U.S. Department of Health and Human Services

National Institutes of Health

Thirty-First Meeting of the Clinical Center Research Hospital Board

June 12, 2026

Contents

Clinical Center Research Hospital Board

Leadership

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

Matthew J. Memoli, M.D., M.S., Principal Deputy Director, NIH, and Designated Federal Official, CCRHB

Members

David M. Baum, PMP, NIH Research Participant, Patient Advocate, and NIH CC Patient Advisory Group Participant (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; and Assistant Vice Chancellor of Children's Health, UCLA Health

Julie Freischlag, M.D., Ambassador, Advocate Health; former 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 (virtual)

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

Stephanie Reel, M.B.A., Former Chief Information Officer (CIO), Johns Hopkins University and School of Medicine; former Interim CIO, Washington University in St. Louis; and former advisor to CIO, University of Michigan

Antoinette Royster, NIH Research Participant, Patient Advocate, and Member, NIH CC Patient Advisory Group Participant

Executive Summary

The Clinical Center (CC) Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 31st meeting in person and via VideoCast on June 12, 2026. 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 9:15 a.m. ET. He introduced Dr. Jonathan Green as the new CC Chief Executive Officer (CEO), highlighting his extensive experience that contributed to a smooth transition into the position. He acknowledged the exceptional contributions that Mr. Pius Aiyelawo made during his tenure as interim CEO.

Matthew J. Memoli, M.D., M.S., Principal Deputy Director, NIH, provided updates on the CC, including development of the pediatric intensive care unit, efforts to improve opportunities for researchers at the CC, and the upcoming launch of a new NIH website. He discussed the importance of connecting clinical and basic scientists to facilitate translational research and a working group focused on revising criteria for clinical scientist evaluations.

Jonathan Green, M.D., M.B.A., introduced himself, sharing his background in clinical and basic research and his commitment to the CC's success. He outlined challenges involved in optimizing CC utilization and presented his vision for the CC, including building new and expanding existing partnerships within and outside of NIH. He emphasized the need for a strategic plan to define future directions of the CC and the NIH Intramural Research Program.

Mr. Aiyelawo, Chief Operating Officer, NIH CC, presented updates on recent CC staffing changes, honors and events, CC priorities, patient activity statistics, and the quarterly report on clinical and safety performance metrics. He concluded by responding to questions posed during the January 2026 CCRHB meeting related to concerns about limitations of the patient portal, an update on the new electronic health record (EHR) system, and ways to keep departing Clinical Fellows engaged with NIH and the CC.

Mr. Sunil Vasudevan, CC Chief Financial Officer and Acting Executive Officer, provided an overview of the CC Office of Patient Recruitment, which aims to accelerate access to NIH clinical trials. The office is exploring opportunities to increase referrals and enrollment, including creating an integrated, standardized patient referral platform as well as building partnerships with providers and provider networks.

Dr. Jon McKeeby and Ms. Leslie Wehrlen presented an update on procurement of a new EHR system for the CC. They highlighted limitations of the current system and the goals of reducing complexity and improving patient safety, quality of clinical care delivery, decision-making and communication across clinical and research care roles, and system availability.

Dr. James L. Gulley, Co-Director, Center for Immuno-Oncology, Center for Cancer Research, and Clinical Director, National Cancer Institute, presented a Gene Therapy Task Force proposal to establish an in-house vector production facility at the CC. The proposal cited significant cost savings and operational benefits, including the potential to produce multiple vectors annually. Dr. Gulley noted the additional staff and infrastructure required to support these activities.

The CCRHB is slated to meet again on October 16, 2026.

Dr. Green adjourned the meeting at 12:03 p.m. ET.

Meeting Summary

June 12, 2026

Welcome and Chair of the Board Overview

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

Mr. Leslie began the meeting at 9:15 a.m. ET and presented a gavel to Mr. Pius Aiyelawo in recognition of his contributions to the CC during his tenure as Acting Chief Executive Officer (CEO) of the CC. Mr. Aiyelawo is continuing in his role as Chief Operating Officer (COO).

Mr. Leslie reported that Dr. Cunningham was unable to attend the meeting.

