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)
71st Meeting
April 13, 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:**
COL Julie Ake
CAPT Melissa Briggs-Hagen
Dr. Robert Eisinger
Ms. Heather L. Hauck
Dr. Rohan Hazra

OAR Leadership:
Dr. David Chang
Ms. Melissa Herrera
Dr. Leslie Marshall

Invited Speakers and Guests:
Dr. Nahida Chakhtoura
Dr. Gregory Greenwood
Dr. Marguerita Lightfoot
Dr. Jon Lorsch
Dr. Henry Masur
Dr. Alice Pau
Dr. Ross Shonat
Dr. Monica Webb Hooper

Welcome and Introductions

Melissa Herrera, M.P.H., OARAC Executive Secretary, Public Health Analyst, 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

Ms. Melissa Herrera and Dr. Luis J. Montaner welcomed participants to the 71st 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 70th OARAC meeting, which was held on January 29, 2026. Minutes from the 70th OARAC meeting were approved by notational vote by the Council in advance of the 71st OARAC meeting.

Ms. Herrera conducted roll call and Dr. Montaner reviewed the agenda for the 71st meeting, noting the inclusion of time for public comments.

Report: OAR Director

Leslie Marshall, Ph.D., Acting Deputy Director, OAR, NIH, on behalf of
Geri R. Donenberg, Ph.D., Associate Director for AIDS Research and Director, OAR, NIH

Dr. Leslie Marshall conveyed Dr. Geri Donenberg's regrets for missing the meeting. She thanked Drs. Montaner and Anne Neilan for agreeing to extend their terms as OARAC members through 2027 and for their service as members of the HIV Clinical Trials Networks (CTN) External Review Working Group. Dr. Marshall explained that the *NIH Strategic Plan for HIV and*

HIV-Related Research 2027–2031 is under review and clearance, and will be released and shared with OARAC members as soon as possible.

At the NIH level, as part of implementing the 21st Century Cures Act, NIH updates its strategic plan no less than once every 6 years. The agency is currently developing the *NIH-wide Strategic Plan* for fiscal years (FY) 2027–2031 and anticipates releasing it in early FY 2027. The NIH-wide plan outlines NIH's vision for biomedical research, capacity, and stewardship by presenting its highest priorities. It is designed to complement and harmonize institute and center (IC) strategic plans across NIH. A request for information (RFI) has been released inviting comments on the framework for the FY 2027–2031 plan and is intended to gather feedback on goals across three priorities: research areas, research capacity, and research operations. RFI responses are due May 26, 2026.

Dr. Marshall noted that NIH Director Dr. Jayanta "Jay" Bhattacharya was named acting director of the Centers for Disease Control and Prevention in February and will continue in this role for the near future. Dr. Rohan Hazra, who is an *Ex Officio* OARAC member and Executive Secretary of the Pediatric ARV Guidelines, is serving as acting director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). Searches are ongoing for a number of permanent IC directors.

Dr. Marshall also announced that CAPT Mary Glenshaw accepted a new position as Senior Advisor to the Director of the Division of Extramural Research at NICHD. CAPT Glenshaw was a steadfast member of OAR's leadership team and advised four OAR directors, including support for Dr. Donenberg's transition into her current role as OAR Director. Dr. Marshall recognized CAPT Glenshaw's many contributions to OAR, specifically her passion for community engagement as a central component of OAR's success. OAR Lead Management and Program Analyst Ms. Katherine Karimy will assume CAPT Glenshaw's former role supporting the HIV Clinical Guidelines. With CAPT Glenshaw's departure, Ms. Herrera is now the OARAC Executive Secretary. Ms. Herrera is a Public Health Analyst at OAR, with expertise in advanced data analytics and public health. She guides strategic investments in areas such as women's health, implementation science, and American Indian and Alaska Native communities. Ms. Herrera's efforts to foster cross-agency collaboration and engage communities to support tribal health were recently recognized with a 2025 NIH Director's Award. As Acting OAR Deputy Director, Dr. Marshall will be serving on an interim basis as backup OARAC Executive Secretary; Dr. Marshall thanked OAR Senior Science Advisor Geetanjali Bansal for serving in this role in recent years.

Dr. Marshall provided an update on the OAR budget, explaining that the 1993 NIH Revitalization Act broadened OAR's authority and included language allowing OAR to execute up to a 3% budget transfer authority, consistent with OAR's mandate to prioritize science in the most urgent areas given the evolution of the pandemic. For FY26, OAR exercised this transfer authority at less than 2%, primarily to advance implementation science activities. Dr. Marshall noted that despite effective prevention and treatment tools, new diagnoses persist, and health disparities remain. Innovations are not reaching those who need them most, necessitating increased investments in implementation science. Additionally, there continues to be emerging issues requiring increased investment, including a growing population aging with HIV and experiencing co-occurring conditions that were also considered in the transfer of funds. For example, AIDS funding was added to the National Institute on Aging's budget for aging, while funds were added to other Institutes to address co-occurring conditions like cardiovascular diseases, alcohol use, and mental health. Execution of the transfer authority was a data-driven process informed by a combination of factors, including which ICs were already investing in these areas, as evidenced

by their current portfolios. The transfer sought to leverage existing and ongoing investments and best position NIH to accelerate research in these areas of science. Dr. Marshall emphasized that OAR continues to support a comprehensive research portfolio from basic discovery, pre-clinical, clinical, and translational research.

