

National Institutes of Health

National Advisory Allergy and Infectious Diseases Council

Minutes of Meeting

September 25, 2025

The 211th meeting of the National Advisory Allergy and Infectious Diseases Council (NAAIDC) convened virtually at 10:30 a.m., on **Thursday, September 25, 2025**. Dr. Jeffery Taubenberger, Acting Director, National Institute of Allergy and Infectious Diseases (NIAID) presided as chair.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public from 10:35 a.m. to 11:45 a.m. and from 1:00 p.m. to 2:48 p.m. The meeting was closed to the public from 8:30 a.m. to 10:30 a.m. and from 11:45 a.m. to 12:00 noon for review and consideration of individual grant applications. Notice of the meeting was published in the *Federal Register*.

Meeting Attendees

Council Members Present:

Dr. Grace Aldrovandi
Ms. Emily Brown
Dr. Mary Estes
Dr. James Gern
Dr. Laurence Morel
Dr. Guy Palmer
Dr. Maria Pascual
Dr. R. Stokes Peebles
Ms. Seema Shah

***Ex Officio* Members Present:**

Dr. Charlesnika Evans
Dr. Terry Rauch
Dr. Jeffery Taubenberger

Council Members Absent:

None

***Ex Officio* Members Absent:**

Dr. Daniel Jernigan

NIAID Senior Staff Present:

Dr. John Beigel
Dr. Carl Dieffenbach
Dr. Kelly Poe
Dr. Daniel Rotrosen

I. Review of Grant Applications

The National Advisory Allergy and Infectious Diseases Council convened in closed session to consider applications in allergy and immunology, microbiology and infectious diseases, and AIDS.

Funding Actions: The Council reviewed 4,429 research and training applications with primary assignment to NIAID for a requested amount of \$1,431,995,146 in first-year direct costs and recommended approval of 2,134 applications with \$780,598,625 in first-year direct costs.

II. Remarks of the Acting Director, NIAID—Jeffery Taubenberger, M.D., Ph.D.

Dr. Taubenberger opened the Council session by welcoming everyone and thanking all the Council members for participating in the meeting. Council members introduced themselves and noted their institution or organization affiliation.

Dr. Taubenberger acknowledged the contributions of five retiring Council members—Ms. Emily Brown, Founder and CEO of Free From Market; Dr. Mary K. Estes, the Cullen Foundation Endowed Chair of Molecular and Human Virology and distinguished service professor in the Department of Molecular Virology and Microbiology and the Department of Medicine at Baylor College of Medicine; Dr. James E. Gern, Professor of Pediatrics and Medicine at the University of Wisconsin School of Medicine and Public Health in Madison and Vice Chair for Research in the Department of Pediatrics; Dr. Laurence Morel, Professor and Chair of the Department of Microbiology, Immunology, and Molecular Genetics at the University of Texas Health Center San Antonio; and Dr. Guy Palmer, Regents Professor of Pathology and Infectious Diseases and the Jan and Jack Creighton Endowed Chair at Washington State University.

Consideration of Minutes of Previous Meeting

Council considered the minutes of the June 2, 2025, meeting and concepts that had been presented and approved them as written.

Staff and Organizational Changes

Dr. Taubenberger presented the recent NIAID staff and organizational changes since the last Council meeting, including the following:

Michael Allen recently joined NIAID as Chief Operating Officer.

Dr. Jill Harper, NIAID Deputy Director for Science Management, is detailed to the National Institute of Neurological Disorders and Stroke, serving as the Acting Deputy Director for Scientific Management and Operations.

Chris Hanson is NIAID's Acting Deputy Director for Science Management. He previously served as the Associate Director for Scientific and Business Operations in the Division of Intramural Research (DIR).

Dr. Veronique Nussenblatt is the new Acting Clinical Director in NIAID. She was serving as Chief of the Infectious Disease Consult Service; Associate Program Director of Infectious Disease Fellowship; and Director of the NIH Residency Electives Program (REP) and Clinical Electives Program (CEP) for Medical Students.

Dr. Dean Follmann has been named Acting Director of the Division of Clinical Research (DCR). He had been serving as Chief of the Biostatistics Research Branch in DCR.

Dr. Heinz Feldmann is the Acting Director of the Integrated Research Facility (IRF) in Frederick, Maryland. Since 2008, he has served as the Chief of the Laboratory of Virology and Chief Scientist of the BSL-4 Laboratories at the Rocky Mountain Laboratories in Montana. Dr. Andrea Marzi is now Acting Chief of the Laboratory of Virology in DIR.

In the Division of Extramural Activities, Shaun Gratton is the Acting Program Director and Chief Grants Management Officer of the Grants Management Program, and Dr. Priti Mehrotra is serving as Acting Director of the Office of Research Training and Special Programs.

In the Division of AIDS, Dr. Maria Fatima Jones has been named Acting Deputy Director of the Therapeutics Research Program, Dr. Dwight Yin is serving as Acting Branch Chief of the Epidemiology Branch in the Basic Sciences Program, Yancy Bodenstein is Acting Branch Chief of the Clinical Research Resources Branch, and Janet O'Brien has been named the Acting Branch Chief for the Protection of Participants, Evaluation and Policy Branch.

