

National Institutes of Health

National Advisory Allergy and Infectious Diseases Council

Minutes of Meeting

April 6, 2026

The 212th meeting of the National Advisory Allergy and Infectious Diseases Council (NAAIDC) convened virtually at 10:30 a.m. on **Monday, April 6, 2026**. 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 10:30 a.m. to 11:45 a.m. and from 1:00 p.m. to 3:32 p.m. The meeting was closed to the public from 8:30 a.m. to 10:30 a.m. 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
Dr. Mary Estes
Dr. James Gern
Dr. Laurence Morel
Dr. Guy Palmer
Dr. Maria Pascual
Dr. R. Stokes Peebles
Ms. Seema Shah

Chairperson Present:

Dr. Jeffery Taubenberger

Executive Secretary Present:

Dr. Kelly Poe

Council Members Absent:

Ms. Emily Brown

***Ex Officio* Members Absent:**

Dr. Terry Raush
Dr. Charlesnika Evans

NIAID Senior Staff Present:

Dr. Robert Eisinger
Dr. Steven Holland
Dr. Daniel Rotrosen
Dr. David Spiro

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 5,127 applications with primary and secondary assignment to NIAID for a requested amount of \$1,765,986,123 in first-year direct costs and recommended approval of 1,805 applications with \$736,121,361 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 introduced ad hoc Council member Louis Shackelford from the Fred Hutchinson Cancer Center, where he serves as Director of External Relations for the HIV Vaccine Trials Network, and Director for the Office of Engagement for the Fred Hutch Center for AIDS Research.

Consideration of Minutes of Previous Meeting and Council Operating Procedures

Council considered the minutes of the September 25, 2025 meeting and concepts that had been presented and approved them as written.

Dr. Taubenberger presented the 2026 calendar year Council Operating Procedures, which Council members had received through the Electronic Council Book. He called for a motion to approve the Council Operating Procedures. The Council Operating Procedures were approved.

Items of Interest

NIAID received written comments on the use of animal models in research. Dr. Gabby Vidaurre, with Science Advancement and Outreach, a Division of People for the Ethical Treatment of Animals, recommended prioritizing and supporting sepsis research and training that focus exclusively on non-animal models and ending the conduct and funding of sepsis research that uses animals. Drs. Jessica Kopew and Catharine Krebs, with the Physicians Committee for Responsible Medicine, recommended prioritizing human-based *in vitro* methods and other new approach methodologies to strengthen the infectious disease portfolio and reduce the reliance on animals in research. The full comments were provided to Council members in the Electronic Council Book.

Staff and Organizational Changes

Dr. Taubenberger presented NIH and NIAID staff changes that have occurred since the September 2025 Council meeting.

NIH Director Dr. Jay Bhattacharya is now serving as the Acting Director of the Centers for Disease Control and Prevention.

Dr. Elisabeth Armstrong was named as the new NIH Chief of Staff. She previously served as Director of the Office of the Executive Secretariat at FDA.

Dr. Richard Woychik is now the Senior Advisor for NIH's Make America Healthy Again Strategy.

Dr. Nicole Kleinstreuer was appointed NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives and will oversee NIH-wide programmatic research and strategic policy initiatives.

Dr. David Goff, Jr., is serving as the Acting Director for the National Heart, Lung, and Blood Institute.

Dr. Amy Bany Adams has been named Acting Director of the National Institute of Neurological Disorders and Stroke.

Dr. Anna Mazzucco is Acting Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Dr. Rohan Hazra was named Acting Director of the National Institute of Child Health and Human Development.

Dr. Robert Eisinger is the Acting Director of the Division of AIDS at NIAID.

In NIAID's Division of Microbiology and Infectious Diseases (DMID), Dr. David Spiro is serving as Acting Director. Other staff changes in DMID include Joy Beeler is Acting Director of the Office of Clinical Research Affairs; Dr. Kaitlyn Morabito is Acting Chief of the Virology Branch; Dr. Seema Nayak is Acting Associate Director for Clinical Research; and Dr. Sam Purdue is Acting Chief of the Bacteriology and Mycology Branch.

Dr. Sally Hunsberger was named Acting Director of the Office of Biostatistics Research in NIAID's Office of the Director.

Dr. Katherine Beck is NIAID's Acting Associate Director for Science Management.

In NIAID's Division of Extramural Activities, Shaun Gratton was selected as the Program Director and Chief Grants Management Officer in the Grants Management Program, and Dr. Priti Mehrotra is the new Director of the Office of Research Training and Special Programs.

Budget Update

Dr. Taubenberger began by noting that more information is expected in the coming days about the Administration's plans for the fiscal year (FY) 2027 President's Budget. However, the initial budget was released and proposes a \$5 billion reduction for the overall NIH budget, along with the elimination of some institutes and centers. Details on NIAID's budget are not available.

He proceeded to review important aspects of the FY 2026 enacted budget. The Consolidated Appropriations Act, 2026 was signed into law by the President on February 3, 2026. NIAID's FY 2026 enacted budget is \$6.6 billion. Dr. Taubenberger noted that the enacted budget includes a \$23

million increase in earmarks, with new earmarks for the Centers for Research in Emerging Infectious Diseases and the Antiviral Drug Discovery programs.

Dr. Taubenberger gave a brief overview of NIAID's funding history and compared the FY 2025 enacted budget with the FY 2026 enacted budget. For FY 2026, the overall increase for NIH is 1.02 percent, with NIAID receiving a .35 percent increase.

NIH Policy Updates

Dr. Taubenberger presented policy changes that have been made across NIH and summarized the impact they will have on how NIAID operates.

NIH introduced its Unified Funding Strategy to guide clear and consistent funding decisions across institutes, centers, and offices (ICOs). The overall goal is to ensure a more robust research portfolio by funding the most meritorious science, addressing health priorities and research gaps, and supporting a robust biomedical workforce. To successfully implement the Unified Funding Strategy, NIAID staff created system enhancements and automations that were successfully piloted for the October 2025 Council round and officially rolled out and used for the January 2026 Council round.

With the lapse in appropriations in the fall of 2025, over 370 peer review meetings were cancelled, which required NIH to make emergency modifications to peer review. Modifications included reducing the number of applications discussed, simplifying summary statements, and releasing summary statements late in the Council round.

NIH introduced Highlighted Topics or HTs, which are a way to communicate research priorities and reduce the need to publish complex funding opportunities. NIAID is the lead on three HTs and has signed on to nine that are led by other ICOs. NIH has also made finding funding opportunities easier by centralizing them into one portal on NIH's Grants & Funding website.

The PF5 is a new grant mechanism NIH developed to support international subawards that allows for effective management of the research while accelerating collaborations and discovery. Dr. Taubenberger presented a graphic that outlined the PF5 structure of an application as it moves through the submission/review/award lifecycle.

Dr. Taubenberger noted that NIH recently updated its Human Fetal Tissue Policy, which ends the use of human fetal tissue from elective abortions. He also mentioned that NIAID is pursuing complementary approaches to the use of animals in research and investing in developing New Approach Methodologies to reduce the use of animal models.

NIH is requesting input from the community on two draft resources on conducting research using implantable devices. Comments are accepted until May 25, 2026, on 1) Considerations in Planning for the Post-Trial Needs of Research Participants Who Receive an Investigational Implantable Device, and 2) Informed Consent for Research Using Investigational Implantable Devices: Points to Consider and Sample Language Resource.

