar to the former diversity supplements—that allow support and protected time for trainees and funding for additional projects for trainees. Trainees need projects to make the effort efficient and allow them to leverage well-run HIV implementation education studies and clinical trials. F31 and F32 awards are excellent, but they are more overbuilt and less efficient than supplements. She suggested expanding existing mentorship programs by creating more flexible funding mechanisms that build on the mentoring that senior faculty already engage in. Many faculty choose academic careers specifically to have impact through their trainees, so supporting this natural mentorship structure could be highly effective. A supplement mechanism would provide targeted support for trainees and maximize the value of current mentoring efforts.

Dr. Riley agreed that K24 awards are crucial because they allow individual researchers to build their mentoring skills; more importantly, the awards provide dedicated time for deliberate mentoring. Now that K24 awards are mid-career awards for associate professors, no equivalent mechanism exists for full professors. Dr. Riley suggested that NIH may want to reconsider this approach. Full professors have more responsibilities and demands that allow them less time for protected mentoring, so without a K24-equivalent mechanism for full professors—the investigators who are best positioned to train the next generation of researchers—are being excluded. Without a dedicated funding mechanism for senior research mentoring, the community will continue to lose experienced mentors, which affects the ability to attract high-quality trainees and decreases the quality of the mentoring programs.

Dr. Kirk suggested incentivizing partnerships between resource-intensive institutions and less-resource-intensive institutions. He highlighted that D43 awards have been instrumental in training the global workforce, but many mentoring mechanisms are limited domestically. He

supported Dr. Pintye's suggestion regarding supplement mechanisms. Small pilot awards have a high return on investment and frequently lead to subsequent K and R awards; pairing these with other mechanisms may be an avenue to explore.

Dr. Montaner opened the broader discussion and noted his surprise at the low F32 award numbers. He encourages his postdoctoral fellows to apply for this award. He wondered whether the F32 awards should also incentivize protected mentor time and provide more reward for mentors because they are very useful for the fellow but require a great deal of effort from the mentor. Dr. Allison agreed; NIMH would fund more F32 rewards if it received more applications. Postdoctoral fellows generally choose T32 institutions. Dr. Montaner noted that fellows whose mentors do not support their applications cannot apply. Dr. Kirk added that postdoctoral fellows do not receive positions unless the principal investigator has a clear funding strategy for them.

Dr. Flores commented that she appreciates R25 funding because many postdoctoral fellows and medical doctors are not interested in infectious diseases, particularly HIV research. She suggested that NIH consider the pipeline and how to attract those college students considering scientific research or medicine into the field of infectious disease and HIV research.

Dr. Pintye commented on the institutional challenges associated with F32 awards. Her university's postdoctoral fellows are unionized and have much higher salaries than the F32 amount; because the university has not identified how to address this discrepancy, it does not promote F32 awards. A mentor with a robust portfolio is needed to absorb the cost. When the fit is right, F32 awards are a great experience for a first-time principal investigator.

Dr. Neilan asked Drs. Varthakavi and Allison to clarify the rationale for K24 awards not being renewable. She also noted that the K24 award is restricted to patient-facing research methods, so some methods OAR is interested in to advance the HIV agenda (e.g., simulation modeling) would not be included. Third, she asked about NIH mechanisms to build the pipeline, such as partnering with professional organizations that offer mentorship awards. Dr. Varthakavi explained that renewal of the K24 award is determined at the institute level. NIDA allows this award to be renewed. She commented that developing partnerships is a great idea but has not been explored and planned to explore these opportunities. She acknowledged that stimulating interest in science at early age and sustaining that interest is beneficial, and her program is examining how to achieve this now that the NIDA summer internship program allowing college students to work in intramural laboratories has ended. Dr. Allison indicated that she does not know the rationale behind the K24 not being renewable within NIMH, but she will follow up.