Dr. Marshall presented a slide highlighting the overall distribution of FY26 HIV funding across NIH ICs, specifying the proportion of HIV funding relative to total NIH research funding. The five institutes with the highest HIV/AIDS allocations are: the National Institute of Allergy and Infectious Diseases (NIAID), National Institute on Drug Abuse (NIDA), National Cancer Institute (NCI), National Institute of Mental Health (NIMH), and NICHD. The FY27 Congressional Budget Justification, which explains the president's budget proposal for HIV research to Congress, has been released and is available on OAR's website. The NIH HIV research budget for FY26 is $3.28 billion, the same as in FY25. The President's Budget for FY27 proposes an almost $600 million, or 18%, reduction in total NIH HIV funding. Dr. Marshall reiterated that the President's Budget is a proposal—Congress will determine the final budget for the next fiscal year.

Dr. Marshall then noted several OAR program updates. OAR continues its efforts to support early-career investigators (ECIs) in HIV research and has already engaged on this issue across several venues this year, including at a DC Centers for AIDS Research (CFAR) symposium, the Conference on Retroviruses and Opportunistic Infections (CROI), and the CFAR Annual Meeting. OAR's NIH ECI Office Hours have been another key effort, connecting 35 program representatives across 14 ICs with 107 ECIs through one-on-one consultations. Looking ahead, OAR will continue this work, with ECI-related engagements with the U.S. Military HIV Research Program and the Mid Atlantic CFAR Consortium (MACC) Nursing Initiative in collaboration with the National Institute of Nursing Research (NINR).

Dr. Marshall provided updates on the HIV and Pharmacy focus area that OAR co-leads with NIMH. Awardees from the multi-IC HIV and Pharmacy request for applications program met for the first time in February to survey each other's work and identify areas of shared scientific interests. This group of grantees will continue to meet to pursue their collective efforts around shared interests, and a webinar series is being developed that will feature pharmacy-centered research from these awards. The series will start on April 27, 2026.

Dr. Marshall then introduced two implementation science efforts now overseen by OAR. The first, the Adolescent HIV Prevention and Treatment Implementation Alliance (AHISA), was established in 2017. AHISA aims to leverage implementation science to enhance the effective use of evidence and help overcome implementation challenges related to the prevention and treatment of HIV among adolescents abroad by catalyzing collaboration and communication among NIH-funded implementation scientists, program implementers, and policymakers. The second effort, the NIH–President's Emergency Plan for AIDS Relief (or PEPFAR) Local Implementation Science Network (LISN), aims to build and strengthen local implementation science alliances by catalyzing long-term, sustainable, region- or country-specific collaborations intended to enhance the quality of HIV prevention and treatment through implementation science. The goal is to generate research and anchor sustainable implementation science capacity in specific countries and regions. Dr. Marshall pointed out that these efforts are just beginning within OAR, and updates will be shared at future OARAC meetings.

Dr. Marshall highlighted a number of recent engagements in which OAR has participated, including a CFAR meeting in Denver, a CFAR-wide webinar on future directions for NIH HIV research, and an ECI pop-up clinic at CROI. She also noted the NIH Intramural NeuroHIV workshop; a Grand Rounds presentation at the University of California, Los Angeles; the

Biomedical HIV Prevention Summit; and the Federal AIDS Policy Partnership's Research Working Group. Upcoming engagements include the NIH Tribal Advisory Committee meeting and the Continuum 2026 conference. In closing, Dr. Marshall reminded Council members that the next OARAC meeting is scheduled for June 25, 2026.

Discussion Highlights

In response to a question from Dr. Montaner related to implementation science supplements, OAR Senior Science Advisor Dr. David Chang explained that the administrative supplements for implementation science in HIV are open to all eligible grants and available for funding by ICs directly or by cofunding with OAR. Any IC that is part of the parent announcement for the administrative supplement can participate.

Dr. Montaner asked for clarity regarding whether the OAR will consider funding grant applications in the new category of grants that are unscored but fundable (i.e., competitive but not discussed, NOT-OD-26-069). Dr. Marshall responded that OAR's goal remains to fund the most meritorious research and secure the best return on research investment to support all people impacted by HIV. She explained that OAR's understanding is that the new NIH funding approach heavily prioritizes both scientific merit and mission alignment, and she commented that she expects OAR would not change how it considers grants and would maintain alignment with IC partners, who administer the grants and make funding decisions. Any flaws identified in peer review will be addressed by program officials at the ICs with the investigators and plans to address any flaws would be presented to OAR.