Noting that CCRHB members had toured the Surgery, Radiology, and Laboratory Medicine (SRLM) wing prior to the meeting, Mr. Leslie asked all members of the Board to introduce themselves.

- Mr. David M. Baum is an NIH patient, a patient advocate, and a participant in the CC Patient Advisory Group.
- Dr. David C. Chin is a Distinguished Scholar at the Johns Hopkins Bloomberg School of Public Health and Johns Hopkins University School of Medicine.
- 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 at UCLA Health.
- Dr. Julie Freischlag recently retired from her positions at Atrium Wake Forest Baptist and Advocate Health and transitioned to an ambassador role at Advocate Health.
- Mr. Steven I. Goldstein is CEO of System Integration at the University of Rochester Medical Center.
- Ms. Stephanie Reel has served as a chief information officer (CIO) at Johns Hopkins University and Johns Hopkins School of Medicine, Interim CIO at Washington University in St. Louis, and advisor to the CIO at the University of Michigan.
- Ms. Antoinette Royster is an NIH patient and patient advocate and a participant in the CC Patient Advisory Group.

NIH Principal Deputy Director's Remarks

Matthew J. Memoli, M.D., M.S., Principal Deputy Director, NIH, and Designated Federal Official, CCRHB

Dr. Memoli welcomed the CC's new CEO, Dr. Jonathan Green, whose experience includes exposure to every aspect of research conducted at the CC. He acknowledged Mr. Aiyelawo for his hard work acting in the CEO position.

Dr. Memoli reported that the NIH Director's office has provided funding for the CC's pediatric intensive care unit (ICU), which will enable research with younger children and attract individuals with an interest in pediatric research to the CC.

The CC Special Clinical Studies Unit (SCSU) is actively training in preparation to care for Ebola patients and address related laboratory exposures.

Over the next year, Dr. Memoli and CC leadership will be working hard to improve utilization of the CC. For example, he is working with Roland Owens, Ph.D., the Acting Deputy Director for Intramural Research, to develop a strategy for incentivizing clinically oriented researchers to advance their careers at NIH and make them want to stay. Considerations include positive experiences and opportunities to conduct the research they want to do.

In addition, Dr. Memoli has been meeting with early career intramural investigators and discussing ways to connect basic science researchers and clinical researchers to advance translation of basic scientific findings. He noted that, once the new consolidated NIH website is launched, the CC website will list scientists by category or specialty area, regardless of Institute and Center (IC) affiliation, making it easier for internal and external collaborators to identify potential research partners and build connections. Dr. Memoli is also encouraging IC intramural programs to partner on new research projects.

Discussion

The following discussion ensued:

- Dr. Chin asked about barriers to collaboration between basic science and clinical researchers. Dr. Memoli described cultural and structural barriers. Pharmaceutical companies and academic centers are wooing strong Fellows and clinical scientists with better pay. Improving opportunities for advancement would help NIH retain talented scientists, but it would require a culture change. For example, evaluation criteria should reflect how progress is defined in the context of clinical research; for example, protocols written rather than publications. Lack of information about what other NIH intramural researchers are doing is another barrier to collaborations.
- Dr. Devaskar suggested that participation in team science should be included in criteria for evaluating clinical scientists. Moving a protocol to fruition requires patience and fortitude, and pediatric clinical trials take even longer because of the extensive follow-up required. Dr. Memoli replied that Dr. Bhattacharya's replication initiative includes updating evaluation criteria to include not only high-profile papers but also team science, data sharing, mentoring, and participating in reviews. The working group in charge of these updates is likely to issue Requests for Information (RFIs).
- Mr. Baum recommended ensuring that the research and clinical information systems are interoperable without unnecessary redundancy. He commented on the disconnect between clinical researchers and academic researchers, some of whom seem uncomfortable interacting with patients.
- Ms. Royster asked how many patients can be sequestered in the SCSU if there is an outbreak. Dr. Memoli replied that the SCSU has seven beds, but the unit may take fewer than seven patients depending on level of patient acuity.
- Mr. Leslie asked about a rule proposed by the Office of Management and Budget requiring that all discretionary grants be approved by senior political appointees prior to issuance. Dr. Memoli explained that NIH is already in compliance with the proposed rule because the NIH Director is a political appointee and has the final word on NIH grants.