Dr. Riley noted that trainee salaries are not a livable wage; a meaningful salary would help attract trainees. She pointed out that science is shaped by those who stay in it, and researchers need to see a future for themselves in science. Building a quality scientific research community starts with a livable wage. Dr. Neilan asked whether NIH would consider the idea of potential salary supplementation from other NIH sources to achieve a livable wage for trainees. Dr. Varthakavi indicated that she is unsure whether this is allowable under current NIH policy. Grants management staff could be engaged to determine whether there are available approaches to make such supplementation possible.

Dr. Kirk emphasized the value of peer-to-peer mentoring, noting that cohort mentoring creates synergy and enables mentees to support one another and progress even when senior mentors are unavailable. Peer-based mentoring in the HIV field is accomplished in many different settings, which is critically important. Virtual meeting platforms have enabled integrated, multinational mentoring groups, and incentivizing mentoring via these platforms could

strengthen collaborative environments. Supporting such mentoring or small pilot projects and leveraging existing grant programs would provide significant opportunities to enhance integration and maximize impact with relatively small investments.

Updates: NIH Advisory Council Representatives

National Institute on Drug Abuse

Vasundhara Varthakavi, D.V.M., Ph.D., Acting Director, HIV Research Program, NIDA, NIH

Dr. Varthakavi reported that NIDA recently received approval for a new HIV research initiative—the Avant Garde Awards for high-risk, high-reward projects focused on HIV and substance use—which is planned for FY27. This concept combines two prior individual program announcements (DP1 and DP2) and is designed to support exceptionally innovative investigators across all career stages. The initiative welcomes proposals spanning basic, clinical, translational, and implementation science that is relevant to HIV and substance use. Research proposals must align with NIH HIV/AIDS research priorities and provide ideas of and justification for projects that cannot be supported by typical R01 mechanisms. Notably, DP1 applications do not require preliminary data.

NIDA is also participating in several multi-ICO efforts, including the Highlighted Topic that encourages implementation science research to advance innovative strategies to deliver biomedical prevention and treatment options toward ending the HIV epidemic. Another upcoming collaboration with NIAID aims to support community-engaged projects that bring evidence-based HIV prevention, diagnosis, treatment, and outbreak-response strategies to disproportionately affected populations. These efforts reflect a broader push to accelerate the translation of scientific advances into real-world impact in communities most affected by HIV.

National Advisory Mental Health Council

Dianne Rausch, Ph.D., Director, Division of AIDS Research, NIMH, NIH

Dr. Dianne Rausch provided updates on forecasted initiatives and Highlighted Topics. NIMH has developed a new funding initiative aimed at understanding the mechanisms behind central nervous system complications in people with HIV, with the goal of identifying modifiable targets for intervention. This initiative will use computational psychiatry approaches, large patient datasets, and innovative model systems to identify therapeutic targets and accelerate mechanism-based treatments for these persistent complications.

NIMH also already has a significant investment in implementation science as part of broader NIH efforts to end the HIV epidemic. The institute's two major areas of priority are neuro-HIV and behavioral and social science. Building on its long history of robust research in these areas, NIMH aims to advance the science of scale-up by studying how to expand the adoption and integration of evidence-based HIV interventions so that they reach more people and have lasting impact.

NIMH has developed two Highlighted Topics relevant to HIV. The first focuses on the transition from pediatric to adult HIV care and addresses the medical, developmental, behavioral, and emotional conditions of children as they transition to adult care to ensure that they have access to age-appropriate care. The second Highlighted Topic addresses chronic disease burden and the role of trauma. Dr. Rausch noted that if a Highlighted Topic does not specifically include HIV

but is relevant to the HIV/AIDS program, researchers can reference it and apply to it through the parent NOFO. Although this Highlighted Topic is not specific to HIV, the NIMH HIV/AIDS program is interested in research that addresses trauma related to HIV and how it affects prevention, treatment, and healthy outcomes. Both topics remain priorities that investigators can pursue without HIV-specific NOFOs. NIMH is always available to answer questions from investigators.