Awards and Events

Dr. Taubenberger announced that Dr. Fred Ramsdell and his colleagues were awarded the 2025 Nobel Prize in Medicine or Physiology for their discoveries concerning peripheral immune tolerance. His interest in non-deletional mechanisms of peripheral tolerance can be traced back to his postdoctoral fellowship in NIAID with the T Cell Development Section headed by B.J. Fowlkes. He will return to NIAID to present the 2026 Kinyoun Lecture at the end of May.

Dr. Stephen Whitehead was recently honored by the Butantan Institute in Brazil for his contribution to the development of the Butantan-DV Dengue vaccine.

Dr. Taubenberger recognized Dr. Wilbert van Panhuis for leading and advocating for open data and scientific collaboration at NIAID. He shaped the current NIAID Emerging Leaders in Data Science Fellowship Program.

Dr. Taubenberger spoke at the Division of Intramural Research retreat in March. In February, he spoke at the Infectious Diseases Clinical Research Program Science Symposium and highlighted his work in influenza research.

Over the last several months, Dr. Taubenberger and members of NIAID's senior leadership team have hosted several town halls, which have provided opportunities to engage with staff and address questions about changes to policies and operating procedures at the Institute.

NIAID is currently updating its Strategic Plan, which is the first update since 2017. The Institute's vision focuses on improving human health through an integrated, person-centered approach to immune-mediated and infectious disease research. The NIAID Strategic Plan Framework centers around three main research priorities: 1) advancing foundational research in immunology, microbial biology, and host-microbe interactions; 2) applying that foundational knowledge to develop and evaluate diagnostic and prevention strategies; and 3) developing treatments and cures. The central focus on immunology ties all the priorities together.

Other Information Items

Dr. Taubenberger gave an update on Long COVID, noting how NIAID is moving forward with its research agenda. RECOVER-TLC's (Researching COVID to Enhance Recovery-Treating Long COVID) goal is to develop safe and effective therapeutic interventions for Long COVID.

Members of Congress continue to have an interest in Long COVID research. On February 26, 2026, Dr. Taubenberger and Dr. Joseph Breen from NIAID, along with representatives from the National Heart, Lung, and Blood Institute and National Institute of Neurological Disorders and Stroke, briefed Senator Kaine and provided an overview of RECOVER programs and RECOVER-TLC clinical trials. On March 5, 2026, Dr. Taubenberger, Dr. Breen, and Dr. John Powers briefed Senator Marshall on Long COVID research efforts.

RECOVER-TLC actively solicits ideas from the community for potential biologics and drugs. Using guiding principles, agents are chosen to advance into clinical trials. Four initial candidates have been selected for further evaluation.

Next, Dr. Taubenberger gave an update on Ending the HIV Epidemic in the United States. Dr. Eisinger, Acting Director of NIAID's Division of AIDS, and Dr. Geri Donenberg, Director, Office of

AIDS Research, noted in a perspective in the *Journal of Infectious Diseases* that as NIH-supported implementation science expands, there is a need for discoveries and novel approaches that build on current options and offer more choices to improve the lives of people affected by HIV. Dr. Taubenberger highlighted some recent publications related to cure research.

Dr. Taubenberger concluded by providing brief scientific highlights on improving clinical outcomes of xenotransplantation; Systems Biology of Early Atopy (SunBEAM) Birth Cohort, which studies how allergic diseases such as atopic dermatitis and food allergies begin early in life; an intranasal drug to prevent or treat influenza; a novel approach for broad protection of respiratory threats; promising results from a Phase 1 study of the NIAID Vaccine Research Center's Nipah vaccine candidate; a potential treatment for *Clostridioides Difficile* infection; and FDA approval of CONTEPO™ (IV fosfomycin) for complicated urinary tract infections.

III. Guest Speaker – Steven M. Holland, M.D., Director, Division of Intramural Research, NIAID

Dr. Holland began by sharing the Division of Intramural Research's (DIR's) priorities, which include producing transformative medicine and biomedical research; taking a bench-to-bedside approach that takes advantage of NIH's Clinical Center, as well as domestic and international clinical sites; responding to public health threats with a focus on drug-resistant microbes, emerging viruses, and creating needed vaccines; and partnering to advance vaccines, therapeutics, and diagnostics for infectious and immunologic diseases.

NIAID's intramural programs are in Bethesda, Maryland; at the Rocky Mountain Laboratories (RML) in Hamilton, Montana; at the Integrated Research Facility (IRF), a new laboratory in Frederick, Maryland; and international sites around the world. The IRF-Frederick was part of the Division of Clinical Research until recently. It's becoming an intramural laboratory and will expand our Biosafety Level 4 portfolio. Dr. Heinz Feldman relocated from RML and is Acting Director, IRF-Frederick.

Dr. Holland shared a snapshot of the number of principal investigators in DIR, which was broken down by tenured and tenure track. He paid tribute to two DIR investigators who died within the last year – Dr. Tom Kristie, senior investigator in the Laboratory of Viral Diseases, and Dr. Byron Caughey, Chief, TSE/Prion Biochemistry Section in the Laboratory of Neurological Infections and Immunity.

Dr. Holland outlined recent DIR staff changes that have occurred, including leadership changes, newly tenured investigators, tenure-track investigators, a new clinical tenure-track investigator, and selected assistant clinical investigators. He noted that DIR created a new pilot program with an internal recruitment structure called the NIAID Scholars Program. Intramural staff can become NIAID Scholars at different levels—basic, clinical, and later career. The Program was advertised to the intramural community, and applications are currently being reviewed.

Dr. Holland recognized Drs. Kyung J. Kwon-Chung, David Sacks, and Jose Ribeiro, who were elected to the National Academy of Sciences, and Dr. Niki Moutsopoulos, who was elected to the National Academy of Medicine. He also acknowledged Dr. Fred Ramsdell, an NIAID alumnus, who was awarded the 2025 Nobel Prize in Medicine or Physiology, who will deliver the Kinyoun Lecture on May 28, 2026.

At RML, a new animal facility (Building 34) is open, and several investigators have moved into the renovated E Wing of the NIH Clinical Center. Dr. Holland highlighted additional ongoing and upcoming DIR facility projects.

Dr. Holland gave an overview of DIR's activities for FY 2025, which included 1,294 publications and approximately 200 ongoing clinical studies.

Dr. Holland highlighted selected areas of DIR research including NIAID's Centralized Sequencing Program, influenza, human immune health, and an anti-sporozoite monoclonal antibody for malaria prevention. He also presented brief updates on a vaccine to block *Plasmodium falciparum* transmission, a single-dose tetravalent Butantan dengue vaccine, longitudinal proteomic profiling of cerebrospinal fluid in untreated multiple sclerosis, and the use of human brain organoids to isolate, transmit, and characterize prion proteins.

He concluded by summarizing DIR's future directions, which include recruiting talented investigators; continuing to support outstanding basic science; fostering bench-to-bedside approaches; making Clinical Center resources available to all labs; promoting pathophysiology, innovative strategies, vaccine targets, diagnostics, and therapeutics; and encouraging extramural and international collaborations.

At the conclusion of Dr. Holland's presentation, a Council member expressed concern that NIH is ending its Continuous Submission Policy; a Policy which allowed applications to be submitted at any time for program directors/principal investigators providing review service. Being a member of a chartered study section is an incredible responsibility, and it takes a substantial amount of time to review a grant application properly. Reviews determine which applicants should be funded and help improve the science of those who are submitting applications. Study section members dedicate two weeks per review cycle to review applications, which takes them away from their research for two weeks. Terminating continuous submission puts an enormous burden on reviewers who spend six weeks a year reviewing applications for NIH and may make it more difficult to recruit reviewers.