NIH Clinical Center Chief Executive Officer Update

Jonathan Green, M.D., M.B.A., CEO, NIH CC

Dr. Green acknowledged NIH leadership for their commitment to the growth of the CC and expressed appreciation to CCRHB members, Mr. Aiyelawo, the entire CC team, and research participants for their contributions to the important work of the CC. He outlined his vision for optimizing CC utilization and helping the CC continue to thrive.

Dr. Green's training included work in inner city hospitals in Detroit and Boston, clinical and research Fellowships at the University of Michigan, and lab-based postdoctoral training at the University of Chicago. He started his own lab at Washington University School of Medicine before joining NIH as Director of the Office of Human Subjects Research Protections in 2018. Dr. Green continues to serve as an attending physician at the CC.

Dr. Green described interaction with patients, investigators, and clinicians as a strong motivating factor for his work. His engagement in global health included a 6-week tour through Southeast Asia aboard the U.S. Naval Ship Mercy, a Partners In Health mission in Liberia during an Ebola epidemic, and working with ICU staff of a hospital in Ethiopia to increase their capacity for taking care of critically ill persons.

Priorities

Dr. Green designated the following as priorities for the CC:

- Providing the best possible care to research participants
- Conducting and supporting clinical research that advances knowledge and improves human health
- Expanding existing partnerships and building new ones to support groundbreaking research
- Ensuring that the CC is optimally utilized and delivers fully on its value proposition by conducting research that only the CC can do and using resources wisely, efficiently, and effectively to advance the mission of NIH and the CC

Dr. Green's strategy for realizing these priorities is to:

- Take care of our people, making sure the CC is a place where people want to come to work and stay.
- Take advantage of the unique CC nature and capabilities to support research that cannot or will not be done elsewhere.
- Create a nimble, forward-facing infrastructure that is responsive to the needs of research participants, the NIH community, and the public.
- Operate in an efficient, effective, transparent, and sustainable manner.
- Expand partnerships and identify new opportunities for growth. Partners include research participants, NIH ICs, and the extramural community.
- Increase awareness of the CC.

Challenges and Opportunities

The CC faces challenges such as the cycle of investigator and staff departures, protocol closures, and a declining patient census. Yet, there are opportunities to reduce frictional forces and increase incentives. For example, NIH leadership is working toward making intramural and extramural pay scales more equitable. The CC has resources to conduct translational research that is difficult to reproduce elsewhere.

Dr. Green is working closely with colleagues in the NIH Office of Intramural Research to define a strategic plan for intramural research across NIH so that the CC can prepare to support intramural research as a group effort.

Discussion

The following discussion ensued:

- Dr. Chin asked Dr. Green to elaborate on the strategic planning process. Dr. Green noted that the leadership group is discussing CC priorities and working with the NIH clinical directors and Dr. Owens to gather the IC clinical directors to share their goals and identify areas of commonality. This will help inform directions for the CC to grow.
- Mr. Baum noted that the CC metrics reported to the CCRHB do not distinguish between new and returning patients; real growth comes from new patients. He noted that the local medical community needs education about NIH to break down fears about losing patients to the CC. Mr. Baum commented that negative interactions with CC Research Fellows have led some patients to drop out of protocols. He noted that some human resources regulations disincentivize clinical and administrative staff from remaining at the CC and hinder succession planning. Dr. Green agreed that better metrics are needed, and he is working with data experts to identify what is feasible and can be presented in a meaningful way. Impact of scientific output is challenging to measure. In terms of the local medical community, the CC offers unique treatment options to benefit their patients, so referrals should be presented as a win-win situation. Dr. Green apologized for the negative interactions with CC team members and asked Mr. Baum to reach out when those happen so that leadership can address the issues.
- Dr. Devaskar asked how Dr. Green envisions partnering with the extramural community. In response to Mr. Baum's remarks about negative interactions with clinical staff, she noted that UCLA's CICARE patient care model includes training for every team member who comes into contact with a patient; something like that might address the rough edges when interacting with patients. Dr. Green responded that partnerships will be expanded in collaboration with NIH leadership; some of the local academic institution partners have expressed interest in expanding those partnerships, and he is confident there are mechanisms in place to make that happen. Some of this will be accomplished by increasing awareness of protocols, and he is hopeful that the new electronic health record (EHR) system will support communication with other facilities. The current EHR does not, which has been a barrier to care of patients who are being treated at other institutions.
- Ms. Royster noted that she encounters doctors who have no idea what NIH does and are under the impression that it is primarily an animal research facility. Dr. Green agreed that outreach efforts need to grow, in concert with NIH leadership and across ICs and clinical research programs.