Dr. Montaner asked whether applicants need to mention the Highlighted Topic on the page with specific aims and if this is how applicants directly connect their application to the Highlighted Topic. Dr. Rausch responded that, although this is evolving, her recommendation is that applicants who have identified a Highlighted Topic of interest contact the listed ICOs and program officers and explain their ideas and identify the best approach. CSR will assign the application to the appropriate ICO based on the Highlighted Topic guidelines even if the application specifies a different ICO. Applicants cannot target a Highlighted Topic to a specific ICO, but if they are interested in a particular ICO, they can talk to that ICO about its priorities and then the program officer can advise the applicant on how to frame the application so it is likely to target the desired ICO. Dr. Varthakavi added that NIH cannot track grants by Highlighted Topic. She has been instructing applicants to indicate in the cover letter that the application aligns with a specific Highlighted Topic and list expertise and key terms that are crucial for the project. Dr. Rausch agreed that the application must be framed in a certain way and project officers are important resources to help applicants with this framing.

NIAID's AIDS Research Advisory Committee (ARAC) Meeting

Robert Eisinger, Ph.D., Acting Director, Division of AIDS, NIAID, NIH

Dr. Robert Eisinger provided an overview of the six concepts that were presented to and approved by the NIAID ARAC at its September 2025 meeting. Each represents a major area of investment in HIV and infectious disease research, and together, they reflect a coordinated effort to strengthen scientific infrastructure, accelerate discovery, and improve public health outcomes.

The first concept—Implementation Science to Advance HIV Prevention, Treatment, and Care—focuses on improving the uptake, reach, and sustainability of evidence-based interventions in communities affected by HIV in the United States. This initiative emphasizes large-scale projects with strong potential for both scientific and public health impact. It will involve collaboration with OAR and co-sponsoring ICOs, underscoring the crosscutting nature of implementation science in the HIV response.

The NIH CFAR program, the second concept, provides institutional infrastructure to foster multidisciplinary HIV research. CFARs reduce duplication; leverage shared resources; and help translate basic science discoveries into new prevention, treatment, and cure strategies. To qualify, institutions must have at least $10 million in annual NIH-funded HIV research. Each CFAR includes required cores—administrative, developmental, clinical, and advanced technology—and must maintain scientific working groups to foster collaboration and innovation.

The third concept centers on the establishment of Centers for Structural Biology of HIV and Other Infectious Diseases. These centers bring together experts in structural biology and microbiology to solve complex biological structures relevant to HIV and other priority pathogens. The initiative expands beyond HIV-only research to include additional infectious agents while also supporting training for the next generation of structural biologists and promoting collaborative, resource-sharing environments.

The Patient Safety Monitoring in International Laboratories (pSMILE) initiative, the fourth approved concept, focuses on evaluating and enhancing the ability of non-U.S. clinical laboratories to participate in NIH-funded and collaborative studies. As part of NIAID's Quality Assurance Toolbox, pSMILE ensures that international laboratories meet Good Clinical Laboratory Practice standards and produce high-quality, comparable data across global clinical trials. This is essential for maintaining data integrity in multisite, multicountry studies and allowing comparability of laboratory data between U.S. and non-U.S. laboratories.

The fifth approved concept—the Regional Prospective Observational Research in Tuberculosis (RePORT) initiative—supports research on tuberculosis and tuberculosis/HIV coinfection. It enables collaboration between U.S. and international scientists studying these two coinfections to improve diagnosis, treatment, and prevention strategies, including for drug-resistant and multidrug-resistant tuberculosis. The program also facilitates the development and evaluation of new tools and technologies to enhance the uptake of tuberculosis prevention and treatment regimens among people with HIV.

The final concept approved by ARAC focuses on the continued operations of the Clinical Research Products Management Center (known as CRPMC), which ensures compliance with Good Manufacturing Practice and Good Clinical Practice standards for NIAID-sponsored clinical trials. It manages the production, storage, and distribution of investigational drugs to clinical trial sites, playing a critical role in supporting HIV research and ensuring that study products are safely and consistently delivered.