COL Julie Ake lauded OAR's continued focus on ECIs and asked whether any implementation science priorities are related to HIV vaccine development. Dr. Robert Eisinger explained that NIAID works closely with other ICs in implementation science and is pivoting to increase its emphasis on this topic. Although NIAID has supported vaccine research for many years, the institute is broadening its research to reflect immune-based prevention strategies with the inclusion of implementation science. Dr. Marshall added that treatment and prevention are at different phases of development than cure and vaccine, and she noted that OAR encourages consideration of implementation science as a component of product design. Dr. Eisinger also commented that NIAID is working to continue supporting training programs for young investigators and recognizes the urgent need to ensure the stability of the new investigator pipeline.

When asked for more details on the reallocation of funds, Dr. Marshall explained that $61 million out of a possible $99 million was reallocated proportionately from across all ICs that have HIV funding. The reallocation was based on a data-driven approach and is reflected in the FY27 Congressional Justification budget. Dr. Neilan commented that OARAC would welcome the opportunity to review the evidence used to determine the data-driven redistribution of funds.

Dr. Neilan asked about opportunities to address the decline in R01 funding rates across all categories, including ECIs. Dr. Marshall responded that OAR continues to commit resources to support ECIs. In recognition of the complexity of the past 16 months, OAR has increased its efforts to support ECI-related engagements and improve ease of access to programmatic officials. She added that OAR's use of discretionary funds benefits ECIs, providing examples from OAR's Innovation Program. Dr. Chang noted that uncertainty was a key theme that arose from OAR-facilitated ECI listening sessions last year—this uncertainty led many ECIs (and their senior PIs) to pause and wait until the impacts of new NIH policies and federal directives materialized. Also anecdotally, he noted that CFARs have been using pilot awards that help

ECIs pivot in new directions, but these activities are difficult to track. He added that assessing the rates of funding will require another year of data but emphasized that OAR continues to maintain a strong focus on maintaining the HIV research workforce. Dr. Montaner commended OAR for doubling the training award budget for FY26 and encouraged the office to ensure that the awards are released before the end of the fiscal year.

NIH Funding Strategy and Peer Review: Q&A With NIH Office of Extramural Research and Center for Scientific Review

Jon R. Lorsch, Ph.D., Deputy Director for Extramural Research, NIH
Ross D. Shonat, Ph.D., Director, Division of Physiological and Pathological Sciences, Center for Scientific Review (CSR), NIH

Dr. Jon Lorsch provided an update on NIH's unified funding strategy that allows all NIH Institutes, Centers, and Offices (ICOs) to operate using the consistent funding principles regarding grants. NIH's new unified funding strategy states that all ICOs should have in their funding policy alignment with NIH's mission and prioritization of scientific merit. Importantly, the strategy emphasizes that ICOs should consider not only scores but all information from peer review. Dr. Lorsch pointed out the significant amount of work peer reviewers engage in, which may not be fully captured in the scores. The new strategy also asks that ICOs integrate a breadth of topics relevant to their own priorities, consider investigators' career stages, promote the sustainability of the biomedical research workforce, promote broad distribution and geographic balance of funding, and align with availability of ICO funds when making decisions.

One significant change for some ICOs is that ICOs are no longer allowed to rely on funding paylines or cutoffs in overall impact scores to determine which applications to fund. Dr. Lorsch emphasized that about half of ICOs already award funds in this manner. He added that a core function of ICO directors and program staff is to consider peer review outcomes within the context of the ICO's and NIH's priorities and strategic plans, and use that information to develop appropriate pay plans. He emphasized that this strategy is not intended to allow increased political influence on funding decision processes; rather, it is intended to allow NIH staff to make the best possible decisions about what science should be funded and use a variety of factors in making these determinations. Dr. Lorsch invited Council members to learn more about issues related to funding decisions on the NIH Grants and Funding website.

Dr. Ross Shonat noted that per NOT-OD-26-029, AIDS application due dates have been removed; this change is effective for the January 2027 council round, which has May 7, 2026, as its last expedited submission date. HIV/AIDS applications will continue to have three receipt dates per year (now submitted on the standard receipt dates). Dr. Shonat commented that this change will lift a substantial administrative burden, particularly in determining whether an application meets the definition of AIDS research after receipt, which can result in an application missing the receipt date if it is determined not to qualify as an AIDS application. This change will assist with NIH's efforts to improve efficiency, strengthen the peer review process, and maximize competition of similar science across the agency.

