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) 67th Meeting October 24, 2024

Virtual (Videocast Link)

Meeting Minutes

Council Members Present

Dr. Ivy E. Turnbull (Chair) Dr. Courtney V. Fletcher Dr. Sonia Castro Flores Dr. Omar Galárraga Dr. Shruti H. Mehta Dr. Luis J. Montaner Dr. Mojgan H. Naghavi Dr. Anne M. Neilan Dr. Diane M. Santa Maria Dr. Sara L. Sawyer

Ex Officio Members Present

COL Julie A. Ake Dr. Victoria J. Davey Dr. Carl W. Dieffenbach Dr. Rohan Hazra Dr. Jonathan Mermin

Advisory Council Representatives

Dr. Marguerita Lightfoot Dr. Melanie Ott

OAR Leadership

Dr. Geri R. Donenberg (OAR Director) Dr. Geetanjali Bansal CAPT Mary Glenshaw (Executive Secretary)

Invited Speakers and Guests

Dr. Shireesha Dhanireddy Dr. Diana Finzi Dr. Roy (Trip) M. Gulick Dr. Wesley I. Sundquist Dr. Franklin Yates

Welcome and Introductions

CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, Acting Deputy Director, OAR, NIH Ivy Turnbull, D.L.P., Ed.M., M.A., OARAC Chair, Deputy Executive Director, AIDS Alliance for Women, Infants, Children, Youth & Families

CAPT Mary Glenshaw and Dr. Ivy Turnbull welcomed attendees to the 67th meeting of the NIH OARAC. A quorum was present. Meeting materials provided to Council members included the agenda, a conflict-of-interest form, and minutes from the 66th OARAC meeting, held on June 22, 2024. Minutes from the 66th OARAC meeting were approved by the Council in advance of the 67th OARAC meeting.

CAPT Glenshaw welcomed Council members and conducted roll call. Dr. Turnbull reviewed the 67th meeting agenda, noting the inclusion of time for public comments.

Report From the OAR Director

Geri Donenberg, Ph.D., Associate Director for AIDS Research and Director, OAR, NIH Diana Finzi, Ph.D., Director, Basic Sciences Program, Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), NIH

Dr. Geri Donenberg commented on assuming the director's role and outlined her background in implementation science, noting that delays between scientific innovation and delivery of interventions result in the loss of benefit for an entire generation of individuals. She emphasized her eagerness to address this loss of benefit. Dr. Donenberg also thanked Dr. Diana Finzi for her dedication as Acting OAR Director. She also noted the appointment of Dr. Sarah Read as the Principal Deputy Director of the National Institute of Allergy and Infectious Diseases (NIAID).

Dr. Donenberg formally welcomed the following new OARAC members:

- Dr. Courtney Fletcher, Professor and Emeritus Dean, Department of Pharmacy Practice and Science, University of Nebraska Medical Center College of Pharmacy;
- Dr. Sonia Castro Flores, Professor of Medicine and Microbiology at the University of Colorado, Denver, Anschutz Medical Campus;
- Dr. Diane Santa Maria, Dean and Professor, Department of Research, Cizik School of Nursing, University of Texas Health Science Center at Houston; and
- Dr. Sara Sawyer is a Professor of Molecular, Cellular, and Developmental Biology, University of Colorado Boulder.

Dr. Donenberg announced that the <u>Fiscal Year (FY) 2026 NIH HIV/AIDS Professional Judgment</u> <u>Budget</u>, or PJ, has been released and is now available on the OAR website. OAR prepares the PJ each year to estimate the funding needed to fully pursue the goals of the NIH HIV research agenda; the PJ is presented directly to the president without modifications through standard budget processes. The FY 2026 PJ is structured to align with the goals that will appear in the next iteration of the NIH Strategic Plan for HIV and HIV-Related Research.

Dr. Donenberg noted several recent OAR engagements, including the 2024 U.S. Conference on HIV/AIDS; the second annual Innovation in HIV Research Symposium hosted as part of the NIH Research Festival; and the AIDS 2024 and HIV Research for Prevention conferences, which showcased the results of the PURPOSE trials. Both PURPOSE trials showed that lenacapavir, a capsid inhibitor, demonstrated 96–100 percent efficacy in preventing HIV acquisition among populations at heightened risk of HIV in various settings, including cisgender women. Lenacapavir's development builds on decades of NIH-supported basic research, and Dr. Donenberg emphasized the need for equitable global access to these innovations.