Updates: HIV Clinical Guidelines Working Groups of OARAC

Pediatric Opportunistic Infections Guidelines

Franklin Yates, M.D., M.A., Medical Officer, NICHD, NIH

Dr. Franklin Yates noted that 9 of the 26 sections in the Guidelines for the Prevention and Treatment of Opportunistic Infections in Children With and Exposed to HIV have been updated recently. Many chapters had not been revised in more than a decade, prompting the panel to prioritize overdue updates and establish 2- or 4-year review cycles for future revisions. The panel also streamlined its editing process by consolidating steps and expanding authorship teams—particularly by adding HIV pharmacologists—to accelerate the publication timeline.

Across the updated sections, multiple clinical areas saw significant revisions. Key changes included updates to *Candida* infection management, such as incorporating new antifungal resistance data and adding alternative therapies. The human papillomavirus section introduced revised guidance on the nonvalent vaccine and expanded treatment considerations for pediatric warts. Additional updates strengthened recommendations for *Pneumocystis* prophylaxis—especially in breastfed infants with perinatal HIV exposure—and revised age-based criteria and therapy regimens for toxoplasmosis. Other sections, including coccidioidomycosis and hepatitis B, were modernized with updated epidemiology, treatment preferences, vaccination guidance, and hepatocellular carcinoma screening recommendations.

The panel also revised the immunization schedule to incorporate new recommendations for COVID-19, respiratory syncytial virus, dengue, and mpox vaccines, as well as updated pneumococcal and catch-up polio vaccines. A major new update, released the day prior to this meeting, adjusted breastfeeding guidance for infants born to mothers with HIV/hepatitis C coinfection, shifting to a shared decision-making model influenced by maternal HIV viral

suppression. Looking ahead, the panel anticipates revising at least eight additional sections in 2026, after which all chapters will be current and aligned with the panel's standardized revision schedule.

Dr. Montaner asked how the panel has considered the rewritten HHS recommendations for pediatric vaccination and whether the panel's recommendations are independent of HHS. Dr. Yates responded that the panel's recommendations remain independent of NIH vaccine guidelines because they deal with a specialized population.

Public Comment

CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, Associate Director of External Engagement, OAR, NIH
Luis J. Montaner, D.V.M., D.Phil., M.Sc., OARAC Chairperson, Executive Vice President and Director, HIV Cure and Viral Diseases Center, The Wistar Institute

CAPT Glenshaw summarized two comments received for the meeting. The first—from Dr. Philip Bolduc, Chair-Elect of the HIV Medicine Association—emphasized the importance of NIH prioritizing efforts to end the HIV epidemic, particularly through expanded use of long-acting injectable PrEP and broader implementation science. The association urges NIH to study the impact of a national PrEP program—especially in the context of declining insurance coverage—on uptake and access and to investigate strategies to maintain PrEP availability for uninsured individuals. The comment also highlights concerns about potential cuts to Medicaid, Affordable Care Act coverage, and the Ryan White HIV/AIDS Program—noting the risk of treatment disruptions for thousands of people with HIV—and calls for research on how such coverage losses affect health outcomes and care access. Additionally, the association encourages NIH to rigorously examine how such structural factors as housing, food security, transportation, stigma, and discrimination influence prevention and treatment, as well as to evaluate low-barrier, person-centered care models, such as street medicine and telehealth. Finally, the comment stresses the ongoing need for strong basic science to advance HIV cure and vaccine research and advocate for continued global research collaboration, given the transnational nature of infectious diseases.

In the second comment, Mr. Jules Levin, leader of the National AIDS Treatment Advocacy Project, expressed concern about the shortened lifespan and accelerated aging experienced by people with HIV, citing research indicating a persistent gap in life expectancy and the earlier onset—by 10 to 15 years—of multiple comorbidities compared with those without HIV. He highlighted that older adults with HIV experience higher rates of these conditions and possess unique, enduring immunological challenges even when virally suppressed on antiretroviral therapy. He also expressed concern that the federal government is not adequately addressing aging with HIV and emphasizes that this population has distinct needs that require far greater attention and dedicated support.

Public comments received in advance of, during, and following this OARAC meeting appear as an appendix to these meeting minutes.