Budget Update

Dr. Taubenberger began with a brief overview of the fiscal year (FY) 2026 budget process. On May 30, 2025, the FY 2026 HHS Budget in Brief was released. The Senate budget markup was approved on July 31, 2025, and the House markup was approved on September 9, 2025.

In September, the House passed two separate continuing resolution (CR) proposals. In the Senate, 60 votes are needed to pass the CR. Neither proposal had sufficient support to pass the CR. Congressional action on a CR is still needed.

The President's FY 2026 budget request for NIAID was \$4.2 billion, which reflects a 36.4 percent decrease from the FY 2025 enacted budget. The House and Senate markups each include approximately \$6.6 billion for NIAID.

For the proposed overall FY 2026 NIH budget, the Senate markup includes an increase of 0.90 percent, and the House markup includes a 0.92 percent decrease from the FY 2025 enacted level.

NIH Policy Changes

Dr. Taubenberger presented several NIH policy changes that are in the process of being implemented.

NIH has developed a centralized website to document changes in funding policies and processes as NIH aligns with new agency priorities—[NIH Grants and Funding Information Status](#). The webpage is updated as new information becomes available.

NIH is no longer issuing awards that include a subaward to a foreign entity. A new collaborative award structure is being developed to support foreign subawards. NIH remains committed to supporting international scientific collaborations as long as they are conducted in a secure, justifiable, and responsible way. While the new award structure is in development, NIH developed short-term solutions to ensure patient safety for ongoing active clinical projects involving foreign subawards. NIH recently announced plans for a new notice of funding opportunity (NOFO) using a new activity code, PF5, which will support new projects with foreign subawards. In the new award structure, foreign subawards will be structured as subprojects directly linked to the prime award.

NIH NOFOs will no longer exclusively focus on animal models of human disease. New NOFOs will be designed more broadly and to include nonanimal research models in addition to traditional animal models. NIH will continue to support projects that use animal models if scientifically appropriate and justifiable, and with appropriate animal welfare oversight.

NIH will not consider applications that are substantially developed by AI or contain sections substantially developed by AI to be original ideas of applicants. Moving forward, NIH will limit the number of competing applications from an individual principal investigator (PI) or multi-PI collaboration to six for all Council rounds in a calendar year. This new policy is effective for applications submitted on or after the September 25, 2025, receipt date. The application limit will be reset for applications scheduled to be reviewed for the January 2027 Council round.

On August 7, 2025, the President issued an Executive Order (EO) – Improving Oversight of Federal Grantmaking. NIH plans to use this as an opportunity to streamline and simplify the process of applying for NIH funding. Major goals are to empower investigator-driven projects, reduce overly narrow NOFOs, and increase efficiency by reducing administrative burden. As a part of this effort, NIH intends to reduce the number of institute and center (IC)-issued NOFOs and expand the number of NIH-wide parent announcements. Non-parent NOFOs will be used only when required to move a particular area of science forward or when there are requirements that are not able to be addressed by available parent announcements.

NIH has also recently introduced the new concept of [Highlighted Topics](#), a centralized list of research priority areas supported by one or more NIH ICs. Highlighted Topics will inform the research community about a specific NIH area of scientific interest that may include new or emerging areas of interest and will encourage investigator-initiated applications in the topic area.

Congressional Briefings and International Collaborations

On July 14, 2025, NIAID and the Biomedical Advanced Research and Development Authority (BARDA) participated in a briefing for congressional staff to Senator John Kennedy of Louisiana on bacteriophage therapy and antimicrobial resistance.

On August 6, 2025, Senate Appropriations Committee staff met with researchers at the Vaccine Research Center. Dr. Sara Andrews highlighted her ongoing research on influenza H5-specific antibodies as potential therapeutic agents. Dr. Eli Boritz presented his studies using FIND-seq, a microfluidics-based technology to isolate rare cells harboring HIV in people on antiretroviral therapy with the goal of elimination or suppressing these cells to prevent HIV persistence.

On September 2, 2025, Dr. John Beigel, DMID; Dr. Joe Breen, DAIT; and staff from NIAID's Office of the Director briefed Senator Roger Marshall (Kansas) on the RECOVER–Treating Long COVID initiative.

Dr. Taubenberger highlighted two recent international activities. NIAID and the Saudi NIH signed a memorandum of understanding on May 13, 2025, to establish a biomedical collaboration between our institutions. On July 17, 2025, a delegation from the French Nuclear Safety and Radiation Protection Authority met with NIAID leadership. The visit focused on the Statement of Intent between NIAID and ASNR signed last year and explored future collaborations on nuclear safety and radiation.

On August 20, 2025, Dr. Taubenberger, Dr. Biegel, and Dr. John Powers briefed the HHS Secretary on NIAID extramural and intramural research programs targeting Lyme disease and Post-Treatment Lyme

Disease Syndrome. Other HHS agencies and offices including CDC, FDA, ARPA-H, and the Office of the Surgeon General participated in this briefing.

NIAID and the Foundation for the National Institutes of Health convened the second annual RECOVER-Treating Long COVID (TLC) Workshop on September 9 and 10, 2025. The Workshop was designed to share with the community the significant progress made since RECOVER-TLC was launched exactly 1 year ago and solicit feedback from the community on key aspects essential for successfully identifying safe and effective treatments for Long COVID.

