U.S. Department of Health and Human Services

National Institutes of Health

Twenty-Ninth Meeting of the Clinical Center Research Hospital Board

May 23, 2025

Contents

Clinical Center Research Hospital Board

Leadership

Jack Leslie, Former Chair, Weber Shandwick; Senior Visiting Fellow, Duke Global Health Institute; Distinguished Professor, Georgetown University; Chair, National Institutes of Health (NIH) Clinical Center (CC) Research Hospital Board (CCRHB)

Nina F. Schor, M.D., Ph.D., Deputy Director for Intramural Research, NIH; Executive Secretary, Designated Federal Official, CCRHB

Members

David M. Baum, PMP, Patient, NIH CC Patient Advisory Group (virtual)

David C. Chin, M.D., M.B.A., Distinguished Scholar, Johns Hopkins Bloomberg School of Public Health and Johns Hopkins University School of Medicine

Regina S. Cunningham, Ph.D., RN, FAAN, Chief Executive Officer (CEO), Hospital of the University of Pennsylvania Health System

Sherin U. Devaskar, M.D., Executive Chair of the Department of Pediatrics at the University of California, Los Angeles (UCLA); Physician-in-Chief, UCLA Mattel Children's Hospital; Assistant Vice Chancellor of Children's Health, UCLA Health (virtual)

Julie A. Freischlag, M.D., CEO and Chief Academic Officer, Atrium Wake Forest Baptist; CEO and Executive Vice President (EVP) of Advocate Health; EVP for Health Affairs at Wake Forest University (virtual)

Steven I. Goldstein, M.H.A., CEO of System Integration, University of Rochester Medical Center (virtual)

Stephanie Reel, M.B.A., Assistant Professor, Johns Hopkins University School of Medicine, Division of General Internal Medicine (virtual)

Antoinette Royster, NIH Research Participant and Patient Advocate

Executive Summary

The Clinical Center (CC) Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 29th meeting in person and via VideoCast on May 23, 2025. The meeting was webcast live and open to the public. A VideoCast recording is available.

Mr. Jack Leslie, CCRHB Chair, called the meeting to order at 9:00 a.m. ET.

Mr. Leslie presented remarks on the potential impact of current challenges that NIH and the CCRHB are facing. He commented on life-saving research discoveries made possible by the CC and highlighted the first person of any age to receive custom gene editing therapy that was built on decades of federally funded research. Mr. Leslie invited members of the board to introduce themselves.

Dr. Nina F. Schor, Deputy Director for Intramural Research (DDIR), described recent NIH challenges and achievements, the impact of budget cuts, and the importance of sustained federal investment in medical research. She introduced new NIH leadership, including Director Jayanta Bhattacharya, M.D., Ph.D.; Principal Deputy Director Matthew Memoli, M.D., M.S.; Acting Deputy Director for Extramural Research Jon Lorsch, Ph.D.; and Acting Deputy Director, Division of Program Coordination, Planning, and Strategic Initiatives Nicole Kleinstreuer, Ph.D. NIH Institutes and Centers currently led by acting directors include the CC, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Human Genome Research Institute, National Institute of Allergy and Infectious Diseases, National Institute of Dental and Craniofacial Research, National Institute of Mental Health, National Institute on Minority Health and Health Disparities, National Institute of Nursing Research, and the National Library of Medicine.

Mr. Pius Aiyelawo, Chief Operating Officer and Acting Chief Executive Officer, NIH CC, provided a CC update on celebrations, honors, and awards since the October 2024 CCRHB meeting as well as recent changes at NIH and the CC. He highlighted Dr. Bhattacharya's top priorities including a focus on improving population health, research reproducibility, rigor, innovation, collaboration, safety, and transparency as well as academic freedom.

Drs. Richard Lee, Clinical Director, National Eye Institute (NEI), Kapil Bharti, Scientific Director, NEI, and Teresa Magone, Chief, Consult Services Section, NEI, introduced a potential treatment for age-related macular degeneration—transplantation of a stem cell-derived retinal pigment epithelium cell patch into the affected eye. They detailed the process for creating the patch from patient stem cells and key elements of the clinical trial. The therapy was cleared by the U.S. Food and Drug Administration for a phase I/IIa trial and has been administered to two patients.

Dr. Barbara Jordan reported that the CC received the Magnet with Distinction™ designation from the American Nurses Credentialing Center, demonstrating excellence in nursing care, interdisciplinary collaboration, and a positive practice environment. She summarized findings from the site visit report and detailed preparations for maintaining this prestigious designation.

Dr. Leighton Chan, Chief Scientific Officer and Scientific Director, NIH CC, outlined his vision for the CC-funded intramural program and metrics of success. He highlighted three CC research projects: Robotic Knee Exoskeletons in Children (Thomas Bulea, Principal Investigator [PI]); a Novel Fungal-Specific Positron Emission Tomography Tracer (Dima Hammoud, PI, and Dr. Rolf Swenson, Director, National Heart, Lung, and Blood Institute Chemistry and Synthesis

Center); and Fully Automated Abdominal Computed Tomography Biomarkers for Type 2 Diabetes Using Deep Learning (Ron Summers, PI).

Ms. Patricia Coffey, Chief Health Information Officer, NIH CC, presented an overview of the CC telehealth program, including its vision and strategic importance. She described CC patient engagement platforms, reported key performance indicators over time, and outlined planned enhancements.

Dr. Jon McKeeby, Chief Information Officer, and Ms. Leslie Wehrlen, Chair, Electronic Health Record (EHR) Executive Steering Committee, NIH CC, provided updates on the CC EHR modernization project, which aims to integrate disparate systems, improve patient safety, and streamline clinical workflows. Progress to date includes a user requirement survey completed by 10% of users, ongoing workflow modeling sessions with significant staff engagement, and plans to complete market research by August 2025.