Upcoming engagements include: (1) the 15th International Workshop on HIV and Aging (OAR has organized a symposium in partnership with the National Institute of Mental Health [NIMH] for trainees and junior investigators to present their research and learn from experts in the field), (2) the 28th Annual National Centers for AIDS Research meeting, and (3) the 83rd Presidential Advisory Council on HIV/AIDS meeting. OAR also leads the annual NIH observance of World AIDS Day, which will focus on commitment to building on the past four decades of work, ensuring all communities are included, and innovating and adapting strategies based on the latest knowledge. The OAR-led <u>NIH World AIDS Day event</u> will take place on December 4 this year, with the theme "Progress, Innovation, and Impact in HIV Research."

Dr. Donenberg reported that the HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP) and White House Office of National AIDS Policy are currently working to develop the 2026–2030 National HIV/AIDS Strategy (NHAS). A request for information has been issued, and

virtual listening sessions will be held to gather additional feedback. OAR has already provided input to inform development of the 2026–2030 NHAS.

Dr. Donenberg noted that OAR is leading the NIH effort to establish HIV research priorities and develop the next NIH Strategic Plan for HIV and HIV-Related Research, which serves as a roadmap for the NIH HIV research program and ensures that funds are allocated in accordance with NIH scientific research priorities. The plan is broad enough to capture all potential areas of research that NIH could fund, but it also will prioritize specific areas and be aligned with the NHAS and the Ending the HIV Epidemic in the U.S. initiative. The plan will be reviewed annually and will continue to evolve to reflect research advances and changing needs.

Over the past year, an internal OAR working group synthesized feedback from internal and external sources to help identify research priorities, gaps, opportunities, and common themes that emerged from information provided by diverse partners, including OARAC. The revised framework was provided to three OARAC task forces—focused on basic biomedical and preclinical research; behavioral, social, and implementation research; and clinical and intervention research—for review and refinement. These task forces are short-term, multidisciplinary working groups convened to provide recommendations on the research priorities using a broad diversity of expertise and experience. Dr. Donenberg thanked the task force members for their work and reminded attendees that another update will be provided at the February OARAC meeting.

To introduce the next item on the agenda, Dr. Finzi described the development of lenacapavir, which was supported by decades of NIH research investment on the mechanisms utilized by HIV to infect cells. Dr. Wesley Sundquist and his team identified the HIV capsid, a cone-shaped shell that protects the viral genome during host infection, as a potential therapeutic target. Lenacapavir was developed in partnership with Gilead, which sponsored the PURPOSE trials.

Structure, Function, and Inhibition of the HIV-1 Capsid

Wesley I. Sundquist, Ph.D., Samuels Professor and Co-Chair, Department of Biochemistry, The University of Utah School of Medicine

Dr. Sundquist explained that his group has been working on capsid research for about 30 years. The two PURPOSE trials showed no infections over 1,939 person-years with lenacapavir; these results, coupled with Gilead's agreement to support generic versions for the lowest-resourced 130 countries, show promise that this innovation will change the progression of the HIV epidemic. Dr. Sundquist pointed out that the community of capsid researchers is excited about the potential of these results and proud of the basic science research contributions that made it possible.

Dr. Sundquist explained that HIV's Gag protein is made as a polypeptide with a number of different functional domains. The central CA region makes important protein–protein interactions at the immature virus stage and, in the mature virus, builds a conical capsid that contains the viral DNA. Initial research sought to understand the structure of the protein, which dictates its function. The protein aligns as a dimer with two copies, and about 750 copies of the CA dimer form into hexameric rings, creating the capsid as a fullerene cone. Both ends of the capsid require the introduction of pentamers, similar to the arrangement of sections of a soccer ball, to close the cone. The development of technologies to crystallize the hexamer and pentamer was critical to supporting the fullerene cone model, allowing structure-based drug design.

Understanding how the hexamers fit together was critical to determining the binding site for lenacapavir, a large, conserved, hydrophobic crevice known as CPSF6.

Dr. Sundquist explained that once the structure was identified, surface mutations could be designed without altering the overall structure. Most of the mutations designed by his team reduced infectivity significantly, showing that even small mutations on surface proteins have very detrimental effects on viral replication. Dr. Sundquist explained that when viral DNA escapes from the capsid, it integrates into the host chromosome, which makes curing people of HIV difficult. Lenacapavir has been highly effective as pre-exposure prophylaxis, but further research could identify a drug with a different mechanism that could be paired with lenacapavir to form a more effective first-line therapy.