Scientific Highlights and Advances

Dr. Taubenberger gave updates on some scientific highlights and advances resulting from NIAID-sponsored intramural and extramural research.

He began by noting several influenza projects, including how nasal and systemic immune responses predict influenza viral shedding in people with complex immunity and how early influenza virus exposure shapes the B cell response to influenza vaccination decades later.

Dr. Taubenberger presented two studies, one that showed human monoclonal antibodies targeting the A35 protein protect from death caused by Mpox and a second showing promising research on a broadly protective human antibody for G1 genogroup noroviruses.

He then highlighted an important HIV clinical study that led to Lenacapavir being the first and only FDA-approved HIV-prevention option offering 6 months of protection. Much of the critical work for this was possible because of a significant investment from NIAID.

In a recent study, 60 participants completing 24 weeks of omalizumab (anti-IgE monoclonal antibody) treatment were introduced to dietary food allergens. Eighty-two percent of participants were able to consume small amounts of their food allergens in store-bought foods and safely continue eating them through a 12-month observation period. Omalizumab treatment could allow safe dietary options for people with multiple food allergies.

Dr. Taubenberger provided research updates on a novel antimicrobial peptide that is broadly active against multiple Gram-positive bacteria, a DMID-funded project through CARB-X that funds Pearl Diagnostics to develop assays to detect bacterial pneumonia in urine samples, and a phase 4 comparative trial of benzathine penicillin-G for the treatment of early syphilis in subjects with or without HIV infection.

He concluded by announcing that NIAID had awarded the Center of Excellence for Systems Modeling of Infection and Immunity Across Biological Scales to Duke University, which establishes the Multiscale Immune Systems Modeling Center of Excellence. The Center's two primary goals are to advance multi-scale computational models of allergic, immunologic, and infectious diseases, and coordinate modeling research across NIAID-funded projects and the broader computational modeling community. This collaborative initiative will support research across NIAID mission areas through sophisticated, computational multi-scale models.

III. Guest Speaker—Jayanta Bhattacharya, M.D., Ph.D., Director, NIH

NIH Director Dr. Jayanta Bhattacharya began by laying out a new vision for NIAID in his pre-recorded presentation.

Two core aims for NIAID now and moving forward will be to address current infectious disease threats and to support innovative research in allergy and immunology.

Dr. Bhattacharya presented his four priorities for Strategic Aim 1: Infectious Disease.

1. End the HIV epidemic in the United States by 2030.
2. Improve outcomes for influenza, bacterial infections, and other pathogens that impact Americans.
3. Address antimicrobial resistance.
4. End dangerous Gain-of-Function (dGOF) research and improve biosafety regulations in the United States.

Next, he summarized priorities for Strategic Aim 2: Allergy and Immunology. NIAID will continue to support research in basic immunology and develop new prevention and treatment strategies for autoimmune and allergic diseases by conducting research on long-term immunologic and inflammatory consequences of acute infections and vaccine injury, investigating infection links to chronic disease, and advancing microbiome science for immune health.

Dr. Bhattacharya then gave details about NIH's strategy for accomplishing ending the HIV epidemic in the United States, along with some of the challenges that remain.

He provided his vision for NIH, which focuses on five priorities: 1) improving population health; 2) ensuring reproducible science; 3) spurring innovation and breakthrough science; 4) maintaining safety and transparency; and 5) ensuring academic freedom.

In conjunction with his vision for NIH, he highlighted four topics related to the priorities:

1. Novel alternative methods—asks researchers to only use animal models that are known to create knowledge that translates over to human health and to consider other non-animal model methods that are better at translating over to human health.
2. Gold standard science plan—raises the bar for research excellence. Gold standard science is reproducible; transparent; communicative of error and uncertainty; collaborative and interdisciplinary; skeptical of its findings and assumptions; structured for falsifiability of hypotheses; subject to unbiased peer review; accepting of negative results as positive outcomes; and without conflicts of interest.
3. Support for early-career investigators—so new ideas continue to flow into biomedicine.
4. A unified strategy to fund projects—ICs will still consider scientific scores when making funding decisions, but they will also consider other critical factors such as whether the proposal aligns with the IC's mission and strategic priorities; how the proposal contributes to the balance within the IC's overall research portfolio; and the investigator's career stage and sustainability of the biomedical research workforce.

Dr. Bhattacharya concluded by thanking the Council members for their time, work, advice, and contributions to NIH.

IV. Report of the Allergy, Immunology, and Transplantation Subcommittee—Daniel Rotrosen, M.D., Director, DAIT

Dr. Rotrosen welcomed the subcommittee members to the 211th meeting of the National Advisory Allergy and Infectious Diseases Subcommittee meeting.

Dr. Rotrosen presented the following scientific and Division activities:

FY 2027 Research Concept Clearances Presented to Division Advisory Council

The subcommittee endorsed and unanimously approved the following two Research Concept Clearances:

Autoimmune Diseases Statistical and Clinical Coordinating Center (AD-SCCC) (U01, Clinical Trial Not Allowed). This initiative will provide clinical study development, regulatory support, management, site monitoring, repository management, manuscript production, study archiving, and biostatistical support for ongoing and future clinical trials in autoimmune diseases, mucosal immunology, and inborn errors of immunity, while maintaining and supporting all relevant regulatory requirements.