Mr. Dan Wheeland, Director, Office of Research Facilities, provided a status update highlighting NIH investment in facilities projects and strong visible progress since the October 2024 CCRHB meeting. Improvements to the environment of care include outpatient exam rooms and nurse station renovations and replacement of electrical infrastructure. Additional projects support specialized capabilities that enable NIH to develop novel diagnostics, therapies, and cures such as the Surgery, Radiology, and Laboratory Medicine Building.

The next meeting of the CCRHB is slated for October 17, 2025.

Mr. Leslie adjourned the meeting at 12:42 p.m. ET.

Meeting Summary

May 23, 2025

Welcome and Chair of the Board Overview

Mr. Jack Leslie, Former Chair, Weber Shandwick; Senior Visiting Fellow, Duke Global Health Institute; Distinguished Professor, Georgetown University; Chair, National Institutes of Health (NIH) Clinical Center (CC) Research Hospital Board (CCRHB)

Mr. Leslie began the meeting at 9:00 a.m. ET and invited members of the Board to introduce themselves.

- Mr. David Baum is a patient member of the CCRHB and the CC Patient Advisory Group.
- Dr. David Chin is a Distinguished Scholar at the Johns Hopkins Bloomberg School of Public Health and Johns Hopkins University School of Medicine.
- Dr. Regina Cunningham is Chief Executive Officer (CEO) of the Hospital of the University of Pennsylvania Health System.
- Dr. Sherin U. Devaskar is Executive Chair of the Department of Pediatrics at the University of California, Los Angeles (UCLA), Physician-in-Chief at UCLA Mattel Children's Hospital, and Assistant Vice Chancellor of Children's Health, UCLA Health.
- Dr. Julie Freischlag is CEO and Chief Academic Officer of Atrium Wake Forest Baptist, CEO and Executive Vice President (EVP) of Advocate Health, and EVP for Health Affairs at Wake Forest University.
- Mr. Steven I. Goldstein is CEO of System Integration at the University of Rochester Medical Center.
- Ms. Stephanie Reel is Assistant Professor at the Johns Hopkins University School of Medicine, Division of General Internal Medicine.
- Ms. Antoinette Royster is a patient participant in NIH research and a patient advocate.

Mr. Leslie remarked on the potential consequences of budgetary challenges on the pace of biomedical discovery. The previous NIH budget of nearly $49 billion ranked the organization as the largest public funder of biomedical research in the world, supporting 300,000 scientists at more than 2,500 institutions, including many cutting-edge medical centers. NIH is not only a funder of research but also an engine of progress.

The CC is the largest hospital in the country devoted exclusively to clinical research and has provided care to more than one-half million patients, the majority of whom are enrolled in cutting edge clinical trials. The strength of the CC depends upon a vibrant, well-funded research ecosystem across all of NIH; research delays will mean fewer breakthroughs and therapies and, ultimately, fewer lives saved.

Mr. Leslie thanked Board members for providing the insight and oversight that keeps the CC strong and ethical.

NIH Director's Remarks

Nina F. Schor, M.D., Ph.D., Deputy Director for Intramural Research (DDIR), NIH, and Designated Federal Official, NIH CCRHB

Mr. Leslie introduced Dr. Schor as the designated federal official.

Dr. Schor described NIH challenges and achievements, highlighting the importance of sustained federal investment in medical research. Maintaining a focus on the NIH mission and vision has never been more important than in the present environment of budget cuts and workforce reductions.

Introduction of Leadership

Dr. Schor announced new NIH leadership.

- Jayanta Bhattacharya, M.D., Ph.D., was sworn in as Director of NIH on April 1, 2025. A health economist by training and a physician, Dr. Bhattacharya has been very rapidly informed about the state of affairs at the CCRHB.
- Matthew Memoli, M.D., M.S., is Principal Deputy Director of NIH. He is a senior clinician with more than 20 years at NIH.
- Jon Lorsch, Ph.D., is Acting Deputy Director for Extramural Research and has served as director of the National Institute of General Medical Sciences since 2013.
- Nicole Kleinstreuer, Ph.D., is Acting Deputy Director for Program Coordination, Planning, and Strategic Initiatives within the NIH Office of the Director. She previously served as director of a toxicology program at the National Institute of Environmental Health Sciences.

Dr. Schor noted that nine NIH institutes and centers (ICs) are led by acting directors. These include Pius Aiyelawo, M.P.A., FACHE, Clinical Center; Carolyn Hutter, Ph.D., National Human Genome Research Institute; Jeffery K. Taubenberger, Ph.D., National Institute of Allergy and Infectious Diseases; Alison Cernich, Ph.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development; Jennifer Webster-Cyriaque, D.D.S., Ph.D., National Institute of Dental and Craniofacial Research; Andrea Beckel-Mitchener, Ph.D., National Institute of Mental Health; Monica Webb Hooper, Ph.D., National Institute on Minority Health and Health Disparities; Courtney F. Aklin, Ph.D., National Institute of Nursing Research; and Stephen Sherry, Ph.D., National Library of Medicine.

Make America Healthy Again Agenda

Dr. Schor outlined key themes from the Make America Healthy Again agenda set by Robert F. Kennedy, Jr., Secretary of the Department of Health and Human Services (HHS). These include combatting chronic disease, prolonging healthy life, and understanding environmental and behavioral contributors to disability and illness. The agenda emphasizes obesity, autism, and Alzheimer's and Parkinson's diseases and eliminates research on diversity, equity, and inclusion and gender ideology.

A current snapshot of NIH intramural labs focused on chronic diseases or conditions and underlying mechanisms of chronic conditions.

Other NIH leadership priorities include incentivizing public access to therapies including drugs and devices; enhancing academic freedom at NIH; and developing novel alternative (non-

animal) models with which to study and combat disease. Over the past 10 years, NIH has significantly decreased the number of animals and the phylogenetic class of the animals used in research.