Closing Remarks and Adjournment

CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, Associate Director of External Engagement, OAR, NIH
Luis J. Montaner, D.V.M., D.Phil., M.Sc., OARAC Chairperson, Executive Vice President and Director, HIV Cure and Viral Diseases Center, The Wistar Institute

CAPT Glenshaw reminded participants to return the conflict-of-interest form that they will receive and to hold April 13 for the next meeting. Dr. Donenberg thanked the participants for attending and for their commitment to ending HIV as a public health threat. She encouraged them to provide any feedback. Dr. Montaner adjourned the meeting at 4:30 p.m. EST.

Certification

I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Luis J. Montaner

Digitally signed by Luis J. Montaner
Date: 2026.04.07 07:45:13 -04'00'

Luis J. Montaner, D.V.M., D.Phil., M.Sc.
Chairperson, OARAC

4/7/26
Date

Mary Glenshaw -S

Digitally signed by Mary Glenshaw -S
Date: 2026.03.27 15:49:23 -04'00'

CAPT Mary Glenshaw, Ph.D., M.P.H.
Executive Secretary, OARAC

3/20/26
Date

PUBLIC COMMENT 1

Public comment received: 12:58 pm on November 13, 2025

Comment made by: Gabby Vidaurre, Ph.D.

Affiliate: Science Advancement & Outreach (SAO), A Division of PETA

Science Advancement & Outreach
A DIVISION OF PETA

1536 16th St. N.W., Washington, DC 20036

November 13, 2025

Dear Members of the Office of AIDS Research Advisory Council:

I am writing as a cellular biologist and Research Associate with the Science Advancement and Outreach Division at PETA to urge the Office of AIDS Research (OAR) to align its upcoming strategic plan with NIH's April 2025 announcement to expand support for non-animal methods (NAMs). With OAR currently developing its new strategic plan, now is the time to set the direction for the next four years by prioritizing human-relevant, non-animal approaches to HIV and AIDS research.

1. **End the use of animals in HIV/ AIDS Research**

After more than three decades of animal-based HIV research, there is still no vaccine or cure. This continued reliance on animal models—especially nonhuman primates—is scientifically unjustifiable. Only humans contract HIV and develop AIDS, and fundamental biological differences between humans and other species, including in CD4 receptor structure,[1] leukocyte antigen genes,[2] and retrovirus restriction factors,[3] prevent animals from accurately modeling human infection and immune response.[4]

These limitations have led to decades of data that fail to translate to humans, diverting resources from more predictive, human-based approaches. In contrast, human based models—including those based on human tissues and cells, patient data, computational modeling, and advanced genomic analyses—are already being used to test potential therapeutics,[5,6,7,8] uncover structural and functional details of the HIV virus,[9] and clarify key biological differences between people living with and without HIV.[10,11,12,13] These approaches are also helping scientists understand how "HIV controllers" naturally suppress the virus without treatment—insights that could inform new therapeutic strategies for others.[14,15,16,17,18]

With NIH now investing in NAM-focused infrastructure—including the Standardized Organoid Modeling Center[19] and initiatives to expand funding and training in human-relevant science[20]—OAR has a pivotal opportunity to lead by example and end its reliance on animal models.

2. **Establish dedicated opportunities for NAMs in HIV/AIDS research**

Although NAMs are already generating important discoveries in the HIV/AIDS field, greater institutional support is needed to scale and integrate these technologies. OAR should:

- Create **dedicated funding streams** for HIV/AIDS studies using non-animal, human-relevant methods.

- Develop a publicly accessible repository of human-relevant data, tools, and models to support collaboration and advance non-animal approaches in HIV/AIDS research.
- Support **collaborative centers** that combine expertise in human virology, immunology, and bioengineering to accelerate HIV research.

3. **Provide training and support for researchers transitioning to NAMs**

Many HIV researchers were trained primarily using animal models and face significant barriers in learning and adopting new methods. OAR can help bridge this gap by:

- Establishing training grants and fellowships focused on human-relevant models of HIV and AIDS.
- Partnering with academic institutions to develop continuing education programs in NAMs.
- Offering early independence and transition awards for scientists committed to replacing animal experiments with human-based approaches.