NIH Clinical Center Chief Operating Officer Update

Pius Aiyelawo, M.P.A., FACHE, COO, NIH CC

Mr. Aiyelawo acknowledged CC staff for their unwavering support throughout his term as Acting CEO and welcomed Dr. Green as the 11th CC leader since its opening in 1953.

Staffing Updates

In February, Dr. Tom Burklow assumed the role of Acting Chief of the Office of Patient Safety and Quality Care (OPSQC), while continuing to serve as Director of the Office of Clinical Research Training and Medical Education, Senior Research Physician, Staff Clinician, and Chief of the National Heart, Lung, and Blood Institute Pediatric Cardiology Consult Section. A search is under way to fill the OPSQC position.

Dr. Barbara Jordan will retire as Chief Nurse Officer, NIH CC, in October. Dr. Jordan was instrumental in leading the CC to achieve the Magnet with Distinction® designation from the American Nurses Credentialing Center in 2024, having demonstrated the CC's excellence in nursing care, interdisciplinary collaboration, and a positive practice environment.

Mr. Aiyelawo acknowledged Mr. Dan Wheeland for facilitating the CCRHB's tour of the SRLM wing. Mr. Wheeland will present a progress report at the CCRHB's October meeting.

Honors and Events

Mr. Aiyelawo summarized recent CC events and honors.

- On May 7, the first annual Clinical Fellows Committee Research Showcase featured 52 posters from a wide range of specialty and subspecialty programs sponsored by NIH ICs.
- The CC honored its nursing staff during Nurses Week, May 6–12, 2026, recognizing the essential role of the CC's exceptional nurses and their daily contributions to patient care and the clinical research environment.
- The 82 Fellows in the NIH CC Graduate Medical Education (GME) Class of 2026 were celebrated during a graduation ceremony on Friday, June 5, 2026. A few of them will stay on as staff clinicians.

CC Priorities

Mr. Aiyelawo noted that the five priority focus areas he presented at the January 2026 CCRHB meeting align well with the priorities Dr. Green presented. CC leadership will continue to focus on accomplishing a safe and seamless transition to the new SRLM wing, which will make a significant difference in terms of additional capabilities the CC brings to support its patients.

CC Statistics

The fiscal year 2026 (FY26) year-to-date average daily census indicates a steady climb, with daily numbers in the 80s. Mr. Aiyelawo noted that the CC lost some investigators who were bringing in a lot of patients, and as those vacant positions are filled, the numbers should continue to rise. He reported growth in transplant, medical oncology, surgical oncology, and metabolic programs. Compared with FY25, the 8-month census average has decreased by 10.1%, and patient visits have decreased by 10.3%. The CC conducts an average of 600 telehealth visits per month.

Follow-Up on CCRHB Requests from the January 2026 Meeting

Mr. Aiyelawo provided responses to CCRHB questions from the January 2026 meeting:

- Ms. Amanda Grove, Acting Chief of the Health Information Management Division, responded to a concern about the process for patients to access lab results and the inability to link results to specific visits. FollowMyHealth® is an off-the-shelf product that does not offer filtering or selection options for lab results. The lack of workflow is a known concern, and this feature is a requirement for the new EHR/patient portal. In the meantime, care team members can post specific lab results into progress notes on the Clinical Research Information System (CRIS) and share them with external resources. Furthermore, when new lab results become available, a comprehensive summary posted in the patient portal on the following business day can be forwarded to an external provider.
- CCRHB members requested a progress update on the new EHR system. Dr. Jon McKeeby and Ms. Leslie Wehrlen are scheduled to present a status report during today's meeting.
- Dr. Joyce Chung responded to questions about ways the CC is keeping Fellows engaged after they complete their Fellowships, such as a Fellow alumni organization. Currently, the CC maintains a database that enables programs to query their graduates about their post-NIH career activities and accomplishments. Dr. Chung will raise this question with the GME Committee.