Dr. Schor described federal-wide workforce reduction efforts, including incentivized retirement offerings, dismissal of probationary employees, non-renewals of term employees, centralization of administrative functions, dissolution of Federal Advisory Committee Act (FACA)-governed committees, and reductions-in-force. Additional distractions and impediments have included freezes on conference participation, hiring, publications, study initiation, and travel; most of these freezes have been lifted.

Dr. Schor listed CC accomplishments since January, including receipt of the Press Ganey Pinnacle of Excellence Award, Nursing Magnet with Distinction™ status, AAALAC International certification of Animal Care and Use Programs, and faculty elections to the National Academy of Medicine, National Academy of Science, American Society of Clinical Investigation, and Association of American Physicians.

Discussion

The following discussion ensued:

- Ms. Royster commented on the atmosphere at NIH when she visited in March and was happy to hear that morale is beginning to rise again. She noted that many people are not familiar with the great work that NIH is doing and supporting, and she suggested working with PBS (the Public Broadcasting System) to shine a light on all the good work that NIH does. Dr. Schor responded that, in the past, self-promotion was viewed as inappropriate for NIH and the scientific community. The public tends to accept negative allegations due to one-sided reporting.
- Mr. Leslie noted that communications staff are no longer at the CC. Mr. Aiyelawo reported that Donovan Kuehn is Acting Chief of Communications.
- Dr. Devaskar commented on the importance of animal models in development of gene therapy and cellular therapeutics for children and adults and asked about efforts to expand that expertise at the CC. Dr. Schor responded that the current administration has endorsed development of non-animal models with an aim of substantial replacement of animal models after validation of non-animal models. But there is no ban on the use of animal models and it is understood that these models may be the best models for specific applications. The current administration prohibits NIH from working on or funding studies involving puberty blockers in children but does not restrict gene therapy studies. A gene therapy initiative funded by the Office of Intramural Research and several NIH institutes in partnership with industry is focused on improving customization of subtypes of adeno-associated viruses that are used as vectors in gene therapy. Although the contracting officers who managed the industry relationships were released from the NIH workforce, Dr. Bhattacharya is working with HHS to enable rehiring these critical members of the workforce.
- Dr. Devaskar asked about plans to negate misinformation at the NIH. Dr. Schor replied that addressing misinformation is a delicate dance. NIH continues to communicate with the public via the NIH Catalyst newsletter and the Speaking of Science podcast and is hoping to embark on a public school campaign.

NIH Clinical Center Acting Chief Executive Officer Update

Pius Aiyelawo, M.P.A., FACHE, Acting CEO, Chief Operating Officer (COO), NIH CC

Mr. Aiyelawo described the past few months as a period of reflection for the CC organization. He thanked Mr. Leslie for his expertise and support as the CC navigated unchartered waters and expressed his appreciation to the outstanding CC leaders and team members who have ensured that patient partners continued to receive safe and quality care throughout this time.

NIH Director Bhattacharya

Mr. Aiyelawo highlighted Dr. Bhattacharya's tour of the CC and summarized his message delivered to all NIH staff on April 1, 2025. The new NIH director's top priorities include a focus on improving population health, research reproducibility, rigor, innovation, collaboration, safety, and transparency as well as academic freedom. These priorities align well with the guiding principles of the CC strategic plan—excellence in clinical scientific discovery and application; compassion for patients, families, and one another; innovation in preventing and solving problems; accountability for optimal use of all resources; and commitment to professional growth and development.

Celebrations, Honors, and Awards

April marked National Volunteer Month. Approximately 80 volunteers—from recent college graduates to retirees—currently assist patients in departments throughout the CC.

The CC celebrated Nurses Week during May 5–12 with a "Courage to Soar" theme. According to CC Chief Nurse Office Dr. Barbara Jordan, CC nurses strive for excellence in clinical care, customer service, research activities, and creation of a positive practice environment.

Mr. Aiyelawo summarized recent honors, including the Press Ganey Pinnacle of Excellence Award to B2 Radiation Oncology and Dowling Apheresis Outpatient Services. Former CCRHB Chair Dr. Norvell Coots was honored posthumously with the 26th Matthew F. McNulty, Jr. Award in recognition of his significant contributions to healthcare sustainability, quality, and customer/patient satisfaction. The CC continues to recognize approximately 70 to 80 length-of-service recipients each quarter.

Timeline of Recent Changes at NIH and the CC

Mr. Aiyelawo outlined changes at the CC since the CCRHB meeting on October 18, 2024.

- An NIH-wide hiring freeze was implemented on January 20, 2025, and extended through July 15, 2025. This applies to the appointments of three pending members of the CCRHB.
- FACA meetings scheduled between January 20 and April 17, 2025, were canceled.
- Communications were paused on January 24, 2025.
- Dr. James Gilman retired as NIH CC CEO on January 31, 2025.
- Mr. Pius Aiyelawo was appointed acting CEO of the NIH CC on February 1, 2025.
- Leadership of 11 CC departments and offices recently retired or departed, including the following: Mr. Justin Cohen, Communications & Media Relations; Dr. Nusrat Rabbee, Biostatistics; Dr. Christine Grady, Bioethics; Ms. Karen Kaczorowski, Patient Support Services; Dr. Gwenyth Wallen, Translational Bio-Behavioral Health Disparities;

Mr. Juris Mohseni (deceased), Office of Financial Resource Management; Dr. Michele Evans, Safety Officer; Ms. Sophia Grasmeder, Patient Representative; Dr. Lisa Portnoy, Animal Program; and Dr. David Wu, Pain & Palliative Care Service.

- Construction of the CC Surgery, Radiology, and Laboratory Medicine (SRLM) wing continued.

CC Statistics

Mr. Aiyelawo reported that the CC year-to-date average daily census through April 30 is lower, due to departure of some investigators, and enrollment in trials is down. Length of patient stay has increased, but all other patient activity measures (in-patient admissions and days, average daily census, outpatient total visits, clinical visits, day hospital visits, and new patients) have dropped compared with the previous fiscal year.