Atopic Dermatitis Research Network (ADRN) (U19, Clinical Trial Optional). This initiative will integrate clinical and translational research to improve our understanding of skin immunology and defense mechanisms by focusing on differences in skin immune responses and structure/function between patients with AD and healthy individuals or controls with other conditions.

V. Report of the Microbiology and Infectious Diseases Subcommittee—John Beigel, M.D., Acting Director, DMID

Director's Report

Dr. John Beigel, Acting Director of the Division of Microbiology and Infectious Diseases (DMID), co-chaired the proceedings of the combined meeting of the Allergy, Immunology, and Transplantation Subcommittee and Microbiology and Infectious Diseases Subcommittee on September 25, 2025. He provided DMID leadership updates, noting that Seema Nayak is the Acting Associate Director for Clinical Research; Joy Beeler is the Acting Director of the Office of Clinical Research Affairs; Sam Perdue is the Acting Chief of the Bacteriology and Mycology Branch; and Kaitlyn Morabito is the Acting Chief of the Virology Branch. He also noted that Jason Caballero has joined the Office of Clinical Research Affairs.

Following staff introductions, Dr. Beigel provided a report on recent activities of note:

- **Two-Dose Therapy for Bacteremia:** A DMID-sponsored clinical trial led by the NIAID-supported Antibacterial Resistance Leadership Group (ARLG) provided the clearest evidence to date for the safety and effectiveness of dalbavancin therapy for complicated *Staphylococcus aureus* bloodstream infections.
- **A Vaccine for Shigella:** Results of an NIAID-sponsored Phase 2 clinical trial showed that the live attenuated oral *Shigella sonnei* vaccine WRSs2 was effective against shigellosis.
- **Advancement of Zoliflodacin:** NIAID has contributed financial and scientific support for the development of Zoliflodacin over many years. This treatment may offer an alternative to current therapy for uncomplicated urogenital gonococcal infection. Since the Subcommittee meeting, Zoliflodacin, under the brand name Nuzolvence, received FDA approval.
- **NIH Trial of Lassa Virus Vaccine:** Enrollment began in March 2025 for a NIAID-sponsored Phase 1 trial evaluating the investigational Lassa vaccine LASSARAB.
- **RECOVER-TLC Workshop:** On September 9 and 10, 2025, NIAID and FNIH co-sponsored a workshop called “Pathways to Treatments, the Second Annual RECOVER-TLC Workshop.” This meeting included researchers, persons with Long COVID, healthcare providers, and others in the Long COVID community. The speakers, including multiple DMID staff, provided updates on the

progress of the RECOVER-TLC initiative, discussed the four treatments that will be tested, and solicited feedback from the community.

FY 2027 DMID Concepts Presented for Clearance

The following concepts were presented to the Council members:

- **Infectious Diseases Clinical Trials Network** - This concept proposes the establishment of a clinical trial network to support the evaluation of therapeutics, vaccines, biologics, diagnostics, and devices targeting infectious diseases, including emerging and chronic infections. The proposed networks would give NIH the capability to rapidly conduct clinical trials and studies addressing public health priorities and the needs of the U.S. population. One Council member voiced strong support for the concept, noting that the related programs this concept will build upon (the Infectious Diseases Clinical Research Consortium and the Vaccine and Treatment Evaluation Units) are successful and together provide an important clinical trials network. Another Council member asked if there would be international sites given the higher incidence of certain infections outside the U.S., noting that such sites will allow for quicker and more statistically robust evaluation. Program staff stated that while the network would consist only of domestic sites, DMID would, based on the needs of the trials and for the best advancement in public health, plan to move forward with international sites in alignment with an NIH framework established for the conduct of international research activities.
- **Clinical Research Network on Antimicrobial Resistance** – This concept aims to renew support for a network to address critical antimicrobial resistance (AMR) clinical research questions. The program will encompass several key components including scientific leadership; operations support; laboratory support; and statistics and data management support. The scientific leadership center will oversee the network’s overarching research agenda on AMR and implement a mentoring program to cultivate the next generation of clinical researchers specializing in AMR. One Council member expressed support for the inclusion of phage studies. Another member noted the need for an increased emphasis on superiority trials designed to prove that new treatments are more effective than the current standards of care.
- **Tuberculosis Research Advancement Centers (TRACs)** – The objective of this concept is to develop the next generation of tuberculosis (TB) researchers. Specifically, this renewal would support a program that provides administrative and shared research support to foster multidisciplinary TB research and provide exceptional mentorship to new investigators. TRACs will provide core facilities, services and mentoring opportunities to achieve the goals of the program. Council members are supportive of this effort and the concept to renew it.
- **Coccidioidomycosis Collaborative Research Centers** – This concept proposes to renew support for collaborative research centers to conduct multi-disciplinary research with clear relevance to the priorities defined in the *NIAID Strategic Plan for Research to Develop a Valley Fever Vaccine*, which encompasses three major research areas: 1) address gaps in *Coccidioides* basic research to support the development of a vaccine; 2) develop tools and resources to support vaccine development; and 3) develop and advance vaccines to prevent coccidioidomycosis. The multidisciplinary centers can leverage unique research resources and patient populations from endemic regions to advance the field. One Council member asked if applications to the program, which will utilize the P01 mechanism, would be reviewed with other P01 applications. Program staff stated that the review process is uncertain at this time given the transition of all grant application reviews to the NIH Center for Scientific Review.