Dr. Shonat noted CSR's mission: to ensure that NIH grant applications receive fair, independent, expert, and timely scientific reviews—free from inappropriate influences—so NIH can fund the most promising research. He provided a reminder of CSR's two-stage review system, which occurs for three rounds of funding each year. Currently, each round has three regular receipt dates and three HIV/AIDS receipt dates. Dr. Shonat explained that, with the removal of HIV/AIDS-specific receipt dates, applications may be assigned either to the six existing HIV/AIDS study sections or to other study sections based on the best scientific fit,

thereby expanding the scope of these study sections to include HIV/AIDS science as appropriate (beginning with the January 2027 Council round). As part of its ongoing responsibility to monitor scientific trends, application volume, and the effectiveness of peer review, CSR regularly evaluates and adjusts study section structures and boundaries as needed. Some study sections may no longer be viable, while others are likely to continue (depending on application numbers and topical patterns). Some standing members serving on HIV/AIDS study sections may be reassigned as appropriate to study sections where their expertise is needed. CSR will study the impact of these changes and after a few rounds, reassess/redesign study section boundaries as needed, with extramural community input.

Discussion Highlights

Dr. Sara Sawyer expressed concern about the effects of eliminating continuous submission deadlines and the potential for a decline in the quality of study section composition. Dr. Shonat responded that continuous submission deadlines created significant complications for CSR and that the approach was not sustainable. He recognized that serving on study sections presents challenges and noted that CSR maintains a late submission policy for those serving on NIH study sections beyond the submission date. He also noted that anecdotally, more people have indicated that they welcome these changes and understand the rationale for them compared with those who are opposed to the changes. Dr. Sawyer pointed out that the difficulty of applying for grants leaves little time to serve on study sections without benefits to the study section members. Dr. Montaner suggested that NIH consider moving the deadline for study section participants back to 6 or 8 weeks after the regular deadline, noting that the current period of 4 weeks does not account for the 2-week internal deadline that is required by many institutions.

Dr. Neilan pointed out that because the new *NIH Strategic Plan for HIV and HIV-Related Research* for FY 2026–2030 has not yet been released and OAR's priorities in that plan have not been announced, the unified funding strategy becomes opaque. Dr. Marshall recognized that challenge and explained that until the new plan is cleared and released, OAR remains guided by the currently approved plan. The new plan will dovetail with the current plan and build on advances and close gaps that still remain. She encouraged Council members to continue referring to the current plan; as soon as the new plan is released it will be shared with Council members.

Dr. Courtney Fletcher pointed out that application review scores already reflect the broad work of the reviewers and asked for additional context for what NIH considered was missing beyond the elements that comprise the application score. Dr. Lorsch responded that considering additional elements of review could be more beneficial in cases of divided reviews or gaps/issues identified by program staff—these types of considerations may not be reflected in application scores. He commented that boiling down an application to a single score loses significant information provided by peer reviewers.

Dr. Montaner asked for clarity about decision-making around the set of applications considered not discussed but fundable, which would not be discussed in study sections. Dr. Lorsch explained that this category was intended as an interim measure because of the lapse in appropriations during the 6-week government shutdown, which caused most of the study section meetings during that period to be cancelled. ICs can still consider these applications for funding but will only have the three reviews to consider (and not the discussion summary and overall score resulting from the discussion). He emphasized that all factors of the unified score

will be taken into consideration, and all ICOs will want to ensure that the science is meritorious before addressing other considerations.

Dr. Sonia Flores asked how program staff funding decisions align with advisory council funding decisions. Dr. Lorsch explained that program staff do not make funding decisions but make recommendations; IC directors have the delegated authority to make funding decisions. Advisory committees also make recommendations on which applications federal officials (i.e., NIH staff) can consider for funding, but these committees do not make funding decisions. The program officer and IC director make funding plans after the advisory council meets. In response to a follow up question from Dr. Flores, Dr. Lorsch explained that in terms of timing, advisory councils usually meet in advance of program staff making funding recommendations.

COL Ake requested clarity on the prioritization of work conducted by international investigators. Dr. Lorsch explained that Dr. Bhattacharya has released a statement reiterating NIH's longstanding policies related to NIH funding of international work. These studies require special characteristics uniquely suited to improving the health of the U.S. population.

Dr. Montaner asked whether the volume of NIH HIV research would result in creating or maintaining some HIV-specific study sections regardless of NIH's plans for study section integration. Dr. Shonat commented that he does not expect the scientific portfolio to decrease and explained that CSR will be considering the best way to cluster the science. He anticipates that some study sections would remain unique to HIV research (possibly those related to comorbidities, coinfections, and HIV immunology) because there are sufficient robust applications in that area.