Dr. Sundquist remarked on Gilead's long-term commitment to targeting the HIV capsid. Gilead developed more than 4,000 compounds, assisted by basic science discoveries, such as the structure of the hexamer. Dr. Sundquist also noted that lenacapavir's most remarkable property is its long-lasting pharmacokinetics, resulting in approval for 6-month therapies. Dr. Sundquist commented on some ongoing experiments to increase understanding of the capsid process.

Dr. Sundquist noted some observations and opinions from his research. Nature compartmentalizes reactions, localizing many important processes within the capsid, and viral capsids can be genetically fragile and targetable. The capsid is energetically balanced, which adds to its fragility. Protein–protein interactions can be effective targets for drugs, and inhibitor insolubility can be beneficial, as in the case of lenacapavir's long action. Dr. Sundquist emphasized the need to consider human behavior, such as adherence, and commented on the importance of long-term programmatic and financial support, as well as industry partnerships, to this success. He added that curiosity-driven basic science often is impactful in unexpected ways, but smaller groups may be the most effective arrangement when understanding is limited.

Discussion Highlights

Dr. Anne Neilan expressed concern that Gilead's agreement for making lenacapavir available in lower-resourced settings has a long timeline and does not cover important intermediate steps. She asked how NIH could incentivize partnerships with the private sector and ensure that the results of innovations are delivered rapidly. Dr. Sundquist explained that although he does not have policy expertise, he shares the concern about the timescale and the need for more rapid implementation. He clarified that his team worked independently from Gilead's development of lenacapavir, allowing both teams to work within their skill areas, so independent funding was critical.

In response to a question about lenacapavir's action on the pentamers, Dr. Sundquist clarified that the exact mechanisms are still being studied and directed attendees to the work of Dr. Owen Pornillos. Lenacapavir makes the hexamer more stable, which improves polymerization but restricts the angle between hexamers. In normal capsids, the angle changes throughout the cone, so this restriction may rigidify the lattice and force it into a flatter shape that is incompatible with the pentamers, which then pop off. This fragile capsid is more susceptible to damage when passing through the nuclear core.

When asked about the intended recipients of this drug and the need to consider behavioral science in its deployment, Dr. Sundquist commented that although he is not an expert in these areas, clinical trials conducted in high-risk populations showed that participants were adherent, and Gilead continues to work on developing a longer timeline. He pointed out that cost-benefit

analyses would be needed, but populations with high infection rates will benefit from this innovation.

Dr. Jonathan Mermin commented that this innovation shows the importance of basic science but noted that a significant amount of basic science does not result in meaningful effects on health. Dr. Sundquist cautioned against micromanagement of basic science given the unpredictability of important discoveries, but he supported emphasizing quality and funding researchers who can articulate the importance of their problem. Dr. Carl Dieffenbach recognized the importance of competition for scientific development and recommended that NIH engage industry in such efforts. Dr. Finzi added that although basic science is expensive, NIH has a unique ability to support this type of work. Dr. Sundquist noted that NIH encourages basic science researchers to consider translation, which is critical.

Dr. Luis Montaner asked for suggestions of new types of academic–industry partnerships. Dr. Sundquist suggested incentivizing the younger generation of researchers who start their own companies, often related to their research discoveries. Dr. Dieffenbach added that Dr. Sundquist's work shows the importance of tool development, which is related to the U54 Specialized Center—Cooperative Agreements program.

Task Force Report-Outs: NIH Strategic Plan for HIV and HIV-Related Research

Geetanjali Bansal, M.Sc., Ph.D., Senior Science Advisor, OAR, NIH Luis Montaner, D.V.M., M.Sc., D.Phil., Chair, Basic Biomedical and Preclinical Research Task Force and Executive Vice President, The Wistar Institute Roy (Trip) Gulick, M.D., M.P.H., Chair, Clinical and Intervention Research Task Force and Rochelle Belfer Professor in Medicine and Chief, Division of Infectious Diseases, Weill Cornell Medicine

Omar Galárraga, Ph.D., Chair, Behavioral, Social, and Implementation Research Task Force and Professor, Health Services, Policy, and Practice, Brown University School of Public Health