Masking Requirement Update

CC masking requirements are based on Maryland influenza and other seasonal virus rates. Masking was required in patient care areas between November 4, 2024, and April 10, 2025. Effective April 11, 2025, masking is optional and upon request.

What to Expect in Summer and Fall 2025

Mr. Aiyelawo noted that, during the summer and fall, the CC will continue to focus on well-being of staff, patients, and research participants as well as care of pediatric patients. More retirements are likely to take place.

From a budget perspective, fiscal year 2025 has been satisfactory, and NIH senior leadership has expressed support for the CC mission. Mr. Aiyelawo expects funding to be sufficient to allow the CC to continue to provide safe and quality care to its patient partners.

CC Quarterly Report

Mr. Aiyelawo indicated that the CC Quarterly Report prepared by Dr. David Lang, Chief, Office of Patient Safety and Clinical Quality, is provided to CCRHB members prior to every meeting. This report will be posted on the CC website for public viewing following the CCRHB meeting.

Discussion

The following discussion ensued:

- Dr. Chin noted the unprecedented number of individuals in acting roles across NIH and asked what limitations this status places on their ability to deliver on the NIH mission.
- Mr. Aiyelawo noted that someone in an acting position has full authority to execute the roles and responsibilities of the position. The CC CEO position was advertised in late December 2024 but then cancelled. Although he expects the hiring freeze to be lifted in mid-July, recruitment might take three to six months. In the meantime, while acting as CEO, Mr. Aiyelawo continues in his role as COO, with support from an excellent CC leadership team.
- Mr. Baum expressed interest in seeing a chart comparing the number of authorized positions versus currently filled positions for each CC department. This would present a meaningful picture and highlight potential risks if those gaps are not filled.
- Mr. Aiyelawo responded that a total of about 1,828 staff remain on board; about 70 have left. He stated categorically that these changes have not affected delivery of safe and

effective clinical care, and he sees no risk at all in terms of the CC's ability to sustain and deliver safe and quality care.

- Mr. Baum noted that Justin Cohen's departure left a gap in two critical areas that have an impact on the numbers. He suggested including the patient voice in plans for improved communications and patient recruitment.

Regenerating Sight: First-in-Human Restorative Surgery for Age-Related Macular Degeneration Using Autologous Cell Therapy

Kapil Bharti, Ph.D., Scientific Director, National Eye Institute (NEI), and Senior Investigator, NEI Ocular & Stem Cell Research Section; Richard Lee, M.D., Ph.D., Clinical Director, NEI; M. Teresa Magone De Quadros Costa, M.D., Chief, Consult Services Section, NEI; and David F. Stroncek, M.D., Chief, Transfusion Medicine Department, NIH CC

Dr. Richard Lee introduced the presentation, noting that this work exemplifies the translational and transformative research that can be conducted especially well within the NIH intramural program and the CC in particular. He introduced NEI Scientific Director Dr. Kapil Bharti and the senior investigator leading the regenerative medicine program for eye diseases. Dr. Teresa Magone De Quadros Costa is the principal investigator and physician leading the clinical trial, and Dr. David Stroncek leads the cell manufacturing facility at the CC.

Age-Related Macular Degeneration (AMD)

Dr. Kapil Bharti provided an overview of the prevalence, impact, and severity of AMD, which affected 19.8 million Americans in 2019 and is expected to affect 288 million people globally by 2040. AMD is responsible for severe vision loss in individuals over age 55 in the developed world. Advanced dry AMD—called geographic atrophy—is a progressive disease, with 50% of patients losing two lines of vision every 2 years.

The macula is a central retinal part of the vision system responsible for daylight and color vision. The retinal pigment epithelium (RPE) is the bottom retinal layer situated between the photoreceptors and the choroidal capillaries that supply blood to the retina. Thus, the RPE supports the health and functioning of the overlying photoreceptors. In AMD, the RPE cells die off, leading to degeneration of the photoreceptors, capillary loss, and eventual blindness.

Therapeutic Approach

Surgeons and physicians hypothesized that implanting an RPE graft with all the structural, anatomical, and functional features required to support the photoreceptors would rescue the photoreceptors and stop AMD progression. Previously, this surgical procedure was successful in a small number of patients, which provided proof of concept for the next step—making a patient-specific RPE graft in a dish and delivering it to the right position in the eye at the right time to try to stop disease progression.

Dr. Bharti described the platform technology used in the CC Center for Cellular Engineering to make patient-specific eye tissue from induced pluripotent stem cells (iPSC). The process begins with deriving iPSCs from the patient's own blood cells followed by quality control (QC) checks. A stepwise developmental biology approach is used to reprogram cells to differentiate into RPE cells, followed by additional QC. RPE cells are placed on a biodegradable scaffold to form three-dimensional tissue layer, which is transplanted into the patient's eye where it is expected to replace dying RPE cells and remain in place for the rest of the patient's life.

Unique challenges associated with replacement cell therapies include the inability to track transplanted cells. In this application, ocular imaging enables tracking of the transplanted graft. Robust manufacturing and quality control mitigate the possibility of transplanted cells becoming rogue. Short- and long-term immune reaction to the transplant is mitigated by using the patient's own stem cells.

Dr. Bharti shared data from the preclinical assessments that formed the foundation for phase I/IIa investigational new drug (IND) application. Biomarkers and convolutional neural networks (CNNs) were used to assess product purity to ensure that the graft comprises RPE cells rather than iPSCs. CNNs measured cell hexagonality, a characteristic that increases as RPE cells mature. This CNN became the first artificial intelligence (AI) QC method approved for cell therapy by the U.S. Food and Drug Administration (FDA).

Dr. Bharti showed examples of non-invasive retinal imaging for long-term follow-up of transplanted human RPE patches in pigs. Comparative images indicated that the transplanted tissue not only regenerated photoreceptors but also the choroid capillaries below the transplant, preventing photoreceptor death.