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

Director's Report

Dr. Rotrosen welcomed the subcommittee members to the 212th meeting of the National Advisory Allergy and Infectious Diseases Subcommittee meeting and presented the following scientific and Division activities.

Staff and Organizational Changes

None

Selected Funding Opportunities

BAA-75N93026R00004: Development of Radiological/Nuclear Medical Countermeasures (MCMs) And Biodosimetry Devices. The goals of this BAA are two-fold. The first goal is to support the development of safe and effective MCMs to mitigate and/or treat normal tissue injuries caused by ionizing radiation from a radiological or nuclear incident, thereby reducing radiation-associated mortality and morbidity. MCMs are not expected to be effectively mobilized for use within the first day after exposure; therefore, MCMs must be efficacious 24 hours or later post exposure. The second goal is to support advancement of biodosimetry biomarkers and/or devices to inform triage and treatment strategies during a radiation public health emergency.

Division Activities

Radiation and Nuclear Countermeasures Program

Biodosimetry U01 Consortium Kick-Off Meeting. On December 12, 2025, an in-person meeting was held in Rockville, Maryland to bring together PIs for eight newly awarded cooperative agreements in the program's biodosimetry portfolio. The consortium aims to address the unmet need of developing assays and/or devices to assess human accidental radiation exposure. The objectives of the meeting were to facilitate creative interactions and provide background on planned research projects. The meeting provided for exchange of ideas and refinement of research, while setting the stage for future collaborations among the research teams. Attendees included the PIs, NIAID staff, regulatory members, and representatives from other US Government agencies.

NIAID/AFRRI 2025 Virtual Annual Meeting. On January 30, 2026, investigators from the Armed Forces Radiobiology Research Institute (AFRRI) provided updates to staff on seven research projects funded by NIAID through an Inter-Agency Agreement (IAA) with the Uniformed Services University of the Health Sciences. In addition to investigator updates, AFRRI leadership briefed staff on research facility capabilities and improvements. The inter-agency Research Coordinating Team responsible for strategizing future research efforts through this IAA were also present. Research projects funded through this IAA focus on development of medical countermeasures to mitigate the effects of acute radiation exposure.

Allergy, Asthma, and Airway Biology Branch

2025 Annual Asthma and Allergic Disease Cooperative Research Centers (AACRC) Annual Face to Face Meeting. On November 18-19, 2025, DAIT/AAABB sponsored the 20th annual meeting of the AACRC investigators in Rockville, Maryland as a hybrid event. The two-day meeting of PIs, co-investigators, trainees, and program staff included presentations from 11 NIAID-funded research AACRCs, as well as six NIAID-funded Program Project grant teams. In addition, the meeting included a special session featuring the work of AACRC opportunity fund-supported junior investigators and inter-AACRC collaborative projects, and a poster session featuring young investigators and trainees.

Alpha-Gal Syndrome Investigator Update Meeting. On December 4, 2025, DAIT/AAABB held a virtual meeting for investigators funded to study Alpha-Gal Syndrome. Representatives from eight research groups provided updates on their research and discussed potential collaborations to further research in the field.

Strategies to Assess the Impact of Environmental Exposures on Allergic Disease and Asthma.

On December 9-10, 2025, DAIT/AAABB held a virtual workshop in Rockville Maryland to: 1) review the evidence linking environmental exposures to prevalence and/or severity of asthma and other allergic diseases; 2) discuss potential mechanisms underlying the associations between specific exposures and disease in order to identify targets for intervention; and 3) share approaches for studying specific exposures in clinical studies and trials. This workshop facilitated interactions between exposure scientists, pulmonologists, and allergists to develop a roadmap for evaluating the impact of environmental exposures on the host immune response in atopic diseases. A manuscript summarizing the recommendations of the workshop is in preparation.

Functional Transcriptomics: The Future is Now - Lessons learned from the AADCRC. On February 27, 2026, in Philadelphia, Pennsylvania at the annual meeting of the American Academy of Allergy, Asthma and Immunology (AAAAI), the NIAID-funded Asthma and Allergic Diseases Cooperative Research Centers (AADCRCs) organized a symposium entitled “Functional Transcriptomics: The Future is Now - Lessons learned from the AADCRC.” Three experts in the field discussed the use of transcriptomics in eosinophilic gastrointestinal diseases, the use of omics to understand the pathogenesis of chronic rhinosinusitis and nasal polyposis, and multiomic approaches for endotyping allergic diseases.

Communication between the Epithelium and Immune Cells: Lessons Learned from the AADCRC. On February 28, 2026, in Philadelphia, Pennsylvania at the annual meeting of the AAAAI, the NIAID-funded AADCRCs organized a workshop entitled “Communication between the Epithelium and Immune Cells: Lessons Learned from the AADCRC.” Three experts in the field discussed the role of epithelial-immune interactions on airway hyperresponsiveness in asthma and chronic rhinosinusitis.

Findings Across 17 Years of the Urban Environment and Childhood Asthma (URECA) Birth Cohort: Organized by NIAID. On March 1, 2026, in Philadelphia, Pennsylvania at the annual meeting of the AAAAI, NIAID organized a symposium entitled “Findings Across 17 Years of the Urban Environment and Childhood Asthma (URECA) Birth Cohort: Organized by NIAID.” Three NIAID-funded investigators reviewed findings of the recently completed URECA study, including the relationship between allergen exposure, allergic sensitization, and respiratory outcomes; asthma phenotypes integrating data from birth through adolescents; and mechanistic insights from multiomic analysis of nasal mucosal cells of urban children raised in low-income neighborhoods.

The Regulatory Role of Microbes in Allergic Diseases. On March 2, 2026, in Philadelphia, Pennsylvania at the annual meeting of the AAAAI, the NIAID-funded AADCRCs contributed to the workshop entitled “The Regulatory Role of Microbes in Allergic Diseases.” Three experts in the field presented on the gut microbiome and the development of atopic disease in infancy, microbial signal regulation of allergic disease development, and the role of the gut microbiome in shaping immune responses to allergens.

Basic Immunology Branch

Immune Mechanisms at the Maternal-Fetal Interface. On December 9, 2025, the annual meeting of the program was held in Rockville, MD. The goal of the program is to gain insight into factors and immune mechanisms that regulate optimal placental development and function,

including interactions between immune and non-immune components that contribute to healthy and adverse pregnancy outcomes. The principal investigators (PI) are from Stanford University, University of California (San Francisco), Cincinnati Children's Hospital, Memorial Sloan-Kettering Cancer Center, Washington University, University of Virginia, and Imperial College of Science, Technology and Medicine (UK). PIs and their trainees presented recent updates and progress from their respective programs. The meeting encouraged investigators to exchange ideas and foster collaborations within the program.

Cooperative Center for Human Immunology (CCHI) Program. The CCHI Program held its annual meeting in Bethesda, Maryland, with both in-person and virtual attendance on December 11 and 12, 2025. Over 100 individuals registered for the event, with more than 80 participating in person. The program supports mechanistic and hypothesis-testing studies to advance understanding of human immune responses to infection, vaccination and adjuvants, and immune-mediated diseases. Investigators from all nine centers presented their research progress, and recipients of the 2025 CCHI Infrastructure and Opportunity Fund also shared their work. The CCHI program continues to provide a platform for building collaborations, sharing best practices, and leveraging resources across participating groups.