- **Accelerating Research and Development of Next Generation Vaccines Against Malaria – A Model for Mosquito-Borne Diseases** – The goal of this concept is to stimulate basic research, discovery, and/or preclinical development activities to enable and accelerate the generation of highly efficacious malaria vaccines against two major human parasites, *Plasmodium falciparum* and *P. vivax*, as well as potentially other mosquito-borne illness, by encouraging cross-fertilization and collaborations across different scientific disciplines and/or with vaccine developers or product development partners. The initiative will specifically seek product candidates or concepts targeting pre-erythrocytic, blood, and/or sexual stages of *Plasmodium* parasites, as well as mosquito vector products to create a highly efficacious and effective vaccine to prevent infection, reduce disease burden, and/or block transmission of malaria and/or other mosquito-borne diseases. Council members expressed support for this concept.
- **Development of Medical Countermeasures for Biodefense and Emerging Infectious Diseases** – This concept proposes continuation of an ongoing program that supports the preclinical and early clinical development of candidate vaccines, therapeutics, diagnostics and platform technologies for a broad array of infectious disease pathogens. Contract mechanisms will be used to support vaccine and therapeutic development through candidate testing, manufacture, preclinical or nonclinical toxicology testing, and early clinical studies which may include Phase 1 and/or Phase 2 clinical trials. Diagnostics development can be most critically supported in the planning, design, development, and verification phases of product development. This program reduces risk and enables candidate medical countermeasures to transition to other funding to support advanced clinical development (Phase 2b and beyond), large-scale manufacturing, and regulatory approval. Council voiced strong support for the program and noted its value in advancing new products.
- **FYI Only: Centers for Structural Biology of HIV and Other Infectious Diseases** – This concept proposes a new joint effort between DMID and the Division of AIDS (DAIDS) to support multidisciplinary consortia of structural biologists, microbiologists, and associated experts to solve complex biological structures related to infections and host responses to HIV and other infectious diseases. Currently, DMID and DAIDS support separate structural biology programs; this concept would merge the two programs. Program staff in DAIDS will present the concept to the AIDS Research Advisory Committee for approval (it was subsequently approved). This presentation allowed DMID staff to inform the infectious diseases research community of the proposed plan.

All DMID concepts were unanimously approved.

VI. Joint Meeting of the AIDS Subcommittee and AIDS Research Advisory Committee (ARAC)– Carl Dieffenbach, Ph.D., Director, DAIDS

Welcome and Approval of Minutes

Kelly Gebo, M.D. (ARAC Chairperson)

Dr. Gebo welcomed everyone to the hybrid meeting. Dr. Abrams called for the Committee vote on approval of the minutes of the September 9, 2024, ARAC meeting. The minutes were approved.

Director's Report

Carl Dieffenbach, Ph.D., Director, Division of AIDS (DAIDS)

Dr. Dieffenbach started with a reflection of Dr. Baltimore's impact on HIV, cancer and gene therapy research, as well as being a driving force at premier academic institutions. Dr. Baltimore died of multiple cancers at his home in Bar Harbor, Maine on September 6, 2025.

Budget Update

The President's budget for FY 2026 was released on May 30, 2025. The Senate version was approved on July 31, 2025, and the House released their version on September 2, 2025. The President's budget has a cut of \$4.2 billion for NIAID, a 36 percent cut, while the House and Senate versions are both at \$6.6 Billion.

Notice of Funding Opportunities Reforms

Dr. Dieffenbach provided an update on the OMB FY 2025 requirement for NIH to use 50 percent of its remaining competing RPG funds to provide multi-year funding in full at the start of the project from a single fiscal year appropriation, not the subsequent budget years. NIH anticipates supporting fewer awards and lower success rates.

Dr. Dieffenbach also provided updates on NOT-OD-25-104, Updated NIH Policy on Foreign Subawards; NOT-OD-25-130, Updated Implementation Guidance of NIH Policy on Foreign Subawards for Active Projects; NOT OD-25-132, Supporting Fairness and Originality in NIH Research Applications; and [NIH to prioritize human-based research technologies](#).

DAIDS FY 2027 Concepts Presented – ARAC Approval Requested

Six proposed FY 2027 research grant and contract concepts were presented by DAIDS program staff for ARAC approval. The concepts are briefly described below.

Implementation Science to Advance HIV Prevention, Treatment, and Care

Rebecca Mandt, Ph.D., DAIDS, Basic Sciences Program

The objective of this FY 2027 initiative is to use implementation science to advance the goal of ending the HIV epidemic. Achieving this goal will require novel, locally tailored solutions, as well as the systematic development of generalized knowledge and scale-up of effective interventions. Projects will leverage multidisciplinary expertise and research-community partnerships to bring evidence-based advances in HIV diagnosis, treatment, prevention, and cluster and outbreak response to communities disproportionately impacted by HIV. Priority areas include:

- Develop, test, and evaluate novel multi-level strategies that engage a breadth of relevant stakeholders within a community.
- Assess implementation of interventions for HIV across multiple geographic locations or settings, using shared frameworks and measures to better understand what works where and why.