HIV Clinical Trials Networks (CTNs) External Review Recommendations

Marguerita Lightfoot, Ph.D., Ronald Naito-John McAnulty Professor in Health Equity, Oregon Health & Sciences University–Portland State University School of Public Health

Dr. Marguerita Lightfoot outlined the recommendations of the external review of the CTNs, which was conducted to advise the OAR director on how to optimize these networks' ability to address the highest-priority emerging HIV research questions in the next funding cycle. The review group was asked to focus on how to strengthen capacity for implementation science and HIV-associated co-occurring conditions while maintaining the scientific strengths in domestic and international clinical research and preserving the core functions of the networks. The group's discussions occurred from January through March 2026, a period that included two complete or partial federal government shutdowns, causing uncertainty and anxiety about the future of the research enterprise. Dr. Lightfoot thanked all who support these networks for their commitment under pressure. The review produced 12 priority areas and 33 recommendations.

The first five recommendations emphasize that the network is a national and international asset that must be preserved as core research infrastructure with a comprehensive, balanced scientific research portfolio designed for real-world contexts. Behavioral and social science research also should be integrated. The next four recommendations focus on strengthening collaboration across the network by formalizing cross-network structures, holding annual planning meetings, sharing specialized expertise among adult and pediatric networks, and structuring bridges between the programs.

The group also recommends increasing collaboration with federal partners by strengthening NIH and federal agency ties, expanding to community clinics and public health systems, and including public health leaders. The networks also should maintain investment in international

research, which Dr. Lightfoot emphasized is indispensable. The group recommends maintaining and expanding international sites, supporting bidirectional knowledge exchange, and investing in workforce and site capacity. Dr. Lightfoot emphasized that stepping back from international HIV research would be a strategic and scientific mistake.

The review also encourages the networks to broaden meaningful community engagement by developing robust organizational structures; making community members partners in research leadership, including all those involved in the everyday care and support of people with HIV within the definition of community; and facilitating advisory participation through centralized systems to notify individuals of opportunities to participate in advisory and research partnership roles across all networks.

The group recommends that the networks maintain social and behavioral science research; Dr. Lightfoot emphasized that implementation science is not a replacement for social and behavioral research. Networks also should assess social determinants of health. Additionally, dedicated organizational structures should be created to integrate research on co-occurring conditions into clinical trials when appropriate, and key co-infections and conditions should be prioritized.

Implementation science should be treated as a core component of the networks, with dedicated implementation science organizational structures, implementation science questions embedded in clinical trials, an implementation science lens applied across the continuum, and centralized implementation science expertise and resources. The networks also should support comprehensive training programs for investigators from communities disproportionately affected by HIV. Adequate and dedicated funding should be reserved for community engagement, implementation science, and social and behavioral research without compromising core scientific activities. Finally, the networks' activities and performance should be evaluated with formal processes, transparent site performance reviews, and independent mid-cycle reviews.

Dr. Lightfoot reiterated that the CTNs remain uniquely positioned to address the domestic and international fight against HIV and co-occurring conditions. By strengthening collaboration, integrating implementation and social science perspectives, expanding and resourcing meaningful involvement of the entire HIV response community, and sustaining the networks' scientific capacity, Dr. Lightfoot emphasized that the networks can continue accelerating progress toward ending the HIV epidemic.

Discussion Highlights

When asked how to help small nonprofits participate in the networks, Dr. Lightfoot emphasized the need to implement structures that facilitate engagement of community partners as co-investigators. She noted her hope that issues making participation difficult for community members, such as lack of payment, would be rectified.

In response to a question about how these recommendations will be integrated into NIH planning, Dr. Marshall explained that the OAR leadership team has reviewed the recommendations and is discussing with NIAID how to incorporate them into notices of funding opportunities (NOFOs) where appropriate. Dr. Eisinger added that NIAID is incorporating the recommendations into the development of the networks' NOFOs, which are in the finalization stage. Many points are reflected in the concepts approved by the AIDS Research Advisory Council and the forecasts issued on Grants.gov.

Dr. Fletcher asked if implementation science fits into the current CTNs, noting that they have been operating for a long time and are very good at what they do. He asked whether a new network focused on implementation science would be more effective than asking the existing networks to change. Dr. Lightfoot explained that some networks are currently integrating implementation science and noted that even early preclinical studies can benefit from an implementation science lens. Dr. Eisinger confirmed that a separate network is not intended and pointed out that the AIDS Clinical Trials Group has established a working group that specifically focuses on implementation science.

COL Ake pointed out that many investigators in the networks, especially internationally, play additional roles in HIV services delivery in their communities and are likely to bring implementation science expertise to their network roles. She emphasized the need to consider talent management and development of leadership groups. Dr. Montaner encouraged leadership to consider forming a working group to evaluate the biosketch, which currently focuses on academic—not community—work and to educate reviewers about the value of these individuals in the research effort. He also suggested establishing a helpline for community members applying to participate in research.

In response to a question about how the vital nature of international collaborations is incorporated into NOFOs, Dr. Eisinger agreed that international sites are crucial to conducting many CTN studies and commented that NIAID intends to ensure that clinical trials units include both domestic and international sites.