Maintaining Immunity After Immunization. The Annual Meeting of the Maintaining Immunity after Immunization program was held virtually on January 13th, 2026. The program supports projects that seek to define the components and mechanisms of immune responses that are essential for induction of persistent or life-long protective immunity following vaccination. In this meeting, investigators described their research progress and discussed areas of possible future collaboration between projects.

Immune Mechanisms of Protection Against Mycobacterium tuberculosis Center (IMPAC-TB). On February 25-27, 2026, the annual meeting of the IMPAC-TB program was held as a hybrid meeting in Rockville, MD. The PIs of three contracts presented overviews of their research, including accomplishments and key scientific advances of the past year. The meeting also featured presentations from early-stage investigators. The overarching goal of the IMPAC-TB program is to identify and characterize immune responses required to protect a host from initial *Mycobacterium tuberculosis* (Mtb) infection, establish latent infection, or that are associated with progression to active tuberculosis (TB) disease. IMPAC-TB is the first NIAID trans-divisional program aiming to better understand TB immunology. The contractors are using comprehensive immunologic approaches, functional assays, complementary animal models, human cohorts, and computational tools to further define protective immunity to Mtb and help the broader TB vaccine community translate findings into improved vaccine strategies.

Adjuvant Discovery and Development Programs. On March 25-27, 2026, the annual contractors meeting of the NIAID Adjuvant Discovery and Development programs was held in Rockville, MD. The Adjuvant Discovery program's objective is to identify novel adjuvants, and the Adjuvant Development program's objective is to advance leading adjuvant candidates for clinical use in the prevention and treatment of immune-mediated (e.g., allergy, autoimmunity) and infectious diseases. The contractors reported on progress made in the past year and presented plans for future work. The meeting also included a session on small business programs and funding, as well as a presentation from NIAID staff on resources available to contractors.

Fc-Dependent Mechanisms of Antibody Mediated Killing. DAIT held an annual meeting on March 30th, 2026, in Rockville, MD for the Fc-Dependent Mechanism of Antibody Mediated Killing program. This program supports basic research to elucidate mechanisms of Fc-mediated antibody functions including ADCC and ADCP. The goal of this program is to generate foundational data sets and tools that can be used to better predict Fc-mediated killing and accelerate the design of vaccines or therapeutics that induce protective antibody:FcR responses. The purpose of the meeting was for grantees to share recent scientific progress and communicate experimental plans for the upcoming year.

Molecular Mechanisms of Combination Adjuvants (MMCA) Program. The MMCA Program held its annual meeting in Rockville, Maryland with both in-person and virtual attendance on March 30 and 31, 2026. During the meeting, the 10 participating investigators presented updates on research performed during all years of their 5-year U01 grants. Presenters spoke about novel findings relating to mechanisms of adjuvanticity in vaccines containing multiple adjuvants. Scientific successes, roadblocks, and ideas for applications of mechanistic findings were discussed by all program grantees.

Transplantation Branch

Immunobiology of Xenotransplantation Cooperative Research Program (IXCRP). On September 11, 2025, in Rockville, Maryland, NIAID held the kick-off steering committee meeting for the IXCRP renewal with both in-person and virtual attendees. This program supports preclinical research on the transplantation of donor pig organs and pancreatic islets in nonhuman primate (NHP) and human decedent recipients with the overarching goal of enabling safe and effective clinical xenotransplantation. The current program includes three U01s and two U19s that consist of five NHP and two human decedent projects in kidney, heart, lung, and liver xenotransplantation. The investigators presented their preliminary work, rationale, and research strategies for new studies. Representatives from the Keeling Center for Comparative Medicine and Research, National Swine Research and Resource Center, and Nonhuman Primate Reagent Resource also attended and provided updates on available resources. The meeting concluded with an interactive and productive discussion on xenotransplantation-specific resource needs.

Xenotransplantation Workshop Planning Meeting. On September 12, 2025, following the IXCRP meeting in Rockville, Maryland, NIAID held a companion workshop planning meeting to gather feedback from various stakeholders in xenotransplantation, including representatives from research, clinical, regulatory, and commercial sectors. The forum focused on identifying and prioritizing research needs to inform future actions and focused workshops. Given the success of this planning meeting and rapid progression of the field (e.g., multiple small, Food and Drug Administration-approved clinical trials in xenotransplantation already underway), DAIT intends to host similar, annual IXCRP-adjunct workshops to develop consensus strategies for addressing challenges to routine clinical xenotransplantation.

Emerging Science and Technologies in Transplantation (ESTT). On September 25, 2025, the annual steering committee meeting for the ESTT consortium was held virtually. The ESTT program was initiated in 2016 to stimulate transplantation immunology in three priority areas reflected in the five current awards: one evaluating the role of the microbiome on transplant outcomes; one incorporating intravital imaging techniques to deepen our understanding of immune cell interactions in the graft; and three focused on targeted therapeutic delivery to avoid or reduce

negative side effects of broadly immunosuppressive drugs. Progress reported by the ESTT steering committee demonstrated advances in these focus areas and revealed opportunities for cross-disciplinary collaborations in transplantation immunology, microbiology, materials science, and molecular and cellular imaging. The meeting was attended by the consortium members and extramural NIAID staff.

Systems Immunology in Transplantation: Advances, Challenges, and Opportunities. On January 27-28, 2026, DAIT staff and members of the extramural research community co-organized this virtual symposium. The symposium attracted over 200 attendees and featured six sessions, two panel discussions, and 28 speakers and moderators from multiple fields. Key discussions highlighted immune digital twins, cross-species mathematical modeling, automated immune dynamics platforms, and integrated multiomic datasets – and how these systems can increase knowledge of transplant immunology and improve outcomes for transplant recipients. Participants also identified critical barriers: the need for enhanced data harmonization, analytic validation, and longitudinal studies to address heterogeneity in genetics and immunosuppression. A forthcoming white paper will summarize these consensus conclusions.

Autoimmunity and Mucosal Immunology Branch

Autoimmunity Center of Excellence Semiannual Meeting. On January 26, 2026, AMIB staff and investigators funded through NIAID's Autoimmunity Centers of Excellence (ACE) held a virtual meeting on recent milestones for ACE clinical trials. Two new clinical trials have opened, including: 1) "AGA01: A Randomized Study of Tocilizumab Discontinuation for Patients with Giant Cell Arteritis in Remission," led by Sebastian Unizony (Clinical Study Lead) of Massachusetts General Hospital (grant awarded to John Stone, MD); and 2) "AIM01: Study of Ublituximab in Early, Active, Autoantibody-Positive Immune-Mediated Necrotizing Myopathy," led by Dr. Julie Paik of Johns Hopkins University. Dr. Amit Bar-Or of University of Pennsylvania provided progress updates on the ongoing trial, "AMS05: Randomized, Blinded Discontinuation Trial of Ocrelizumab in Early Relapsing Multiple Sclerosis," which should complete enrollment in 2026. Dr. Judith James of the Oklahoma Medical Research Foundation presented her plans to assess the relationship between reactivation of Epstein Barr Virus and induction of interferon pathways associated with flare in patients with Systemic Lupus Erythematosus.

2025 Annual Meeting of the Immune Drivers of Autoimmune Disease (IDAD) Program. On September 29, 2025, IDAD investigators and NIAID program staff convened in Rockville, Maryland for the annual program meeting. During the event, IDAD investigators presented their progress on the development of preclinical autoimmunity cohorts and discussed how these cohorts are enhancing our understanding of the immunologic states and dynamics that lead to autoimmunity. The meeting also featured a virtual discussion with IDAD and external AI/ML experts, highlighting state-of-the-art advances in AI/ML applications for immunology and autoimmunity prediction. The gathering provided valuable opportunities for investigators to collaborate and synergize, maximizing the impact of the IDAD program.