Key Elements of the Clinical Trial

Dr. Magone presented an overview of the clinical trial that is underway to assess the safety and preliminary efficacy of this transplantation approach in humans—can the surgery and implantation be performed safely in humans, does the implant raise any long-term safety concerns, and does the treatment restore function? Safety will be determined by assessment of visual acuity change and summary of adverse events 12, 24, and 60 months after transplantation as well as changes in microperimetry and multifocal electroretinogram responses.

Eligibility criteria include age 55 or older and general health compatible with surgery and immunosuppression. The first cohort will enroll five patients with vision of 20/100 or worse related to geographic atrophy, followed by seven additional patients with vision of 20/80 or worse related to geographic atrophy. Surgery is performed after approval is received from the Data and Safety Monitoring Committee. Eligibility criteria include age 55 or older and general health compatible with surgery and immunosuppression. Because these are older patients who have multiple comorbidities, the trial team will engage caregivers and implement enhanced medical monitoring.

Dr. Magone outlined the consent process, which emphasizes that this is an investigational trial rather than a treatment, potential risks related to surgery and immunosuppression, and the long follow-up period. She noted that immunosuppression begins one month before surgery and continues for approximately three months after.

Trial partners include Dr. Stroncek's team at the CC Center for Cellular Engineering as well as the Internal Medicine and Anesthesia Departments. Dr. Magone noted that cells expire within 2 days of manufacturing, so the process requires close coordination with the clinical team. Because the transplantation is a novel low-volume, high-risk surgical procedure, the complete surgical team receives dedicated training time with the preclinical and clinical teams, including sessions in the main operating room and in an animal facility.

Postoperative care involves a face-down position for about one week following the procedure because of the gas bubble that stabilizes the graft inside the eye and weekly visits to ensure detection of any adverse events and enable mitigation of possible complications.

Dr. Magone noted that this is the first autologous iPSC-derived cell therapy phase I/IIA trial that received an IND approval from the FDA. Two patients have received transplants in the study. The trial has enabled other autologous phase I INDs in non-ocular spaces.

Discussion

The following discussion ensued:

- Dr. Chin applauded the accomplishments. He asked about the causal mechanism underlying AMD and whether the transplanted cells might undergo the same degeneration. Dr. Magone explained that the causes of AMD are multifactorial, such as genetic and environmental (e.g., smoking). The hope is to avoid degeneration of the implanted cells, but because this is a phase I trial, longevity of the RPE graft is not known. The central macula is the most perfused area in the retina.
- Dr. Bharti added that inflammation, oxidative stress, and aging processes are thought to lead to degeneration of these cells. These processes occur with time, but it is hoped that the freshly transplanted cells would require another 80 years to reach that stage. The continuing mechanistic studies in pigs demonstrate that the cells retained for longer periods are regenerating parts of the retina.
- Mr. Baum asked how the visual acuity is measured and whether this technique could be used for central serous chorioretinopathy (CSCR) or keratoconus. Dr. Magone noted that acuity is measured as best corrected vision in the patient's worst eye. She noted that the CSCR disease progress is different from the AMD progress, but, in theory, small areas of cells could be replaced. Keratoconus can be treated via corneal transplants or corneal crosslinking; tissue growth approaches are not suitable because the underlying cause of keratoconus is weakness of the collagen fibers rather than cellular dysfunction.
- Dr. Devaskar commended the team on their phenomenal work and asked about potential for use in other retinal disorders, such as retinal detachment due to oxygen toxicity. Dr. Magone responded that if the trial is successful, the same principle might be implemented to treat other degenerative retinal diseases. In the future, it might be possible to replace the retina. This is just the start.

Magnet with Distinction™ Designation

Barbara A. Jordan, D.N.P., RN, NEA-BC, Chief Nurse Officer, Nursing Department, NIH CC

Dr. Jordan reported that the CC was designated as Magnet with Distinction™ by the American Nurses Credentialing Center in November 2024, one of only 22 organizations in the world to receive this elite award. This designation recognizes organizations that not only meet the 100 Magnet standards but also exceed those standards in more than 10 categories.

Site Visit Report

According to the ANCC executive summary, the site visit substantiated that all written expectations were met with no document deficiencies and exceeded expectations in the following areas:

1. The NIH CC Operating Room has achieved/maintained 51% or greater improvement in professional board certification (actual 62% improvement).

2. The organization achieved/maintained 80% or greater of professional registered nurses who have earned a baccalaureate or higher degree in nursing (actual 90.9%).
3. The organization's data for catheter-associated urinary tract infection outperformed the benchmark and comparison cohort provided by the vendor's national database for the majority of eight quarters on 100% of the inpatient units.
4. The organization's data for patient falls with injury outperformed the benchmark and comparison cohort provided by the national database for the majority of eight quarters on 100% of the inpatient units.
5. The organization's data for patient burns outperformed the benchmark and comparison cohort provided by the national database for the majority of eight quarters on 100% of the units.
6. The organization's data for unplanned postoperative transfers/admissions outperformed the benchmark and comparison cohort provided by the national database for the majority of eight quarters on 100% of the units.
7. The organization's patient experience data for courtesy and respect outperformed the benchmark and comparison cohort provided by the vendor's national database for the majority of eight quarters on 100% of the inpatient units.
8. The organization's patient experience data for patient engagement/patient-centered care outperformed the benchmark and comparison cohort provided by the vendor's national database for the majority of eight quarters on 100% of the inpatient units.
9. The organization's patient experience data for responsiveness outperformed the benchmark and comparison cohort provided by the vendor's national database for the majority of eight quarters on 100% of the inpatient units.
10. The organization's patient experience data for safety outperformed the benchmark and comparison cohort provided by the vendor's national database for the majority of eight quarters on 100% of the inpatient units.