Updates: NIH Advisory Council Representatives

National Advisory Mental Health Council

Gregory Greenwood, Ph.D., Deputy Director, Division of AIDS Research, National Institute of Mental Health (NIMH), NIH

Dr. Gregory Greenwood outlined a forecast initiative titled Impact of Immunotherapies on Central Nervous System (CNS) Outcomes in People with HIV: Potential Benefits, Challenges, and Risks. HIV establishes a CNS reservoir quickly, and the neuroinflammatory processes continue after suppression in the periphery. This initiative consists of a developmental phase in which researchers will define reproducible CNS disease models and test whether immunotherapy candidates can engage HIV- and CNS-relevant cells and a confirmatory phase in which they will test CNS engagement *in vivo*, link biomarkers to cognitive and behavioral changes, and build the translational safety package needed to support a trial in humans. The result will be a purpose-built immunotherapeutic agent for CNS HIV remission and the first rigorous evidence base for whether clearing the virus in the brain can improve mental health and neurocognitive outcomes.

NIMH also has interest in three highlighted topics published between January and March: the OAR-led Implementation Science to Optimize HIV Prevention and Treatment; Multidisciplinary Studies of HIV/AIDS and Aging, led by the National Institute on Aging; and Drug Discovery for Nervous System Disorders, led by the National Institute on Drug Abuse.

National Advisory Allergy and Infectious Diseases Council

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

Dr. Eisinger outlined the concepts approved by NIAID's council, most of which focused on recompetition of the CTNs, which Dr. Eisinger emphasized continue to provide findings

essential to the development of crucial strategies for the prevention and treatment of HIV and its associated comorbidities. The CTNs represent coordinated multidisciplinary research advancing HIV/AIDS prevention, treatment, and implementation science and conduct biomedical and implementation research that improves the uptake of evidence-based safe and effective prevention and treatment studies across the lifespan. The networks also conduct high-impact clinical studies that are critical to findings that benefit those with or at risk for HIV and HIV-associated diseases. Each CTN is composed of a leadership and operations center, a laboratory center, a statistical and data management center, and clinical trials units and clinical research sites.

One CTN will be supported for each of four scientific agendas: HIV Therapeutics and Cure and Prevention and Treatment for HIV-Associated Comorbidities in Adults; HIV Prevention and Treatment in Maternal, Adolescent, and Pediatric Populations; Biomedical HIV Prevention Strategies for Adults and Adolescents; and Immune-Based Prevention for HIV and HIV-Associated Diseases. The four networks will be the HIV/AIDS Adult Therapeutics Clinical Trials Network; the HIV Maternal, Adolescent, and Pediatric Clinical Trials Network; the HIV Prevention Research Clinical Trials Network; and the Immune-Based Prevention Trials Network. The leadership and operations centers were reissued for 7 years, and NIAID anticipates awarding four grants. Funding was also reissued for laboratory centers, statistical and data management centers, and clinical trials units. The forecasts are now available on Grants.gov, and NIAID intends to issue the NOFOs at the end of the summer, with applications due by January 2027. The institute also intends to recompete all four CTNs described by December 1, 2027. Dr. Eisinger also noted contract recompetes for the Immunology Quality Assessment Program, preclinical services for HIV therapeutics, and NIAID specimen repository. He also confirmed that NIAID intends to fund the Martin Delaney Collaboratories in FY28 or calendar year 2027.

Discussion Highlights

When asked how investigators are encouraged to access the CNS in humans, Dr. Greenwood explained that the concept is broadly written and allows for novel alternative models (NAMs), such as organoids, and tests of the degree to which the immunotherapy enters the CNS. He emphasized that NIMH supports using the right model with the right scientific question.

Updates: HIV Clinical Guidelines Working Groups of OARAC

Adult and Adolescent Antiretroviral (ARV) Guidelines

Alice K. Pau, Pharm.D., Staff Scientist/Clinical Pharmacist, NIAID, NIH

Dr. Alice Pau explained that since Dr. Donenberg has expressed OAR's intent to continue supporting the guidelines, the panel has made a concerted effort to recruit new members, and some members have finished their extended terms. New co-chairs include Dr. Henry Masur as the government co-chair and Dr. Jason Baker as the academic co-chair. Dr. Safia Kuriakose has assumed the role of assistant executive secretary, and many new scientific and community members have been added. Dr. Pau also thanked outgoing members for their service.

The Adult and Adolescent ARV Guidelines were last updated in September 2025, and the panel is working toward a fall 2026 update. Many sections are being revised, and a new section has been added on the principles of antiretroviral therapy (ART). Key research questions and knowledge gaps also are being developed for the sections to be updated.