By supporting these initiatives, OAR can ensure that its next strategic plan positions the field to deliver more predictive, human-specific discoveries, thereby accelerating progress toward ending the HIV/AIDS epidemic and improving human health outcomes.

Thank you for considering these recommendations.

Sincerely,

Gabby Vidaurre

Gabby Vidaurre, Ph.D.
Research Associate
gvidaurre@peta.org

[1] Humes D, Emery S, Laws E, Overbaugh J. A Species-Specific Amino Acid Difference in the Macaque CD4 Receptor Restricts Replication by Global Circulating HIV-1 Variants Representing Viruses from Recent Infection. *J Virol*. 2012;86(23):1247212483. doi:10.1128/JVI.02176-12

[2] Kumar N, Chahroudi A, Silvestri G. Animal models to achieve an HIV cure. *Curr Opin HIV AIDS*. 2016;11(4):432-441. doi:10.1097/COH.0000000000000290

[3] Song B, Javanbakht H, Perron M, Park DH, Stremlau M, Sodroski J. Retrovirus Restriction by TRIM5α Variants from Old World and New World Primates. *J Virol*. 2005;79(7):3930-3937. doi:10.1128/JVI.79.7.3930-3937.2005

[4] Hu SL. Non-human primate models for AIDS vaccine research. *Curr Drug Targets Infect Disord*. 2005;5(2):193-201. doi:10.2174/1568005054201508

[5] Deeks HM, Walters RK, Hare SR, O'Connor MB, Mulholland AJ, Glowacki DR. Interactive molecular dynamics in virtual reality for accurate flexible protein-ligand docking. Paci E, ed. *PLoS One*. 2020;15(3):e0228461. doi:10.1371/journal.pone.0228461

[6] Baassi M, Moussaoui M, Soufi H, et al. Towards designing of a potential new HIV-1 protease inhibitor using QSAR study in combination with Molecular docking and Molecular dynamics simulations. Ghosh A, ed. *PLoS One*. 2023;18(4):e0284539. doi:10.1371/journal.pone.0284539

[7] Zhang YJ, Chen L, Xu J, et al. Evaluation of novel HIV-1 protease inhibitors with DRV-resistance by utilizing 3D-QSAR molecular docking and molecular dynamics simulation. *New J Chem*. 2022;46(45):21885-21897. doi:10.1039/D2NJ04492G

[8] Wang R, Zheng Q. Multiple molecular dynamics simulations and energy analysis unravel the dynamic properties and binding mechanism of mutants HIV-1 protease with DRV and CA-p2. *Microbiol Spectr*. 2022;10(2):e0074821. doi:10.1128/spectrum.00748-21

[9] Saha I, Saffarian S. Dynamics of the HIV Gag lattice detected by localization correlation analysis and timelapse iPALM. *Biophys J*. 2020;119(3):581-592. doi:10.1016/j.bpj.2020.06.023

[10] Xie G, Luo X, Ma T, et al. Characterization of HIV-induced remodeling reveals differences in infection susceptibility of memory CD4+ T cell subsets in vivo. *Cell Rep*. 2021;35(4):109038. doi:10.1016/J.CELREP.2021.109038/ATTACHMENT/DD9335E3-A2AE-4B21-B703-B888B3ACCC05/MMC1.PDF

[11] Collora JA, Liu R, Pinto-Santini D, et al. Single-cell multiomics reveals persistence of HIV-1 in expanded cytotoxic T cell clones. *Immunity*. 2022;55(6):1013-1031.e7. doi:10.1016/j.immuni.2022.03.004

[12] 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

[13] Wang XM, Zhang JY, Xing X, et al. Global transcriptomic characterization of T cells in individuals with chronic HIV-1 infection. *Cell Discov*. 2022;8(1):29. doi:10.1038/s41421-021-00367-x