To inform strategies and/or evaluate the impact of interventions, researchers are strongly encouraged to engage with people with lived experience, and to leverage multidisciplinary innovations across fields such as data science, modeling, epidemiology, public health, nursing, medicine, and implementation science.

This initiative will support proposals that seek to improve the delivery of health care and services for HIV in geographic areas disproportionately affected by the epidemic. Research should incorporate implementation science principles, theories, models, or frameworks. Studies should take a multidisciplinary approach to understanding the context of implementation setting(s), and develop and

evaluate implementation strategies. Investigators would be particularly encouraged to include cost-related outcomes (e.g., resources expended, program costs, cost-effectiveness). Studies should be designed in close collaboration with implementing partners such as local governmental departments, community-based organizations, clinics, and social service agencies. We anticipate these proposals to be large-scale studies that build on the existing base of work in implementation science, epidemiology, and related fields. Clinical research studies are allowed, and clinical trials are optional; however, drug or device safety trials with registrational requirements to the FDA will not be supported. Clinical trials investigating the optimal implementation of FDA-approved drugs at the clinic and/or system level would be appropriate.

Ballot Voting Outcome

The Implementation Science to Advance HIV Prevention, Treatment, and Care concept was unanimously approved by the voting members of the Committee.

Centers for AIDS Research

Eric Refsland, Ph.D., DAIDS, Basic Sciences Program

The objective of the CFAR program is to foster high-quality HIV/AIDS research by establishing shared resources and services to increase collaborations and multidisciplinary research within an institution and between institutions, and by facilitating translation of basic research findings into vaccine, therapeutic, prevention and HIV cure strategies in a synergistic and cost-effective manner. Another goal of the CFARs is to mentor and support the next generation of HIV researchers.

The CFAR program enables the establishment of shared core facilities to support HIV/AIDS research at institutions with at least \$10 million in annual NIH-funded HIV research. All CFARs must include an Administrative Core and a Developmental Core and at least one Clinical Core, one Advanced Technology Core, and one Implementation Science Core. At least one Scientific Working Group (SWG) is also required. An SWG is defined as a group of investigators (HIV or non-HIV) who share a common interest in a specific area of scientific focus that is critical to addressing the HIV epidemic but is a gap or underdeveloped at the CFAR institution(s). The goal of an SWG is to promote multidisciplinary collaborations. The Developmental Core provides research support to early career investigators and investigators new to HIV/AIDS research. This includes pilot studies, evolving research opportunities, and high-risk/high-impact collaborative studies. CFARs will also have the option to include a Special Programs component, designed to foster the development of innovative programs to end the HIV epidemic, as well as larger mentoring and training programs to meet the needs of broader populations. Support for animal and clinical research is allowed. Clinical trials are not allowed.

Ballot Voting Outcome

The CFAR concept was unanimously approved by the voting members of the Committee.

Centers for Structural Biology of HIV and Other Infectious Diseases

Karl Salzwedel, Ph.D., DAIDS, Basic Sciences Program

The Centers for Structural Biology of Infectious Diseases will be engaged in cutting-edge structural biology research that informs key aspects of pathogen biology and host responses relevant to NIAID priorities of prevention, diagnosis, treatment, and cure of infectious diseases. The overall objective of the initiative is to attract the best scientists in diverse disciplines to develop and improve technologies that address questions related to the structural biology of HIV and other pathogen/host cell interactions across a broad range of spatial and temporal scales. The Centers are expected to facilitate new collaborations,

offer services and resources to the research community, leverage resources across the entire program, and train the next generation of scientists engaged in structural and computational biology of infectious diseases.

The initiative will support dynamic, multidisciplinary consortia of microbiologists, virologists, immunologists, structural biologists and computational scientists to drive the pace of discovery, leverage common resources, offer services and resources to the scientific research community, facilitate new collaborations, and engage and train researchers in structural biology of infectious pathogens.

- Centers will support research on all aspects of structural biology related to HIV and other human pathogens ranging from viruses to bacteria, to fungi, to other eukaryotic pathogens, including the structural, dynamic and functional interplay of macromolecular complexes formed between components of the pathogen(s), host cell, immune system, and medical interventions.
- Centers should be built around four diverse scientific projects that apply innovative approaches to solve distinct scientific questions that address knowledge gaps of significance to one or more NIAID research priorities in diagnosis, prevention, treatment, or cure of infectious diseases.
 - Three projects should support HIV and/or priority HIV co-pathogen research; one project must address non-HIV-related pathogens.
 - Up to three scientific Cores should provide services and drive technological development in support of two or more of the projects.
 - A Developmental Core will support the training and mentoring of next-generation structural biologists. The Core will manage a Cooperative Development Awards program that invites proposals from across the infectious diseases research community to recruit new talent into the Center and/or address emerging research needs. The Core may also support small pilot projects and travel awards to support career development of junior members.
 - An Administrative Core will support daily operations, manage resources, facilitate communication and ensure timely progress toward Center goals.
- Centers should determine higher-order structures across a broad range of resolution scales, including subcellular, cellular and tissue organization, that add context to molecular structures and their function.
- Centers should push the limits of technological advances and leverage state-of-the-art approaches including artificial intelligence, molecular dynamics, and protein design technologies.
- Each Center must include the identification and validation of new molecular targets for discovery of therapeutics, immunologic or vaccine components, and/or curative strategies for infectious diseases.
- Collaborations with established NIAID programs, such as Centers for AIDS Research (CFAR), the Consortia for HIV/AIDS Vaccine Development and Immunology (CHAVDI), Martin Delaney Collaboratories for HIV Cure Research (MDC), CEIRR, CREID, CIVICs, ReVAMPP, CARBIRU, TBRU, and/or ICEMR, are encouraged to facilitate translational research.
- Centers may also collaborate with researchers at U.S. government sites, for example the NIAID Vaccine Research Center, U.S. military infectious diseases programs, DOE National Labs, the NCI HIV Dynamics and Replication Program, or any other investigator with the skills and interest to contribute to the goals of the Center.
- Demonstration of substantial institutional support for appropriate equipment and other physical resources available to the investigators is highly encouraged. The Center will participate in an annual, NIAID-sponsored scientific meeting for programmatic evaluation of the Centers program. NIAID will evaluate the Centers' continued impact on the field in technology development and high value research to help determine whether to reissue the notice of funding opportunity.