Concepts Presented for Clearance

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

NIH Tetramer Core Facility (Contract)**Presenter: Dr. Halonna Kelly**

This initiative will support the continued operation of the NIH Tetramer Core Facility (TCF), a centralized reagent resource providing MHC class I, non-classical MHC, and MHC class II tetramers; CD1 ligands; and related products to the global research community. Activities include producing and distributing both premade and custom quality-controlled reagents; optimizing production processes; and managing a multi-functional web-based system for order submission, tracking, and technical support.

Immune Mechanisms of Protection against *Mycobacterium Tuberculosis* Centers (IMPAC-TB) (Clinical Trial Optional)**Presenter: Dr. Nancy Vázquez Maldonado**

The IMPAC-TB program is focused on understanding protective immunity against Mtb, where significant knowledge gaps remain. This initiative will continue to support the comprehensive understanding of protective immunity in people with and without HIV, including identification of immune signatures associated with risk or protection from disease/infection, and identification and pre-clinical testing of protective antigens/immune epitopes.

Radiological and Nuclear Medical Countermeasures Product Development Support (PDS) (Contract)**Presenter: Dr. David Cassett**

This initiative will continue and expand nonclinical and clinical efforts for product development of radiation/nuclear medical countermeasure candidate drugs and biodosimetry devices for possible inclusion in the Strategic National Stockpile for use during a radiation emergency.

Development of Candidate Medical Countermeasures (MCMs) and Technologies Against Radiological/Nuclear or Chemical Threats (U01 Clinical Trial Not Allowed)**Presenter: Dr. Thomas Winters**

This initiative will support research to investigate mechanisms of injury and develop interventions to diagnose, mitigate, and/or treat injuries in victims of exposure during a mass casualty, public health radiation, or chemical emergency.

Cooperative Program for Modeling Clinical Transplantation (CPMCT) (U01 Clinical Trial Not Allowed)**Presenter: Dr. Patricia Kehn**

The objective of this initiative is to promote the development or refinement of new approach methods (NAMs) and mouse models of transplantation that demonstrate improved potential for direct clinical translation and reduce the need for nonhuman primate models.

V. Report of the Microbiology and Infectious Diseases Subcommittee – David Spiro, Ph.D., Acting Director, DMID**Director's Report**

Dr. David Spiro, 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 April 6, 2026. He provided DMID leadership updates, noting that Sarah Meyer has joined the Office of Clinical

Research Resources as a Medical Officer, and Rajeev Gautaum is serving as the Acting Chief of the Basic Research Section in the Virology Branch.

Following staff introductions, Dr. Spiro provided an overview of the scientific priorities he will advance as the Acting Director of DMID:

Protecting Americans in an Interconnected World: Dr. Spiro noted that the foremost priority of the NIH is to support science that improves the health of all Americans. He stated that DMID's mission is shaped by a core reality: infectious diseases do not respect borders. In an interconnected world, local outbreaks can rapidly become global threats, and global diseases ultimately affect the health and security of people in the United States. To meet this challenge, Dr. Spiro said DMID focuses on three key areas: 1) supporting foundational research on both U.S. endemic and globally significant pathogens; 2) advancing discoveries into real-world interventions targeting respiratory viral threats, high-burden global diseases, antimicrobial resistance, sexually transmitted infections, vector-borne diseases, emerging high-consequence pathogens, and parasitic infections; and 3) generating clinical evidence that improves health outcomes by conducting clinical trials in both U.S. and international settings, and ensuring study populations reflect those at risk in the United States.

Sustained Scientific Preparedness: Dr. Spiro reported on NIAID's updated strategic vision (*Nat Med* DOI: 10.1038/s41591-025-04160-1 (2026)), which no longer includes biodefense and pandemic preparedness as distinct strategic priorities. He emphasized that sustained scientific preparedness remains central to DMID's approach and involves three phases: pre-outbreak discovery and candidate development; rapid clinical evaluation and sample collection during an outbreak; and post-outbreak optimization, learning, and development of next-generation tools. The overarching goal is straightforward: when a pandemic begins, countermeasures should be ready to enter clinical testing. Achieving this requires long-term investment, coordination, foresight, and a commitment to institutionalizing lessons learned.

Expanding the Definition of Antimicrobial Resistance: Dr. Spiro reported that NIAID is intentionally challenging traditional thinking about antimicrobial resistance (AMR), noting that AMR has historically been defined by lab-based susceptibility tests, but this definition is incomplete. In clinical practice, infections that appear susceptible in vitro can still lead to poor outcomes. This disconnect has prompted a shift to viewing AMR as therapy failure in patients, not just bacterial resistance. The shift moves from a bacteria-centric to a patient-centered perspective, with meaningful clinical implications. Importantly, this is an expansion, not a replacement, of existing research efforts as this reframing opens new opportunities for scientific discovery and aims to improve public health.

Cross-Cutting Initiatives: Dr. Spiro stated that DMID is also advancing key cross-cutting initiatives that will strengthen the conduct of research:

- **Enhancing biorisk management** by applying a conservative, transparent process to review all grants and contracts for dangerous gain-of-function research in accordance with Executive Order 14292. Further, DMID will continue working with high-containment laboratories funded by DMID to ensure compliance with biosafety and biosecurity policies and to promote a culture of responsibility, transparency, and accountability.

- We are also committed to **reducing animal use and expanding viable alternatives**. Recent investments in organoids, in vitro systems, and computational models continue to advance the development of alternative approaches. In parallel, DMID is conducting systematic reviews to identify opportunities to responsibly reduce reliance on non-human primate and canine models where feasible.

Concepts Presented for Clearance

The following concepts were presented to the Council members:

The Centers of Excellence for Influenza Research and Response (CEIRR)

Presenter: Dr. Lauren Byrd-Leotis

This concept will renew support for the CEIRR program, which was originally established in 2007. With each renewal, the CEIRR program has evolved to address additional research questions and advance the field of influenza research with significant discoveries related to aspects of basic virology, such as receptor binding, viral replication and reassortment; to medical countermeasure development; to influenza immunology; and to understanding and establishing risk factors of pandemic potential for novel influenza strains. The program has generated nearly 4,000 publications and more than 10,000 reagents that are available to the research community. Additionally, training opportunities, required for CEIRR, have been vital to program success both through an established program for trainees to complete work in other CEIRR labs and through support for students and new or early-stage investigators, resulting in a strong retention rate for researchers within the program and field. The concept was unanimously approved.

The Influenza Data Processing and Communication Center (iDPCC)

Presenter: Dr. Lauren Byrd-Leotis

This concept will renew support for the CEIRR companion program, the iDPCC, a state-of-the-art influenza data processing center that provides appropriate cleaning and curation for data collected and generated by the CEIRR program and facilitates CEIRR network collaboration and sample sharing by maintaining data standards and virtual sample repositories. The iDPCC also submits CEIRR data to public data repositories. In addition to basic data tracking and reporting, the iDPCC develops advanced cloud-based analytics to interrogate data generated by the Program. This allows further understanding of the scope (geographic, host, etc.) of sampling, as well as the prevalence of influenza in sampled species. The concept was unanimously approved.