Perinatal HIV Guidelines

Nahida Chakhtoura, M.D., Chief, Maternal and Pediatric Infectious Disease Branch, Division of Extramural Research, NICHD, NIH

Dr. Nahida Chakhtoura noted that the Perinatal Guidelines released an update in March; the three sections shared with the Pediatric ARV Guidelines will be updated in May. Highlights of the update include recommendations for providers to discuss oral and injectable pre-exposure prophylaxis during pregnancy and breastfeeding options with their patients; the classification of dolutegravir as an alternative ART regimen for use in pregnancy for individuals without prior exposure to long-acting treatments; and recommendations around hepatitis B coinfection. The updates also addressed use of direct-acting antivirals for hepatitis C coinfection in pregnancy and the approval of lenacapavir.

Adult and Adolescent Opportunistic Infection (OI) Guidelines

Henry Masur, M.D., Chief, Critical Care Medicine Department, Clinical Center, NIH

Dr. Masur explained that the Adult OI Guidelines Panel consists of more than 150 members in 23 section groups updating 32 chapters. Each chapter is reviewed quarterly and revised on a rolling basis as needed. After discussions with Dr. Pau and the Adult ARV Guidelines Panel, the Adult OI Guidelines have added a new section, When to Start ART. The panel also is working to add new members that expand the panels' representation.

Dr. Masur noted that annual page views remain steady throughout 2024 and 2025 and show that the guidelines continue to be heavily used. The chapters addressing the same five OIs that were most problematic in the 1980s are the most consulted today, but the chapters on rarer OIs also are important because resources on these OIs are scarce. Most usage originates in the United States, but many other countries use the guidelines, as well. Dr. Masur noted that so far in 2026, the chapters on bacterial enterics, varicella zoster virus, and immunization, as well as the roster and financial disclosure list, have been updated.

Discussion Highlights

Dr. Montaner asked whether tracking usage by state or ZIP code to identify gaps in regional coverage is possible. Dr. Masur commented that analyzing usage data is complicated, noting that urban areas would have higher usage because of the higher number of patients. Dr. Pau pointed out that many people use mobile devices, but phone numbers might not align with users' current locations. Dr. Chakhtoura noted that identifiable information collected via analytics is limited. She suggested that usage in community settings versus academic centers could be reviewed.

NIMHD and HIV/AIDS Research: Advancing towards Solutions

Monica Webb Hooper, Ph.D., Acting Director, National Institute on Minority Health and Health Disparities (NIMHD), NIH

Dr. Monica Webb Hooper commented that health disparities research remains valued and supported by NIH, noting that NIMHD's mission focuses on improving minority health and reducing health disparities to improve overall population and public health. NIMHD also seeks to understand the complex drivers of population differences in health outcomes and support innovation that strengthens research and practice. Dr. Webb Hooper emphasized the need to ensure that scientific progress benefits all populations.

NIH's unified funding strategy outlines specific priorities with a goal of coordinating across ICs to operate more strategically. A central pillar is to balance supporting high-risk strategies and focusing on health issues that matter most to the public and serve real-world needs. NIH is accelerating investment in transformative tools, such as NAMs and artificial intelligence, as well as increasing oversight to ensure international research can be better tracked and upholds the same standards expected domestically. The unified strategy also specifies that NIH continues to support research advancing the health of all Americans, including a strong commitment to considering health disparities. Dr. Webb Hooper noted that investigators must employ specific and measurable concepts in health disparities research; she recommended avoiding vague references to underserved populations and encouraged the use of precision in how disparities are defined, measured, and addressed. She added that precision increases rigor and enhances the translational ability and impact of the work.

Dr. Webb Hooper defined health disparities as a measurable difference in health between specific population groups, determined through quantifiable, data-driven metrics. She noted that identifying a disparity does not assume that the causation and attribution are known; she emphasized that causes must be evaluated through careful investigation using careful study design. She encouraged investigators to begin with clear, empirical observations and develop testable hypotheses about mechanisms and interventions.

Dr. Webb Hooper noted the need to move beyond epidemiology to studies that investigate biological, behavioral, environmental, and clinical mechanisms that contribute to observed differences across populations and evaluate how modifiable risk factors contribute to disease burden. She commented that the field has largely focused on measuring differences in outcomes but now must move toward science that focuses on developing interventions and implementing them on a population level.

Dr. Webb Hooper explained that disparities are costly, increasing the case for addressing them through scientific approaches. The measurable differences in HIV burden across populations emphasize the importance of continuing to focus on HIV as a public health issue. Black or African American and Latino or Hispanic populations account for a larger share of new HIV diagnoses in the United States than other populations, and measurable differences persist for these populations along the entire HIV care continuum.

NIMHD participates in OAR's NIH-wide HIV strategic planning process to align investments across ICs and ensure work addresses key priorities, supporting both individual projects and collaborative structures to advance a broad and integrated HIV research structure. NIMHD also participates actively in other OAR efforts by funding studies across the full research spectrum focused on improving HIV outcomes in populations with a high prevalence of disease. Dr. Webb Hooper emphasized NIMHD's interest in multilevel influences on HIV risk, prevention, and care.