- Clinical trials are not allowed but clinical research using human blood and tissues is encouraged. Animal research using appropriate models is allowed.

Ballot Voting Outcome

The Centers for Structural Biology of HIV and Other Infectious Diseases concept was unanimously approved by the voting members of the Committee.

Patient Safety Monitoring in International Laboratories

Daniella Livnat, B.Sc., DAIDS, Therapeutics Research Program

This initiative is expected to provide a contractual resource that will continue to work with more than 150 mostly non-U.S. laboratories (Labs) in approximately 20 countries to provide a comprehensive and uniform approach to evaluate initial and on-going capability and readiness to carry out NIAID-funded and collaborative clinical trial protocols by 1) supporting and monitoring Good Clinical Laboratory Practices (GCLP); 2) supporting and monitoring the quality and reliability of protocol-specified laboratory test results; 3) providing Labs with various means of assistance, guidance, and training to improve the quality of laboratory operations; and 4) hosting and maintaining the existing electronic data management system. Options to increase level of effort, to support unanticipated increases in demand related to oversight of additional Labs, are also within the scope of the contract. This activity will continue to help achieve:

- Safety of trial subjects.
- Safety of those performing the testing.
- Quality of trial laboratory data and accountability to regulatory authorities (FDA, EMA) for investigational new drug/registrational studies.
- Increased recognition and appreciation of the fact that good laboratory practices lead to better general local laboratory operations and service.
- Cross-network/non-network harmonization in laboratory operations and oversight.

This initiative will:

- Help Labs achieve and maintain GCLP for organization and personnel, verification of reagent and instrument performance specifications, quality management, equipment maintenance and facilities, and personnel safety. These ensure quality and integrity of study data and accurate reconstruction of studies. This aim will be accomplished through guidance for the resolution of laboratory audit findings/GCLP deficiencies, review of a Lab's standard operating procedures (SOPs), implementation of corrective actions to avoid future deficiencies, and review of method verification and validations performed by participating Labs.
- Determine the ability of Labs to accurately and reliably perform all tests indicated in trial protocols (e.g., chemistry, hematology, pregnancy, HIV and TB diagnosis). This will be accomplished by:
 - Purchasing and arranging shipment of appropriate Proficiency Testing (PT) panels which include unknown (blinded) samples provided by an external source.
 - Monitoring and grading PT results.
 - Guiding Labs in the investigation of root causes to prevent future failures.
 - Assisting Labs to correct identified deficiencies.
- Provide guidance and training to Labs to achieve GCLP and test proficiency through email and phone communications, interactive web conferences, presentations at investigator meetings and regional training events, and visits of various durations to Labs as needed.

- Maintain a 508 and FISMA-compliant web-based information repository that includes password-protected Lab-specific documents such as records of resolution of each Lab's audit findings and performance in PT panels, as well as an open-access resource library that includes guidance documents and SOPs for various laboratory procedures. Examples of resource documents include a checklist and guidance for moving a Lab to a new location, and instructions for validating instruments. The contractor will provide each participating Lab with controlled access to its own documents and provide NIAID and Network lab managers with controlled access to all documents.
- Post GCLP audit reports (conducted by another resource) and Action Plans that capture audit observations and guidance for resolution; Lab-specific reports indicating the degree of performance for each round of PT; summary reports indicating to DAIDS and the Networks the proficiency status of all Labs; and trimester Progress Reports provided to DAIDS.

Ballot Voting Outcome

The pSMILE concept was unanimously approved by the voting members of the Committee.

Regional Prospective Observational Research in Tuberculosis

Nicole Espy, Ph.D., DAIDS, Therapeutics Research Program

The overarching objective of this initiative is to enable a network of U.S. and international scientists to advance tuberculosis (TB) science, particularly relevant to people living with HIV (PLWH). Specific objectives include 1) advance the current understanding of community, host, and microbial factors that impact outcomes of TB infection and disease, including subclinical TB and drug-resistant TB (DR-TB); 2) facilitate the development of tools to improve treatment outcomes at the individual and population level; and 3) inform strategies to curtail the TB epidemic at the public health level. To achieve this, this initiative will support Regional Prospective Observational Research in Tuberculosis (RePORT) networks that will leverage U.S. and international scientific collaborations and existing clinical research infrastructure to capacitate a wide range of research.