Statistical and Data Coordinating Center

Presenter: Dr. Seema Nayak

The objective of this concept is to renew support for a Statistical and Data Coordinating Center (SDCC) to provide comprehensive and consistent statistical and data management support for DMID clinical research studies and trials spanning a wide range of infectious diseases and candidate products, including vaccines, diagnostics, biologics, devices, and therapeutics. Specifically, the program will provide a comprehensive array of statistical and data management support services, including web-based data collection, management and quality control; statistical consultation, design and analysis; assistance in study materials development with related web-based reports and training; assistance with site management; electronic specimen

tracking; and data reports to support safety/regulatory requirements.. It is a key part of the infrastructure necessary for clinical trial implementation. The concept was unanimously approved.

Diagnostics Preclinical Services

Presenter: Dr. Paul Eder

This concept will renew a program that offers in-kind, gap-filling services to qualified diagnostics developers in various stages of development (task areas) where a developer's critical need has been identified and is a major hurdle in their progress towards clearance. The task areas within which NIAID will provide support include regulatory consulting; protein production (including enzymes, reporter proteins, and monoclonal antibodies); chemical synthesis (including probes, reporter molecules, large nucleic acids); clinical specimens and isolates; development, verification, and validation for immunoassays, nucleic acid amplification assays, and next-generation sequencing assays; and pre-GMP pilot manufacturing. This initiative may support clinical studies as part of final validation of a diagnostic product. The program is being recompeted early to ensure adequate offerors in all 6 task areas offered under the program. The concept was unanimously approved.

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

ARAC Meeting Attendees

Council Members Present:

Dr. Grace Aldrovandi
Ms. Seema Shah

ARAC Members Present:

Dr. Kelly Gebo (Chairperson)
Dr. Timothy Henrich
Dr. Raphael Landovitz
Dr. Lishomwa Ndhlovu

Ex Officio Members Present:

Dr. Anne Neilan
Dr. Charlesnika Evans

Ex Officio Members Absent:

Dr. Geri Donenberg
Dr. Henry Masur
Dr. Robyn Neblett Fanfair

Ad Hoc Participants:

Mr. Louis Shackelford

Executive Secretary Present:

Mr. Martin

NIAID Senior Staff Present:

Dr. Robert Eisinger

Dr. Gebo, the ARAC Chairperson, called the meeting to order and requested approval of minutes from the previous meeting. A motion was made, seconded, and the minutes were approved.

Director's Report

Program, Scientific, and Budget Updates

Dr. Eisinger opened with an acknowledgement of Dr. Carl Diefenbach's leadership of the Division of AIDS from 2008–2025. Dr. Diefenbach joined the Division in 1992 as Chief of the Preclinical Therapeutics Group, was promoted to Director of the AIDS Basic Sciences Program in 1996 and named Division Director in 2008. He currently serves as Senior Adviser to the Acting Director of the

Fogarty International Center. The committee recognized his contributions with a round of applause.

Dr. Eisinger followed with a budget overview:

- The NIAID FY2026 Budget is \$6.6 billion, a ~\$23 million/0.35% increase over the prior year; however, the budget has been essentially flat for four years.
- The NIH FY2026 budget is \$48.9 billion, a ~\$500 million/1.02% increase over the prior year.
- In FY2023-FY2025, the NIAID HIV AIDS funding level was relatively flat at ~\$1.911 billion/year. In FY2026 there is a marked decrease of ~\$38.9 million, resulting in a budget of ~\$1.87 billion. This ~\$38.9 million decrease was the result of the OAR's utilization of their 3% transfer authority.

Dr. Eisinger discussed the NIAID goals and division priorities to continue basic, pre-clinical, and clinical research toward ending the HIV/AIDS pandemic; develop a safe and effective HIV vaccine and improved combination prevention strategies; advance novel treatment approaches and pursuit of a cure, as well as continue supporting implementation science research.

Dr. Eisinger highlighted key collaboration such as PROJECT SEARCH (rural HIV incidence in Kenya and Uganda) and NIAID partnerships with the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institute on Aging (NIA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Mental Health (NIMH), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

Concepts Presented for Clearance

Clinical Trials Network (CTN) Concepts — Overview

Dr. Eisinger gave an overview of the DAIDS/NIAID Clinical Trial Network (CTN) concepts. Four networks are proposed for re-competition, each consisting of: a Leadership and Operations Center (LOC), Laboratory Center (LC), Statistical and Data Management Center (SDMC), and Clinical Trial Units (CTUs).

The four networks and their scientific agendas include:

- HIV/AIDS Adult Therapeutics CTN — HIV therapeutics, cure, and treatment of HIV-associated comorbidities in adults
- HIV Maternal, Adolescent & Pediatric CTN — HIV prevention and treatment in maternal, adolescent, and pediatric populations
- HIV Prevention CTN — Biomedical HIV prevention strategies for adults and adolescents
- Immune-Based Prevention Trials Network (IBPTN) — Immune-based prevention for HIV and associated diseases

HIV/AIDS Adult Therapeutics Clinical Trial Network (CTN) Leadership & Operations Center (LOC)

Dr. Peter Kim, Director of Therapeutics Research, DAIDS, NIAID, presented the HIV/AIDS Adult Therapeutics CTN LOC. He presented background, key accomplishments, and future priorities.

Background:

- 40.8 million people live with HIV globally as of 2024
- In the U.S., only 50–75% of people living with HIV are in medical care; of those, approximately two-thirds are virally suppressed

Key Accomplishments:

- ACTG 5357: Demonstrated viral suppression with novel medication combinations, laying the groundwork for ultra-long-acting regimens
- ACTG 5359 (LATITUDE Study): Long-acting injectable therapy shows effective for individuals with adherence challenges
- ACTG 5332 (REPRIEVE Study): Defined optimal statin use to prevent cardiovascular disease in people with HIV
- ACTG 5360: Simplified treatment paradigm for scale-up; established a 1-month TB prevention regimen (down from 9 months) and a 4-month treatment regimen
- HIV Cure Research: Advances in biomarker identification, broadly neutralizing antibodies (bNAbs), and reservoir studies
- Infrastructure: 183 labs globally (88 international); largest controlled TB program globally; Early-Stage Mentorship Program advanced 20+ investigators
- Rapid response: Ran the only U.S. Phase III trial evaluating tecovirimat (TPOXX) for mpox

Future Priorities:

- Novel, durable interventions (long-acting formulations, bNAbs, modulatory therapies)
- ART-free remission and cure
- Non-viral HIV complications and coinfections (cardiovascular disease, hepatitis B/C, TB)
- Integrated care for people with HIV
- Expanded implementation science embedded in all network activities
- Streamlined protocol development and accelerated implementation

Vote on the Concept:

- Motion made, seconded, and approved

HIV Maternal, Adolescent & Pediatric Clinical Trial Network (CTN) (IMPACT Network) Leadership & Operations Center (LOC)

Dr. Sheryl Zwierski, Director of the Prevention Sciences Program, DAIDS, NIAID, presented the HIV Maternal, Adolescent & Pediatric CTN LOC. She provided background, described the need for the network, key accomplishments, and future directions.