Preparing for Redesignation

Dr. Jordan presented 4-year milestones toward maintaining the Magnet with Distinction™ designation. The process requires thousands of pages of documentation, including a gap analysis in year 1 (2025), interim reports due in year 2 (2026), application in year 3 (2027), and document submission and a site visit in year 4 (2028). Action items for the coming months include re-engaging the Magnet Document Team, initiating the recurring Magnet Ambassador Team and Magnet Steering Committee, and identification of narrative examples. Dr. Jordan noted that several Magnet team members have left the CC.

Dr. Jordan thanked the Board members who participated in the ANCC site visit and in community engagement activities.

Discussion

The following discussion ensued:

- Dr. Cunningham offered congratulations for this impressive achievement that reflects the important work that has been done. She commented on how impressed she was by the earlier story about the nurse who identified the use of VELCRO to manage instrument handoffs during ophthalmology surgery conducted in darkness, and she suggested this

would be a great narrative to highlight in the next application. Dr. Cunningham noted that this report was a tribute to leadership who persevere despite intense pressure.

- Mr. Baum commented that the award is a tribute to the quality of nursing staff throughout the CC and their role in making patients' lives better even through the systems that support direct patient care. He noted that many people do not realize the contributions made by the many nurses at the CC who are not directly engaged in patient care.

Report from the Office of the Chief Scientific Officer

Leighton Chan, M.D., Chief Scientific Officer (CSO) and Scientific Director, NIH CC

Dr. Chan provided a brief self-introduction, including his educational background and his research experience and focus areas. He served as Chief of the CC Rehabilitation Medicine Department from 2007 to 2024 and acting CSO from March 2023 to October 2024 when the position was formalized.

Dr. Chan described his current responsibilities. He reports to CEO Aiyelawo and supervises all funded investigators, staff scientists, and students. He also reports to DDIR Schor for all NIH clinical protocols related to timely and appropriate initial and ongoing scientific review and helps monitor compliance with required reporting of results from all CC clinical trials to ClinicalTrials.gov.

Vision

Dr. Chan outlined his vision for the CC-funded intramural program.

- Embrace the new NIH Director's major aims:
    - Improving population health by focusing on chronic diseases
    - Being ambitious and not afraid to fail
    - Maintaining safety and transparency
    - Reducing use of animals in research
    - Ensuring reliable results
    - Encouraging academic freedom
- Use research resources to support the recruitment and retention of CC clinicians.
- Demand excellence.

Dr. Chan's goals include moving CC research findings into the community, enhancing utilization of the CC as a clinical environment where investigators conduct their research, and recruiting and retaining the individuals required to run a high-quality hospital and providing them with necessary resources. In addition, he aims to retain the CC's standing as a top training ground for students and clinicians, which involves providing access to patients and a thriving set of labs as well as high-quality, motivated mentors.

CC Research Budget

Dr. Chan noted that the CC research budget (i.e., currently 4.3% of the CC overall budget) funds research in 12 departments—pediatrics, biostatistics and clinical epidemiology, bioethics, perioperative medicine, laboratory medicine, clinical care medicine, rehabilitation medicine, transfusion medicine, radiology and imaging sciences, translational biobehavioral and health

promotion, animal program, and the clinical pharmacology lab—35 investigators, 49 staff scientists, 74 staff clinicians, and 102 research students and visiting fellows.

Metrics of Success

Dr. Chan provided details on several metrics of success. In the past 18 months, CC authors have published approximately 800 papers in peer-reviewed journals (about 1.2 papers per day). Overall, 18 of these papers appeared in high-impact journals such as the *New England Journal of Medicine*, the *Journal of the American Medical Association*, *Nature*, and *Science*. Based on Board of Scientific Counselors reviews, most researchers are ranked as outstanding, the top level. Dr. Chan noted that two investigators received tenure in the past two years, and two more are up for tenure, including Dr. Sameer Kadri in the Critical Care Medicine Department who recently won the prestigious Oswald Avery Award from the Infectious Disease Society of America.

Dr. Chan described the Research Award for Staff Clinicians (RASCL) award system that is designed as an incentive to recruitment and retention of clinicians, given the NIH low salary structure. Each year, 5–7 two-year projects are selected for RASCL awards and funded at $60,000–$100,000 per year.

CC Research Project Highlights

Dr. Chan highlighted three CC research projects.

- Robotic Knee Exoskeletons in Children (Thomas Bulea, Principal Investigator [PI]) is designed to address the crouch gait in children with cerebral palsy and forestall several loss of mobility in adulthood. The project has progressed from concept and early technology through late phase technology to a commercially available, FDA-approved system in 8 years.
- Novel Fungal-Specific Positron Emission Tomography (PET) Tracer (Dima Hammoud, PI, and Dr. Rolf Swenson, Director, National Heart, Lung, and Blood Institute, Chemistry and Synthesis Center) aims to develop and validate imaging biomarkers in animal models of infection for translation to human applications. Fungal infections cause 75,000 hospitalizations and 7,000 deaths in the United States each year. An imaging biomarker approach surpasses existing tests that are highly invasive and not specific enough to be clinically useful. Next steps for the project include one-dose/one-species toxicity testing in rats toward human trials in 2025.
- Fully Automated Abdominal Computed Tomography Biomarkers for Type 2 Diabetes Using Deep Learning (Ron Summers, PI) applies an AI model to screen for early indicators of diabetes. The approach can detect changes in the pancreas years before patients are clinically diagnosed.

Discussion

The following discussion ensued:

- Dr. Chin asked how new restrictions on international trainees affect NIH. Dr. Chan responded that over time, it will be difficult to recruit visiting fellows from certain countries.
- Dr. Schor explained that initial restrictions on bringing in new fellows and students did not apply to clinical trainees who were needed for patient care in the hospital. Currently,

there are restrictions on bringing on individuals from countries on the State Department watch list or who receive any funding from a foreign country.