Dr. Geetanjali Bansal introduced the three strategic plan task forces, which represented a broad diversity of expertise and experience. The strategic plan framework has three research goals and one capacity goal, each with a specific set of objectives. The task forces were charged with developing key funding priorities for the next five fiscal years for each of the objectives under these goals. Each task force worked on a set of objectives with a primary focus on the objectives that aligned with their expertise. All task forces identified funding priorities for objectives related to community-engaged research and capacity building. Task forces were asked to consider the strategic plan's guiding principles—equity, inclusion, community engagement, and potential for greatest public health impact—and the appropriate balance of breadth and specificity.

Drs. Luis Montaner, Roy Gulick, and Omar Galárraga acknowledged task force members and thanked them for their time and commitment. They presented the draft recommendations for funding priorities under each of the following goals and objectives:

Goal 1: Enhance discovery and advance HIV science through fundamental research.

- Objective 1.1: Advance Understanding of HIV biology, virology, immunology, and pathogenesis
- Objective 1.2: Elucidate the pathogenesis of HIV-associated comorbidities, coinfections, and complications

- Objective 1.3: Investigate the epidemiologic aspects of HIV and associated co-infections, comorbidities, and complications
- Objective 1.4: Elucidate behavioral and social factors and processes

Goal 2: Advance the development and assessment of novel interventions for HIV prevention, treatment, comorbidities, and cure through preclinical, translational, and applied research pipelines.

- Objective 2.1: Support preclinical and translational research
- Objective 2.2: Advance clinical research, trials, and other intervention studies of HIV prevention, vaccine, treatment, comorbidities, and cure strategies
- Objective 2.3: Develop and evaluate innovative and integrated models of care and services for HIV prevention, treatment, care, cure, and HIV-associated complications, comorbidities, and coinfections

Goal 3: Optimize public health impact of HIV discoveries through implementation science and dissemination of research findings.

- Objective 3.1: Enhance implementation science
- Objective 3.2: Promote community-engaged and community-led HIV research
- Objective 3.3: Improve dissemination through communication research

Goal 4: Build research workforce and infrastructure capacity to enhance sustainability of HIV scientific discovery.

- Objective 4.1: Expand workforce capacity
- Objective 4.2: Strengthen research infrastructure and capacity
- Objective 4.3: Enhance methods and technologies

Discussion Highlights

Dr. Donenberg asked about creating a process to prioritize these recommendations into more defined areas. Dr. Montaner clarified that the charge for the task forces was to enumerate four to six priorities within each objective, and they were specifically instructed not to rank them. The task forces focused on being inclusive of current efforts and adding components not yet emphasized. Dr. Galárraga added that prioritization requires "listening to the people closest to the pain." Dr. Dieffenbach commended the task forces for prioritizing community engagement and noted that prioritization often occurs at the institute level because of the funding responsibilities.

Dr. Neilan thanked the task force leadership for their hard work and suggested that the OAR portfolio analysis could be used to help identify how funding has mapped to previous strategic plans.

COL Julie Ake commended the team for developing a comprehensive list of topics, especially those related to addressing critical logistical bottlenecks (e.g., access to Good Manufacturing Practices). She also noted that the recommendations under Goal 3, and within Objective 3.2 in particular, very effectively indicate the importance of looking at resource-limited global settings.

Dr. Montaner commented that after the final recommendations are shared, it might be helpful for institutes to look at the priorities on community-engaged research and capacity building that were generated by each task force separately. Some differences and specific suggestions may not have emerged when the recommendations were coalesced for this presentation. Dr. Gulick

noted that the task forces tried to keep their recommendations broad to allow flexibility and innovation.

CAPT Glenshaw explained the next steps. The OARAC members have two weeks to submit any additional comments to the Chair, Dr. Turnbull. After that, the chairs of these task forces and Dr. Turnbull will compile a written report that will be shared with the OARAC for final comment before it is submitted to Dr. Donenberg as the recommendation of the OARAC.