Background & Need:

- ~120,000 new HIV infections in children under 14 globally per year (unchanged in recent years)
- ~75,000 annual deaths in children under 14
- ART coverage for pregnant women stagnated at ~84%
- Only ~55% of children under 14 who need ART are accessing it; ~46–47% are virally suppressed (vs. 78% access and 73% suppression in adults)
- New antiretroviral approvals lag 8–10+ years for pediatric populations
- ~1.2 million children developed TB in 2024; ~175,000 died

Key Accomplishments:

- IMPACT 2017 (MOCHA Study): Long-acting medication study in adolescents
- P1115: 4 of 6 neonates meeting ART cessation criteria achieved long-term viral suppression (HIV remission/cure potential)
- IMPACT 2034: Informed global dosing guidelines for dolutegravir in young children
- P1108: Dosing guidance for youngest children
- IMPACT 2023: Supported approval of remdesivir in pediatric populations
- Contributed to consensus frameworks for inclusion of pregnant and postpartum women in HIV and TB trials

Future Priorities:

- Expanded implementation science
- Renewed focus on prevention of vertical HIV transmission and postnatal prophylaxis
- Accelerated antiretroviral access and regulatory approvals
- ART-free remission strategies, particularly for young children
- New anti-TB regimens for drug-sensitive and drug-resistant TB
- Enhanced focus on neurocognitive development and mental health

Vote on the Concept:

- Motion made, seconded, and approved

HIV Prevention Research Clinical Trial Network (CTN) (HPTN) Leadership & Operations Center (LOC)

Dr. Sheryl Zwierski, Director of the Prevention Sciences Program, DAIDS, NIAID, presented the HIV Prevention Research CTN LOC. She provided background, described the need for the network, key accomplishments, and future directions.

Background & Need:

- ~1.3 million new HIV infections globally per year; 32,000–39,000 in the U.S.
- Only ~37% of people globally in need of HIV prevention are accessing combination prevention
- ~1.2 million people in the U.S. estimated to benefit from PrEP; ~590,000 currently receiving it
- Significant disparities in PrEP uptake among young Black MSM in the South, women, and Hispanic/Latino populations
- Women account for ~19% of new U.S. infections but only ~8% of PrEP prescriptions
- Long-acting injectable PrEP accounts for <5% of PrEP prescriptions in the U.S.

Key Accomplishments:

- HPTN 052: Changed international HIV prevention and treatment guidelines
- HPTN 704: Improved antiretroviral use and reduced mortality
- HPTN 083 / 084: Supported long-acting injectable PrEP approval and adolescent label inclusion
- Ongoing collaboration with HVTN on broadly neutralizing antibody prevention studies

- SCHOLARS Program: Fostered early-stage investigators who have advanced to independent research careers

Future Priorities:

- Expanded implementation science throughout the product development lifecycle
- Integrated prevention strategies addressing HIV and STIs concurrently
- Novel non-vaccine biomedical prevention methods and multipurpose prevention technologies (e.g., combined HIV + pregnancy or STI prevention)
- Innovative clinical trial designs (including AI-assisted processes and real-world evidence) to address feasibility challenges
- Focus on long-acting products with extended duration of protection

Vote on the Concept:

- Motion made, seconded, and approved

Immune-Based Prevention Trials Network (IBPTN) Leadership & Operations Center (LOC)

Dr. Cesar Boggiano, Director, Vaccine Research Program, DAIDS, NIAID, presented the Immune-Based Prevention Trials Network LOC. He provided background, described the need for the network, key accomplishments, and future directions.

Background & Need:

- ~1.3 million people living with HIV and ~39,000 new infections annually in the U.S.
- TB increasing; STIs highly prevalent — both intersect with HIV risk
- Need for durable, scalable, cost-effective immune-based strategies to complement existing tools

Key Accomplishments:

- AMP (Antibody-Mediated Prevention) Trials: First evidence that a passively administered monoclonal antibody can prevent HIV acquisition in humans
- Multiple TB trials conducted across thousands of patients
- Advances in immunogen discovery and germline-targeting immunogen safety validation
- Strong community engagement initiatives, including the HVTN Registry

Future Priorities:

- Induce protective immunity through novel adjuvants and refined boosting strategies
- Advance antibody-mediated prevention with long-acting antivirals
- Analytical treatment interruption studies to understand immune-mediated viral control
- Expand efforts for HIV-associated infections (TB, STIs)
- Integrate implementation science for real-world scalability
- Stronger emphasis on mucosal immunology and broader immune system arms
- Incorporation of self-collected specimens to enhance trial efficiency

Vote on the Concept:

- Motion made, seconded, and approved

HIV/AIDS Network Laboratory Centers (LC)

Ms. Daniella Livnat, Program Officer, DAIDS, NIAID, presented the HIV/AIDS Network LC concept. This concept is a grant reissuance with a 7-year duration for up to 4 awards. Ms. Livnat provided the objectives of this concept, importance of LC to the clinical trial network enterprise, and future direction for this initiative.

Objective:

- Establish LC providing framework for laboratory leadership, structure, and activities supporting network research agendas and clinical trial laboratory components.

Laboratory Types:

- Clinic-based labs (local sample processing, point-of-care testing)
- Site-affiliated labs (safety tests, diagnostics)
- Specialized labs (immunology, pharmacology)

Importance:

- Provide leadership, structure and oversight for all the laboratory associated activities in the network.
- Close collaboration with NIAID Quality Assurance resources
- Collaboration with Data Management Centers to ensure reliable laboratory data capture and specimen tracking.

Changes/Emphasis for the Initiative:

- Increased LC capacity for emerging infectious diseases
- Laboratory oversight framework for cross-institutional/cross-institute protocols
- Rapid identification of assays with regulatory status (e.g., FDA-cleared) for emerging threats
- Accessible laboratory guidance materials supporting implementation research and home sample collection

Vote on the Concept:

- Motion made, seconded, and approved

Statistical and Data Management Centers (SDMC)

Dr. Akinlolu Ojumu, Program Officer, DAIDS, NIAID, presented the Statistical and Data Management Centers (SDMC) concept. This concept is a grant reissuance with a 7-year duration for up to 4 awards. Dr. Ojumu provided the objectives, key accomplishments, and future direction for this concept.

Objective:

- Provide statistical and data management leadership; coordinate design, execution, collection, monitoring, and analysis of clinical trial data in compliance with regulatory standards.

Key Accomplishments:

- Upgraded Medidata systems; implemented remote source review for clinical site monitoring

- Piloted machine learning and AI to enhance data review efficiency (Medidata Clinical Data Studio)
- Incorporated CDISC standards (CDASH, SDTM, ADaM)
- Developed modernized web-based randomization system
- Designed specimen repository website for data and specimen sharing
- New dynamic dashboards for monthly site performance evaluations

Changes/Emphasis for the Initiative:

- Development of biostatistical frameworks for implementation science using novel statistical methods
- Composite endpoints incorporating behavioral and system-level effectiveness measures
- Retooling data management infrastructure for implementation science contexts (e.g., EHR integration, real-world data sources)
- Harmonization and standardization of systems, platforms, and processes across SDMCs and clinical research sites to improve efficiency amid constrained resources

Vote on the Concept:

- Motion made, seconded, and approved

HIV/AIDS Clinical Trial Units (CTU)

Ms. Manizhe Payton, MPH, Director of Office of Clinical Site Oversight, DAIDS, NIAID, presented the HIV/AIDS Clinical Trial Units initiative. This concept is a grant reissuance with a 7-year duration with 45-65 anticipated awards. Ms. Payton provided an overview of the CTU concepts stating that CTUs are cohesive, integrated units anchored by an administrative office and multiple Clinical Research Sites (CRS) with some of these CRS known as "core" (portfolio-funded) and "protocol-specific" (temporary, protocol-driven). She described how each CTU must affiliate with at least 1 of the 4 HIV/AIDS networks and contain 1–8 sites per network. Ms. Payton provided key accomplishments, the funding model, and future directions for this initiative.