Dr. Webb Hooper commented that minority health and health disparities research at NIH aims to improve health outcomes, adding that this necessitates that research be translated into action. This requires improving prevention strategies, optimizing screening and early detection, enhancing treatment effectiveness, improving management of disease, and reducing morbidity and mortality. Dr. Webb Hooper reiterated that health disparities science requires precise language, clear definitions of population groups with explicit criteria and disease definitions, quantifiable metrics, standardized measurement of outcomes, transparent and reproducible analytic methods, careful interpretation of observational data, and avoidance of ambiguous terminology.

The PhenX Toolkit offers a method for researchers to collect social determinants of health and demographic data; Dr. Webb Hooper encouraged investigators to adopt these measures to standardize how these data are collected. She also recommended that investigators specify which determinants they are studying and avoid the umbrella term. The NIMHD website offers metrics for operationalizing health disparities using quantifiable measures. Dr. Webb Hooper reiterated that rigor is critical to advancing the science and noted that high-quality health disparities research often integrates multiple measures. NIMHD is interested in research that proposes novel ways to assess data. Dr. Webb Hooper pointed out that community-engaged research is an important approach that can be overlaid on any study design.

Dr. Webb Hooper recommended that researchers select an appropriate reference population by considering the scientific questions and potential for generalizable results. She also suggested that researchers leverage modern biomedical tools and take advantage of the rapid digital transformation in health care, but she cautioned that they must be very careful about not introducing unintentional bias into the data. The Science Collaborative for Health and Artificial intelligence Reduction of Errors (SCHARE) effort aims to strengthen the foundation for AI in health by reducing errors and improving model performance across populations. It provides datasets, includes a data repository, uses NIH-endorsed common data elements, and offers secure collaborative workspaces. Dr. Webb Hooper noted that the SCHARE Think-a-Thons are designed to introduce new users to data science; many are available on NIH VideoCast.

Dr. Webb Hooper emphasized that the present moment provides health disparities researchers the opportunity to reflect on and refine their science, innovate for the future, and ensure investments are driving population health improvements. NIMHD is prioritizing science that is asking novel or unexplored questions, interventions, and population implementation. She recommended that researchers be specific about the problems and populations to be studied, choose the right mechanism, choose actionable endpoints, and be solution focused. She also noted an available training opportunity at the Health Disparities Research Institute that will bring ECIs to the NIH campus to learn about careers in minority health and disparities science.

Discussion Highlights

Dr. Flores pointed out that many pipeline programs have been terminated and asked how to ensure investigators from minority backgrounds have a path into research. Dr. Webb Hooper responded that NIMHD worked with investigators to bring back many of the projects terminated the previous year. She emphasized that community members want researchers who understand them and care about their health. NIMHD and health disparities research overall tends to appeal to a diverse set of investigators. Dr. Webb Hooper recommended that research teams consider who they will involve and hire to conduct groundwork before they begin their applications.

Dr. Neilan noted that OAR is charged with coordinating HIV research across ICs and asked what activities NIMHD could undertake with other ICs to help them follow these suggestions for increasing the precision of disparities research. Dr. Webb Hooper explained that the NIMHD definition of health disparities is available on its website, and staff disseminate information as much as possible. She hoped that NIMHD could participate in more engagements this year and noted that the landscape is evolving.

Dr. Montaner asked about NIMHD's commitment to sustaining research centers in minority institutions, noting that this category was dropped to zero in the 2027 OAR budget. Dr. Webb Hooper replied that the Research Centers and Minority Institutions program is congressionally

mandated; it is ongoing, and no changes are planned. Dr. Marshall planned to investigate the budget and provide Dr. Montaner an informed answer offline.

Public Comment

Melissa Herrera, M.P.H., OARAC Executive Secretary, Public Health Analyst, 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

Ms. Herrera stated that no public comments had been received. The January meeting received three comments, which can be found on the meeting minutes. Any comments received over the next 4 weeks, through May 11, will be published. Public comments following this OARAC meeting appear as an appendix to these meeting minutes.

Closing Remarks and Adjournment

Melissa Herrera, M.P.H., OARAC Executive Secretary, Public Health Analyst, 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

Ms. Herrera announced that the June 25 meeting will occur in person and asked members to return their conflict-of-interest forms. Dr. Marshall thanked Dr. Lightfoot for her in-person attendance and noted that the current plan is to publish the CTN recommendations in their entirety. Dr. Montaner adjourned the meeting at 4:30 p.m. EDT.

Certification

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

Luis Montaner

Digitally signed by Luis Montaner
Date: 2026.07.09 15:07:29 -04'00'

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

Date

MELISSA HERRERA -S

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Date: 2026.07.09 11:05:54 -04'00'

Melissa Herrera, M.P.H.
Executive Secretary, OARAC

07/09/2026

Date