[14] Galperin M, Farenc C, Mukhopadhyay M, et al. CD4 + T cell–mediated HLA class II cross-restriction in HIV controllers. *Sci Immunol*. 2018;3(24):eaat0687. doi:10.1126/sciimmunol.aat0687

[15] Claireaux M, Robinot R, Kervevan J, et al. Low CCR5 expression protects HIV-specific CD4+ T cells of elite controllers from viral entry. *Nat Commun*. 2022;13(1):521. doi:10.1038/s41467-022-28130-0

[16] Etemad B, Sun X, Li Y, et al. HIV post-treatment controllers have distinct immunological and virological features. *Proc Natl Acad Sci USA*. 2023;120(11):e2218960120. doi:10.1073/pnas.2218960120

[17] Real LM, Sáez ME, Corma-Gómez A, et al. A metagenome-wide association study of HIV disease progression in HIV controllers. *iScience*. 2023;26(7):107214. doi:10.1016/j.isci.2023.107214

[18] Kennedy BD, Blazkova J, Justement JS, et al. Comprehensive analysis of HIV reservoirs in elite controllers. *J Clin Invest*. 2023;133(3):e165446. doi:10.1172/JCI165446

[19] National Institutes of Health. NIH establishes nation's first dedicated organoid development center to reduce reliance on animal modeling. September 25, 2025. Accessed November 6, 2025. https://www.nih.gov/news-events/news-releases/nih-establishes-nations-first-dedicated-organoid-development-center-reduce-reliance-animal-modeling

[20] National Institutes of Health. NIH to prioritize human-based research technologies. April 29, 2025. Accessed May 2, 2025. https://www.nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies

PUBLIC COMMENT 3

Public comment received: 1:09 pm on January 29, 2026
Comment made by: Jules Levin
Affiliate: National AIDS Treatment Advocacy Project (NATAP)

I just heard you say PWH live as long or close to normal age survival and PWH may not be exceptional. This is simply not true and does not reflect the data and research around aging. PWH have shorter lifespan reported at CROI several years ago in a Kaiser study by Julia Marcus by about 9 years for those starting ART with under 500 cd4 which is most of us solder PWH and even today is 30% who have delayed start of ART. PWH can have by as much as 10-15 earlier onset of many comorbidities and PWH who are older have higher rates of comorbidities than people without HIV.

These misperceptions is why the federal govt is simply not doing an adequate job regarding aging if others feel the same way, and clearly aging and HIV does not get the attention it should get. I am very disappointed to hear you say that. Indeed the affects of HIV persist, we remain an exceptional group with unique issues including a unique abnormal immunology despite ART and viral suppression that persists.

Jules Levin

PUBLIC COMMENT 3

Public comment received: 3:11 pm on January 29, 2026

Comment made by: Philip Bolduc, M.D.

Affiliate: HIV Medicine Association (HIVMA)

Office of AIDS Research Advisory Council Meeting
January 29, 2026
Statement for the Record
Philip Bolduc, MD, Chair-Elect, HIV Medicine Association

Thank you for the opportunity to offer comments on behalf of the HIV Medicine Association in advance of your meeting on January 29. We respectfully request that for future meetings the agenda be made publicly available further in advance to allow time for comments to be submitted prior to the meeting.

We appreciate that the National Institutes of Health has identified Ending the HIV Epidemic (EHE) in the United States as a priority with a focus on improving uptake and access to HIV prevention and treatment and specifically leveraging long-acting injectables (LAI) for Pre-exposure Prophylaxis (PrEP) and for HIV treatment. HIVMA supports the need for implementation science to ensure that all of the lifesaving HIV prevention and treatment modalities available today, including LAI options, are reaching everyone who could benefit from them. However, if we are to make meaningful progress in improving health outcomes for people with HIV and reducing new HIV transmissions, a broader implementation science agenda is needed.