- Ms. Royster commented that the PET scans of the pancreas Dr. Chan had shown seemed very clear and wondered why pancreatic cancer is so difficult to diagnose. Dr. Chan replied that some types of pancreatic cancer are more aggressive than others, and some are more amenable to treatment. Noting that he is not an expert, he offered to put Ms. Royster in contact with someone who can address her question.
- Dr. Chan concluded by thanking Mr. Aiyelawo and Dr. Schor for their strong leadership and support during challenging times.

Telehealth at the Clinical Center

Patricia Coffey, M.S., RHIA, CPHIMS, CPHI, FAHIMA, Chief Health Information Officer, Health Information Management Division, Department of Clinical Research Informatics, NIH CC

Ms. Coffey presented an update on the CC virtual health program, which was established to connect patients and other partners in research with critical resources by leveraging innovative patient engagement tools and platforms toward seamless integration of virtual interactions and digital solutions into the care and research continuum.

When the program was established in April 2020, the Microsoft Teams platform was used. In February 2023, the CC transitioned to a telehealth platform.

Vision and Strategic Importance

The CC virtual health program vision is to promote access to pioneering clinical research through innovative telehealth strategies that prioritize patient safety and deliver high-quality clinical care. The program addresses challenges in modern healthcare within a research-intensive institution while supporting the NIH mission of turning discovery into health.

CC Patient Engagement Platforms

Ms. Coffey described functionality of the CC's integrated virtual health platform, ThinkAndor®. Current functions include virtual visits, virtual rounds, and a digital "front door" for appointment reminders and digital check-in. Screening questionnaires are in development. Planned functions include remote patient monitoring via devices that send data from the home to the CC, telesitting that offers close monitoring of patients while in the facility, and AI agents that provide ambient documentation.

Other virtual patient engagement solutions implemented by the CC include eICU, which supports centralized patient monitoring and surveillance; iMed Consent, which streamlines the informed consent process with electronic signatures; and the FollowMyHealth® patient portal. One additional solution is in a "go-live" phase: Mobile Patient Experience for preregistration collection and validation of patient demographics.

Key features of the web-based Andor® Health include integration with the CC Electronic Health Record (EHR) Clinical Research Information System (CRIS); patient list population for virtual rounds; single sign-on for staff using NIH credentials; virtual application support; and integration with patient portal for appointments. Andor Health complies with privacy and security requirements, using secure real-time transport protocol with encryption. The platform is

managed with Authority to Operate and Privacy Impact Assessment, and no recordings, visit data, or files are shared or stored by the Andor platform.

Ms. Coffey shared views of sample screens, including a dashboard, virtual rounding, questionnaire, and clinical trial workflow (care plan). The CC telehealth iPad cart has an updated battery holster with charging pass-through, a Bluetooth® speaker, updated iPad case, and laminated information card.

Key Performance Indicators over Time

Ms. Coffey reviewed key performance indicators over time, noting that the number of telehealth visits has remained steady with increases of approximately 6% each year. The number of unique patients with telehealth visits fluctuates; a recent drop may be attributed to the clinical trials that are currently active.

The telehealth visit success rate is above 95% and trending upward; reasons for unsuccessful visits (e.g., patient or physician unable to join) are being examined. The average patient platform ratings for video was 4.5 for April 2025; the target rating is 4.75.

Average visit lengths have trended down to around 60 minutes. Visit lengths may have been higher initially due to platform complexity. This is being monitored to ensure that visit conversations are meaningful.

Patient wait times have improved since January 2024, with about 40% of patients having no wait time. However, a fair number of patients are waiting 30 minutes for their provider to join. The support center is monitoring the dashboard to ensure that providers join, contacting providers if they have not joined within 10 minutes, and advising patients about the visit status.

Future Enhancements

The mobile patient registration platform will be fully implemented by the end of this year. Additional screening questionnaires are being prepared. Additional platform components will be analyzed (e.g., ambient listening and remote patient monitoring) to inform implementation if they are deemed necessary.

Work will continue to fully integrate virtual health platform with the CC EHR, monitor and improve on key performance indicators, explore e-consent options, and conduct a patient satisfaction survey.

Discussion

The following discussion ensued:

- Dr. Chin noted that, during the COVID-19 pandemic, requirements to hold licenses in every state where a physician practiced were relaxed, but that is no longer the case. Ms. Coffey responded that NIH legal counsel considers the federal employee's license to be portable to practice across the country.
- Dr. Freischlag commented on the value of telehealth, especially for postoperative patients, remote patient monitoring that makes it possible for acute care patients to go home sooner, and AI ambient notetaking.
- Mr. Baum asked about the reasons for the longer wait times and patient no-shows. Ms. Coffey responded that the team is exploring wait times across institutes and patient appointment types to identify trends. They will identify and address the causes.

- Dr. Freischlag remarked that she experiences what she termed "weird shows," where patients join appointments from their cars or in the grocery store.
- Ms. Royster asked about lab vendors for patients doing telehealth visits, especially for those in rural areas. Ms. Coffey reported that work is under way on a tract to centralize outside labs. Telehealth technology works well for connecting patients in rural areas with their providers.

New Clinical Center Electronic Health Record: Status Update

Jon McKeeby, D.Sc., M.B.A., Chief Information Officer, NIH CC; and Leslie Wehrlen, MSN, RN, OCN®, ACRP-CP®; CAPT (RET), U.S. Public Health Service; Deputy Chief, Office of Research Support & Compliance (ORSC); and Chair, EHR Executive Steering Committee, NIH CC

Dr. McKeeby provided background on the CC EHR modernization project. Since purchasing the Eclipsys clinical management software in 2004, three separate parent companies have controlled the product line: Eclipsys (2004–2010), Allscripts (2010–2022), and Altera (2022 to the present).The system is fragile, extremely complex, and difficult to maintain. Annual satisfaction survey scores are low, with numerous reported usability issues.