Key Accomplishments (Current Period):

- Supported 4 HIV/AIDS CTNs across 101 clinical research sites
- Contributed to development and execution of 165+ protocols
- Enrolled 40,000+ participants
- Successfully pivoted to support mpox and COVID-19 research

Funding Model:

- Core Funding: Annual infrastructure/salary support based on geographic location, CTU size, and number of network affiliations
- Protocol Funds: Layered on top of core funding, determined per protocol by the networks

Future Priorities and Areas of Emphasis:

- Implementation Science: Leverage relationships with community care centers and non-traditional sites
- Fiscal Accountability: Enhanced tracking of federal funds; performance management across CTU components

- Community Engagement: Foundational to operations; requires strong leadership, communication plans, and community structures

During the discussion, members raised concerns about restrictions on resource-sharing for international CTU sites under the current federal funding mechanisms. Manizhe Payton acknowledged the challenge and the critical importance of international sites to the research agenda.

Vote on the Concept:

- Motion made, seconded, and approved

Immunology Quality Assessment (IQA) Program

Ms. Daniella Livnat, Program Officer, DAIDS, NIAID presented the IQA Program contract concept. This is a contract for a seven-year duration with one anticipated award with NICHD potentially partnership. Ms. Livnat provided the objective for this initiative, key accomplishments, and changes for this new initiative.

Objective:

- Evaluate and enhance laboratory ability to participate in NIAID-funded trials by monitoring reliable performance of immunological assays, PBMC processing, and good clinical laboratory practices (GCLP).

Key Accomplishments:

- Improved proficiency testing panel quality, distributed to 40 labs
- Monitored and enhanced PBMC freezing quality in ~100 labs (U.S. and international)
- Provided guidance for method validation during instrument replacements
- Demonstrated TransFix-preserved whole blood maintains CD4 measurements for at least one week (critical for shipped samples)
- Validated soluble TNF-alpha receptor as a study endpoint

Changes/Emphasis for New Initiative:

- Allow regional, non-U.S. lab evaluation of PBMC quality (to avoid prohibitive international shipping costs)
- Support for point-of-care and decentralized immunological tests aligned with implementation research goals
- Method technology transfer and guidance documents for sample processing

During the discussion, Dr. Aldrovandi highlighted the exceptional quality of IQA-supported PBMC outputs, noting unsolicited positive feedback from external collaborators including pharmaceutical industry partners.

Vote on the Concept:

- Motion made, seconded, and approved

Pre-Clinical Services for HIV Therapeutics

Mr. Roger Ptak, DAIDS, NIAID, on behalf of colleagues in the Therapeutics and Basic Sciences Research Programs presented the Pre-Clinical Services for HIV Therapeutics contract concept. This initiative is for a request for proposals for one Indefinite Deliverables/Indefinite Quantities contract for a seven-year period with up to 18 contracts with 2-3 contractors per task area. Mr. Ptak provide objectives, proposed task areas for this contract, key accomplishment of the current contract, and changes/emphasis for the new initiative.

Objective:

- Support discovery and development of therapeutic agents and diagnostics for HIV and associated coinfections (TB, hepatitis B/C) by filling resource gaps for investigators who lack capacity to conduct pre-clinical work.

Task Areas:

- In vitro testing and screening
- Synthesis of therapeutic agents
- Efficacy models (HIV, HBV, TB)
- Dosage form development
- Pre-clinical pharmacology and toxicology
- Diagnostics development support (new addition)

Key Accomplishments:

- Development of TAC (Targeted Activator of Cell Kill) molecules for latent HIV reservoir elimination
- Synthesis of novel HIV inhibitors advanced to in vivo studies
- Pharmacokinetic/pharmacodynamic evaluation of HIV-1 transcriptional inhibitors targeting the viral reservoir
- Dry powder TB formulation with superior efficacy at one-tenth standard dose
- GMP manufacture of lipid-based antiretroviral formulations; long-acting formulations for 4 novel/newly approved therapeutics

Changes/Emphasis for New Initiative:

- HIV Reagent Program transferred to DMID (no longer part of this contract)
- Incorporation of alternative models and new approach methodologies (NAMs)
- Expanded efficacy models to include TB meningitis and nontuberculous mycobacteria (NTM)
- New diagnostics task area supporting multiplex platforms for simultaneous detection of HIV and coinfections

Vote on the Concept:

- Motion made, seconded, and approved

NIAID Specimen Repository

Dr. Jim Lane, Deputy Director, Vaccine Research Program, DAIDS, NIAID, presented the initiative for the NIAID Specimen Repository contract renewal. This initiative is for contract renewal for a seven-year duration with one anticipated award. Dr. Lane provided the objectives for this initiative, a background, key accomplishments, supporting information for this repository approach.

Objective:

- Continue comprehensive services of the NIAID Specimen Repository: receive, catalog, process, store, and distribute specimens from NIAID-sponsored epidemiological and network studies.

Background:

- Repository operational since 1988; stores over 9 million specimens
- Primary sources: HPTN, HVTN, IBPTN, and MACS/WIHS cohort (one of the largest and most comprehensive HIV cohort studies in the U.S., combining data from men and women with and without HIV since 1984)

Key Accomplishments:

- Received 1.3 million and distributed 197,000 specimens during current contract period
- Supported immunologic and virologic studies for network and external investigators
- 400+ MACS/WIHS papers published during current contract period; ~80 relied directly on repository specimens
- Research areas supported: cardiovascular and pulmonary health, neuropsychological outcomes, aging, psychosocial factors, and health disparities

Strengths of Centralized Repository Model:

- Access to diverse, well-characterized specimens across HIV+ and HIV- populations
- Specimens provided at no cost to investigators, lowering barriers and accelerating discovery
- Consistent storage conditions ensure integrity, reliability, and reproducibility

Vote on the Concept:

- Motion made, seconded, and approved

Public Comments

Ms. Elizabeth Levinger, U.S. and Global Health Policy Director, Treatment Action Group (TAG) provided public comments on behalf of the Treatment Action Group (TAG). TAG endorsed ARAC support for renewing all four networks (ACTG, IMPACT, HPTN, IBPTN) and emphasized the following priorities: Continuum from discovery to implementation — maintain a smooth pipeline from basic science through implementation science focused on reducing new infections, illness, and death. She asked for a coherent implementation science agenda — based on gap analysis identifying questions not addressable by implementing agencies such as SAMHSA and requested restoration of international site funding — essential for adequately powered studies (e.g., long-acting PrEP, TB coinfection, maternal/pediatric populations); continued activity in South Africa specifically noted as critical. She addressed the issue of coinfections and comorbidities — TB, STIs, substance use disorder, cardiovascular disease, cancer, and frailty. She asked for a focus on the highest-risk populations — communities of color, LGBTQ+ individuals, women, people who use drugs, incarcerated and immigrant populations. She requested strong cross-network priorities such as sustained community engagement investment; codified mechanisms for cultivating junior scientists domestically and internationally; encourage joint cross-network protocols; comprehensive support for core functions including community engagement across all networks.

VII. Adjournment

The meeting of the Council adjourned at 3:32 p.m., on Monday, April 6, 2026.

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

 -S-
Signed by Christopher T. Hanson,
Acting Deputy Director for Science
Management and Executive Officer,
on behalf of Jeffery Taubenberger, M.D., Ph.D.
Chair, National Advisory Allergy and
Infectious Diseases Council
Acting Director, National Institute of Allergy
and Infectious Diseases

5-21-26
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

5-20-26
Date

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