Updates From the NIH Advisory Council Representatives

Update: AIDS Research Advisory Committee (ARAC)

Carl Dieffenbach, Ph.D., Director, Division of AIDS, NIAID, NIH

Dr. Dieffenbach provided an update on the most recent ARAC meeting, which focused on the upcoming renewal of the NIAID HIV/AIDS Clinical Trials Networks funding and adjustments to address changing priorities and establish a forward-looking agenda through 2034. Outreach is being conducted to gather input from partners and community members, and Dr. Dieffenbach stressed the importance of centering this effort on communities. Currently, NIH proposes to maintain the four existing leadership groups, and the proposed themes are innovation and collaboration. Dr. Dieffenbach noted that collaborations can help expand the strategic opportunities for implementation research. The networks were essential to research during the early stages of the COVID-19 pandemic, and Dr. Dieffenbach emphasized the importance of maintaining this enterprise in a way that will allow it to pivot quickly to address the next pandemic.

Dr. Dieffenbach commented that the overarching goal for prevention research is to develop tools and technologies that will reduce HIV incidence domestically and globally. He noted that control of the HIV pandemic cannot be achieved through lenacapavir alone, so a vaccine that is safe, effective, and durable remains the goal. Prevention of comorbidities also is critical. Dr. Dieffenbach noted the need to create equity, optimize pediatric antiretroviral therapy, and work with partners to implement discoveries at scale, and he emphasized the importance of working across the lifespan and including people infected perinatally.

National Advisory Mental Health Council (NAMHC)

Marguerita Lightfoot, Ph.D., Associate Dean for Research, Oregon Health & Science University and Portland State University School of Public Health

Dr. Marguerita Lightfoot reported on staffing changes at NIMH and noted that the institute is celebrating of its 75th anniversary. Other key initiatives include placing a spotlight on maternal mental health and developing resources around the responsible use of AI. Dr. Lightfoot reported that in July, the House Appropriations Committee approved the fiscal year 2025 (FY25) Labor, Health and Human Services, Education, and Related Agencies (LHHS) Bill, and in August, the Senate Appropriations Committee approved the LHHS Bill with \$2.7 billion for NIMH, including an increase for mental health research and restoration of funding for innovation projects, including the *All of Us* Research Program, Cancer Moonshot, and Brain Research Through Advancing Innovative Neurotechnologies[®] (BRAIN) Initiative.

Dr. Lightfoot noted two HIV-related research studies highlighted at the last NAMHC meeting: one studying how HIV infection of the central nervous system (CNS) contributes to latency and

the other focused on mental health interventions for transgender and nonbinary adolescents, which will be relevant to the health of people with HIV. The meeting also noted one HIV-related concept clearance focused on treatment strategies for CNS complications in people with HIV and two featured funding mechanisms related to a research education mentoring program for HIV investigators and a study of the mechanisms of reciprocal interactions between HIV-associated neuroinflammation and CNS persistence.

National Advisory Council on Drug Abuse (NACDA)

Melanie Ott, M.D., Ph.D., Director, Senior Investigator, Gladstone Institute of Virology and Immunology, Professor of Medicine, University of California, San Francisco

Dr. Melanie Ott provided highlights from the most recent NACDA meeting. One highlighted paper notes the use of therapeutic interfering particles in prevention of HIV, and Dr. Ott commented that the major point of interaction is the capsid. The PURPOSE 4 study, specifically designed for people who inject drugs, is currently enrolling participants to test lenacapavir. Dr. Ott pointed out that the rate of overdose death in people with HIV is more than twice the rate in people without HIV. One study showed that most people with HIV who overdose are receiving care for their HIV, so HIV care centers may need to add overdose education components. Dr. Ott also noted a new network formed by the National Institute on Drug Abuse to address addiction in the criminal justice system; one specific goal is to build research and capacity to address the unique needs of individuals with HIV and substance use disorder as they transition between the criminal legal system and the community.

Update: HIV Clinical Guidelines Working Groups of OARAC

Prevention and Treatment of Opportunistic Infections in Adults

Shireesha Dhanireddy, M.D., M.P.H., Director, Madison Clinic; Director, Harborview Infectious Diseases & Travel Clinic; Co-Founder, S.H.E. (Safe.Health.Empowered) Clinic