EHR System Goals

The goals for a new integrated EHR system are monolithic. The new system should streamline patient throughput and clinical workflow to provide the patient story in a concise manner; improve patient safety and quality of clinical care delivery; improve patient experience and engagement; improve decision-making and communication across clinical and research care roles; reduce complexity to support systems from security patching, configuration, and customization; and improve system availability.

Dr. McKeeby noted that funding for the update has not been provided. MITRE is working with the CC to prepare for procurement and working on all the procurement activities that can be developed without funding approval. He hopes to complete market research by the end of August.

EHR System Progress

Ms. Wehrlen described formation of the EHR Modernization Executive Steering Committee, which includes 22 members from different CC departments, ICs, administrative areas, and patients. The Committee developed a project rationale that prioritizes empowering dedicated patient care teams to deliver exceptional service and support; ensuring unparalleled security, efficiency, and reliability; drives innovation; promotes user satisfaction; and is responsive to evolving needs.

To date, requirements have been collected, documented, and are in final review; a CRIS User Requirement Survey was conducted; and clinical workflow modeling has begun. Modeling involves mapping step-by-step processes involved in delivery of patient care services. Each task, decision, point, and interaction with the EHR system is identified. Workflows are contained in service line groups, and related services lines are categorized as clinical, clinical research, or administrative.

Ms. Wehrlen reported on the status of the modeling work and shared a modeling example. Next steps will include additional workflow modeling, quality reviews, and training an internal NIH team to conduct the business process modeling work.

Discussion

The following discussion ensued:

- Dr. Chin asked whether the new EHR will include ambient recording of encounters. This function makes a big difference in terms of documenting clinician reactions to EHR implementation. Dr. McKeeby responded that this is included in the requirements along with some of the other virtual health functions.
- Mr. Baum complimented the way that Ms. Wehrlen had addressed Steering Committee concerns. During the open discussion, members realized that many things occur in a hospital that they did not fully understand and had opportunities to integrate those activities into the plan as they were identified.

Facilities Presentation to the Clinical Center Research Hospital Board

Dan Wheeland, P.E., Director, Office of Research Facilities, NIH

Mr. Wheeland provided a status update on facilities projects currently underway. These include:

- Refreshing outpatient exam rooms on floors 3, 7, 8, 9, 12, and 13 including new floor, wall, and ceiling finishes with built-in infection control
- Replacement of the drainage systems for the Building 10 courtyards
- Renovation to increase capacity of the post-anesthesia care unit and pre-op
- Upgrades to aging nurse station workspace, including appropriate lighting and properly installed electrical wiring and fixtures
- Renovation of the pharmacy and permanent intravenous admixture unit for compliance with new criteria and to increase capacity and house dedicated air handling equipment
- Provide compliant air handling equipment and space for radiopharmacy and cell labeling facility
- Renovate and modernize cell processing facilities
- Construction of the SRLM building, including a catheterization lab and interventional radiology
- Construction of a reliable electrical switching station and emergency generators for the Building 10 complex

In many cases, these projects require strong coordination to preserve the environment of care, infection control, and safety while conducting renovations near ongoing patient care operations.

SRLM Progress

The SRLM project involves additions to the existing facility and renovation of existing space. The project is currently in its second phase, which is construction of the new addition, with a target completion in December 2026. At that point, the National Cancer Institute will move into the upper floors of the addition. Spaces vacated by NCI will be renovated, enabling the Department of Radiology and Imaging Sciences to occupy contiguous space on floor 1 and the Department of Perioperative Medicine to occupy continuous space on floor 3.

Mr. Wheeland shared images of precast façade panels that were constructed offsite in a controlled environment as well as a utility vault project to house the new generators that will serve both the SRLM and the Clinical Research Center (CRC).

Mr. Wheeland highlighted the NIH investment in facilities projects and strong, visible progress made since the October 2024 CCRHB meeting.

Discussion

The following discussion ensued:

- Ms. Royster reported that she was very impressed by the renovated exam rooms she saw during her visit in March. She asked whether counter heights would accommodate someone in a wheelchair. Dr. Jordan explained that Nursing Department staff were involved in the design of the nurse stations. Nurse stations in patient care units have areas that meet Americans with Disabilities Act requirements and will be accessible where medical support assistants sit.
- Ms. Royster asked whether the building that houses the electrical equipment will use solar power. Mr. Wheeland responded that solar power required to support the facilities would exceed available space. However, one of the sustainability features incorporated into the facility is a green roof over the generator fuel tanks; this serves as a beautiful and functional terrace with views of the CRC expansion.
- Dr. Chin commented that morale in the face of adversity has been remarkable.

Closing Remarks and Adjournment

Mr. Leslie adjourned the meeting at 12:39 p.m. ET.

/s/

Nina F. Schor, M.D., Ph.D.

Executive Secretary and Designated Federal Official (DFO),
NIH Clinical Center Research Hospital Board

Deputy Director for Intramural Research, NIH

/s/

Mr. Jack Leslie

Chair, NIH Clinical Center Research Hospital Board

Former Chairman, Weber Shandwick
Senior Visiting Fellow, Duke Global Health Institute
Distinguished Professor, Georgetown University

Definitions of Abbreviations and Acronyms

AI	Artificial intelligence
AMD	Age-related macular degeneration
CC	Clinical Center
CCRHB	Clinical Center Research Hospital Board
CEO	Chief Executive Officer
COO	Chief Operating Officer
CRC	Clinical Research Center
CSO	Chief Scientific Officer
DDIR	Deputy Director for Intramural Research
EHR	Electronic health record
EVP	Executive Vice President
FACA	Federal Advisory Committee Act
HHS	Department of Health and Human Services
ICs	Institutes and Centers
NEI	National Eye Institute
NIH	National Institutes of Health
PET	Positron Emission Tomography
PI	Principal Investigator
QC	Quality Control
RPE	Retinal pigment epithelium
SRLM	Surgery, Radiology, and Laboratory Medicine
UCLA	University of California, Los Angeles