HIV prevention

To identify innovative ways to ensure PrEP is reaching those in need in communities across the country, **we urge NIH to evaluate the impact that a National PrEP Program that expands upon existing PrEP public health initiatives, including by integrating LAI PrEP, would have on efforts to end the HIV epidemic in the U.S.** PrEP remains underutilized with many more people who could benefit from it not having access due to a number of factors, including a lack of health coverage, stigma and discrimination, limited knowledge of PrEP and poor provider access, among other barriers.[i] [ii] Furthermore, we are concerned that PrEP uptake will worsen in the near future resulting from health coverage losses due to cuts to the Medicaid program and to higher premiums for Affordable Care Act (ACA) Marketplace coverage. **Supporting research to evaluate the impact of health coverage losses on PrEP utilization and effective strategies to maintain PrEP access among an uninsured population also will be important.**

HIV treatment

Research has demonstrated that people with HIV with health insurance coverage have better outcomes.[iii] [iv] [v] We are also concerned that deep cuts to the Medicaid program and loss of ACA coverage due to premium increases coupled with flat or reduced funding for the Ryan White HIV/AIDS Program will erode access to HIV treatment. We are already seeing this in Florida where an estimated 16,000 people living with HIV without other sources of coverage are expected to lose

access to AIDS Drug Assistance Program (ADAP) assistance, and therefore to HIV treatment, due to deep cuts being implemented to the program on March 1. The cuts are attributed in part to the state's Department of Health anticipating a shortfall in ADAP funding as a result of rising ACA premium costs. **Given that increasing access to HIV treatment is a key tenant of the EHE initiative to keep people healthy and to reduce HIV transmissions, rigorous evaluations of the impacts of health coverage losses on the health outcomes of people with HIV and effective strategies to sustain and increase access to HIV care and treatment in resource-constrained environments in the U.S. will be important.**

Social and economic factors and low-barrier care models

We strongly urge for the EHE implementation science agenda to also rigorously evaluate and identify solutions to the role of housing, socioeconomic status, food security, transportation, stigma and discrimination, and other structural barriers in limiting uptake of HIV prevention and treatment. In addition, rigorous evaluations of low-barrier, person-centered models of health care delivery, such as street medicine[vi] and expanded access to telehealth, are needed to realize their full potential.

Basic science and global collaborations

In tandem with implementation science, **critical basic science also must be maintained to advance efforts to develop an HIV cure and vaccine as these could transform the current treatment and prevention paradigms**. We also must **think globally and sustain support for global research collaborations as HIV, like all infectious diseases, cannot be isolated by geographic boundaries**. In addition, many of the critical advances in HIV prevention and treatment in the U.S. were based on international trials in high-prevalence countries.

Thank you again for the opportunity to offer comments for the record. Please do not hesitate to contact me or the HIVMA Executive Director Andrea Weddle with questions regarding HIVMA's recommendations.

Contact Information:

Philip Bolduc, MD
HIVMA Chair-Elect
philip.bolduc2@umassmed.edu

Submitted by:

Andrea Weddle
Executive Director, HIVMA
aweddle@HIVMA.org

---

[i] Sullivan, PS, et al. Implementation strategies to increase PrEP uptake in the South. Curr HIV/AIDS Rep. 2019 Aug;16(4):259-269.
[ii] Kamitani, E, et al. Strategies to eliminate inequity in PrEP services in the US south and rural communities. J Assoc Nurses AIDS Care. 2024 Mar-Apr ;35(2) :153-160.

[iii] Furl, R, et al. Determinants of facilitated health insurance enrollment for patients with HIV disease, and impact of insurance enrollment on targeted health outcomes. BMC Infect Dis. 2018 Mar 16;18(1):132.
[iv] Edmonds, A, et al. Health insurance and initiation of direct-acting antivirals for hepatitis C in US women with Human Immunodeficiency Virus. Clin Infect Dis. 2023 Jul 26;77(2):258-264.
[v] McManus, KA, et al. Affordable care act qualified health plan coverage: association with improved HIV viral suppression for AIDS Drug Assistance Program clients in a Medicaid nonexpansion state.
[vi] Center for Health Care Strategies. Financing Mechanisms for Street Medicine and Other Low-Barrier Models of Care. February 2025.