Description: This initiative will support the establishment of independent observational research networks in the United States and globally to address TB and TB/HIV research priorities and promote evidence-based strategies towards ending the TB/HIV epidemic. The outcomes of the projects conducted through these networks are expected to address domestic and global TB and TB/HIV biomedical and clinical research questions and inform the national TB control strategy in the U.S. and each respective country. Research projects supported through this initiative may include, but are not limited to, the following areas:

- Characterization of host and microbial factors and mechanisms that affect the risk, dynamics, pathophysiology, and transmission of TB and DR-TB in children and adults.
- Discovery, development, and/or validation of new biomarkers and diagnostics for active and subclinical TB, including those that predict progression to active TB, and treatment outcomes.
- Evaluation of the impact, pathogenesis, and clinical outcomes of associated TB comorbidities, including HIV and diabetes.
- Evaluation of interventions, such as TB vaccines, that impact the transmission, incidence, and prevalence of TB (including subclinical TB) and elucidation of mechanisms and markers of protection to support continued development and/or evaluation of these interventions.
- Conduct of pragmatic clinical trials of efficacious interventional strategies to collect real-world evidence or conduct of observational and implementation studies that bridge the knowledge-practice gap in TB diagnosis, treatment, and prevention.

The following areas will not be supported under this notice of funding opportunity:

- Collection of only epidemiological data.
- Establishment of de novo clinical cohorts (i.e., clinical research that does not build upon existing cohorts of active TB patients and their close contacts).
- Clinical trials that propose to evaluate the efficacy of an intervention (e.g., first-inhuman studies or drug/device safety trials).

Research supported through these networks is expected to leverage clinical data and specimens collected through existing cohorts of active TB participants and/or their close contacts. The successful applicant must leverage existing prospective observational cohorts and have access to clinical specimens and concomitant data collected at pre-defined time points for individuals being treated for active TB and TB/HIV, and/or close contacts of individuals with TB disease.

Applicants are strongly encouraged to include a multidisciplinary research team of investigators with access to existing resources (e.g., clinical research sites and laboratories, data management center, and specimen biorepository). Additional samples and clinical data may be collected if needed for the research proposed. The applicant is expected to implement the research protocol in accordance with established RePORT International standards, and in coordination with the RePORT International Coordination Center (RICC).

Ballot Voting Outcome

The RePORT concept was unanimously approved by the voting members of the Committee.

Clinical Research Products Management Center

Thucuma Sise, Pharm.D., BCPS, cGMP, R.Ph., DAIDS, Office of Clinical Site Oversight

This initiative is to provide continued operations of a Clinical Research Products Management Center (CRPMC) that adheres to current Good Manufacturing Practice (cGMP) and Good Clinical Practice (GCP) in support of the clinical trials networks of NIAID. In addition, this initiative will support the clinical site pharmacy oversight responsibilities. This initiative will have flexible options to provide clinical study products management in clinical trials of emerging or pandemic infectious diseases as the need may arise and Institute priority.

Description: This initiative will support the management of study products in support of NIAID-sponsored clinical trials. These activities will include but are not limited to the following:

- Receive shipments of study products (e.g., therapeutics, vaccines, biologics).
- Store and maintain study products under appropriate and secure conditions.
- Distribute study products to authorized clinical research sites both domestically and internationally.
- Recall and process study product returns, which may include:
 - Return of study product to the manufacturer.
 - Coordinating the destruction of unused study products as directed.
 - Verifying unused quantities and witnessing product destruction at international sites.
 - Maintain readily available, computerized electronic records of study product management activities.

- Maintain all applicable Trial Master File (TMF) documents related to study product management.
- In limited circumstances, provide for a mechanism for the procurement of commercially available products not available through donation.
- Provide support for site pharmacy oversight activities.
- Establish and maintain a quality program for all activities.
- Ensure that all activities are conducted in accordance with federal, local, and international regulations governing study product including but not limited to the CFR, ICH GCP, cGMP, Good Distribution Practices (GDP), Good Documentation Practices, and all applicable regulations or guidance.

Ballot Voting Outcome

The CRPMC concept was unanimously approved by the voting members of the Committee.

Ballot Voting Outcome:

All six of the concepts presented were unanimously approved by the voting members of the Committee.

VII. Adjournment

The meeting of the Council adjourned at 2:48 p.m., on Thursday, September 25, 2025.

We do hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

- S -
 Jeffery Taubenberger, M.D., Ph.D.
 Chair, National Advisory Allergy
 and Infectious Diseases Council
 Acting Director, National Institute of Allergy
 and Infectious Diseases

2/25/2026
 Date

- S -
 Kelly Poe, Ph.D.
 Executive Secretary
 National Advisory Allergy and Infectious
 Diseases Council
 Director, Division of Extramural Activities
 National Institute of Allergy and Infectious
 Diseases

2/22/2026
 Date

Council will formally consider these minutes at its next meeting; any corrections or notations will be incorporated in the minutes of that meeting.