Dr. Shireesha Dhanireddy shared updates to the <u>Guidelines for the Prevention and Treatment of</u> <u>Opportunistic Infections in Adults and Adolescents With HIV</u>. She noted 36 new members and 7 new subject group leads who have replaced retiring members in 2023–2024. The Centers for Disease Control and Prevention (CDC) has chosen not to appoint a co-chair; Dr. John Brooks, former CDC co-chair and recently retired CDC officer, will continue as an independent co-chair. Recent updates have been made to the Bacterial Enteric Infections, Candidiasis, Human Papillomavirus (HPV), Leishmaniasis, *Mycobacterium avium* Complex (MAC), *Mycobacterium tuberculosis, Pneumocystis* Pneumonia, and Toxoplasmosis sections, as well as the roster and Tables 1, 2, and 3. The MAC and HPV sections underwent major revisions; the *Pneumocystis* Pneumonia section and the Toxoplasmosis tables have been simplified. In response to data from the Anal Cancer High-Grade Squamous Intraepithelial Lesions Outcomes Research (ANCHOR) study, the HPV section was updated with the first guidelines for anal cancer screening in people with HIV. Updates to the Coccidioidomycosis, Community-Acquired Pneumonia, Cryptococcosis, and Histoplasmosis sections will be published soon.

Antiretroviral Agents in Adults and Adolescents with HIV

Roy (Trip) Gulick, M.D., Rochelle Belfer Professor in Medicine and Chief, Division of Infectious Diseases, Weill Cornell Medicine

Dr. Gulick presented on behalf of the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV. He noted that in February 2024, recommendations were published related to statin use in people with HIV as a primary prophylaxis for cardiovascular disease based on results from the Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE) study. A manuscript is being prepared and will be submitted to the Annals of Internal Medicine for publication. The Guidelines released updates in September 2024. A new section on antiretroviral therapy (ART) management for transplant candidates and recipients was added. In the What to Start section, dolutegravir (DTG)/abacavir (ABC)/lamivudine (3TC) has been changed from one of the recommended initial regimens to an alternative regimen; some regimens were removed from the list of initial ART regimens; and discussions on treating people with HIV who have a history of using integrase strand transfer inhibitors (INSTI) for prophylaxis were expanded. Several sections were updated to address long-acting cabotegravir/rilpivirine. Updates also were made to the sections on Adherence to the Continuum of Care, Cost Considerations and ART, Drug-Drug Interactions, Drug-Resistance Testing, Early (Acute and Recent) HIV Infection, Hepatitis B Virus/HIV Coinfection, HIV and the Older Person, Substance Use Disorders and HIV, Transgender People with HIV, Tuberculosis/HIV Coinfection, and Women with HIV sections, as well as the Drug Characteristics Tables. Future plans include adding a section on metabolic and cardiovascular complications in people with HIV and updating several sections that were discussed during the September 2024 Panel retreat.

Pediatric Opportunistic Infections Guidelines

Franklin Yates, M.D., M.A., Medical Officer, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH

Dr. Franklin Yates reported on updates to the <u>Guidelines for the Prevention and Treatment of</u> <u>Opportunistic Infections in Children With and Exposed to HIV</u>. He described recent efforts to restructure the revision process for Pediatric OI Guidelines. For example, the Panel has been expanded to allow formal pharmacological review of each section, and a new authorship guide has been developed to help maintain consistency among sections and across the other Guidelines. A new section on COVID-19 has been published, and updates to the sections on Bacterial Infections, Hepatitis B Virus, Hepatitis C Virus, HPV, and Preventing Vaccine-Preventable Diseases in Children and Adolescents with HIV Infection—as well as Appendices C and D and Tables 4 and 5—are expected before the end of the year.

Discussion Highlights

In response to a question about the lack of a CDC co-chair on the Adult OI Panel, Dr. Dhanireddy explained that CDC staff will continue serving as section review group members and provide any necessary expertise.

Public Comment CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, Acting Deputy Director, OAR, NIH

No public comments were received.

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Closing Remarks and Adjournment

Ivy Turnbull, D.L.P., Ed.M., M.A., OARAC Chair, Deputy Executive Director, AIDS Alliance for Women, Infants, Children, Youth, & Families

CAPT Glenshaw reminded members that the next meeting is scheduled for February 20, 2025. Dr. Donenberg thanked the attendees. Dr. Turnbull adjourned the meeting at 4:25 p.m. ET.

Certification

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

/s/ Ivy Turnbull

2/4/2025

Date

Ivy Turnbull, D.L.P., Ed.M., M.A. Chair, OARAC

/s/ Mary Glenshaw

CAPT Mary Glenshaw, Ph.D., M.P.H. Executive Secretary, OARAC 2/5/2025

Date