Mr. Aiyelawo noted that the Foundation of the National Institutes of Health (FNIH) recently launched a new NIH alumni network designed to keep former NIH staff connected, engaged, and inspired. The network will provide former NIH staff with lifelong opportunities for engagement and professional development, including mentoring the next generation of scientists.

Quarterly Report on Clinical and Safety Performance Metrics

Quarterly reports from the CC OPSQC are provided to CCRHB members prior to each meeting in person or via secure access file. In addition, the report is posted after each meeting on the CC Clinical and Safety Performance Metrics Executive Dashboard.

Clinical Center Patient Recruitment

Sunil Vasudevan, M.E., M.S., Chief Financial Officer and Acting Executive Officer, NIH CC

Mr. Vasudevan presented an overview of the Office of Patient Recruitment (OPR) team, which was part of the CC communications team that is now within the NIH Office of Communications and Public Liaison (OCPL).

The team includes Ms. Nikita Curry as supervisor of patient recruitment and Ms. Mandy Mansaray as program coordinator of the Clinical Research Volunteer Program.

The OPR mission is to accelerate access to NIH clinical trials through innovation, digital transformation, and participant-centered recruitment. The OPR provides ICs and intramural investigators with recruitment services, including recruitment strategy development and evaluation of strategy effectiveness, community outreach, research match support, patient screening and referrals, and data optimization.

Mr. Vasudevan noted that OCPL is developing an NIH-wide communication strategy and adapting to the consolidated media platforms for outreach activities.

The National Cancer Institute (NCI), the National Human Genome Research Institute, the National Institute of Allergy and Infectious Diseases, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the National Institute of Mental Health account for 80% of requests. More ICs are requesting assistance.

Contact Center information specialists help members of the public find studies of interest, match them to a trial, and connect them to NIH research teams. Mr. Vasudevan explained that contact volume has dipped, risen, and dipped again because of federal shutdowns, policy changes, and other factors.

The OPR payment team helps process payments to healthy volunteers and provides guidance and training to research teams on study participant compensation. In October 2025, payment processes were changed to comply with an Executive Order requiring that payments be issued via direct transfers to bank accounts or debit cards. The debit cards were problematic during rollout, and the team is working with solutions such as virtual debit cards as well as wire transfers for international payments.

Mr. Vasudevan explained that CC name recognition and relationships with physicians as referral partners affect OPR success. Opportunities to increase referrals and enrollment include creation of an integrated, standardized patient referral platform; marketing activities, including branding; outreach to provider networks and partnership formation; and intake systems for improved patient and volunteer experience.

The OPR is investing in technology and infrastructure enhancements, such as phone system upgrades for increased reliability. The call center is testing a TrialGPT tool. In addition, the OPR will test a chatbot, under development with the National Library of Medicine, with which potential patients can interact.

Discussion

The following discussion ensued:

- Ms. Reel noted that the OPR seems to be working with several very different populations—healthy volunteers, patients, and physicians—which would require different strategies. She asked whether the same people are charged with doing all of this work. Mr. Vasudevan responded that this is the case. Mr. Aiyelawo explained that the OPR team is not providing these services for every IC.
- Dr. Chin suggested that the OPR move from direct outreach to every group to a more wholesale approach; for example, aggregations of patients and state-level medical societies. Mr. Aiyelawo responded that OCPL is building a broad strategy for the entirety of NIH.
- Mr. Baum asked how the OPR accounted for the lower percentage of patient conversions in 2025. The overall call rate was down, but the percentage of calls was also down. He suggested targeting the National Eye Institute and National Institute of Neurological Disorders and Stroke to increase activity. Mr. Vasudevan replied that many factors led to the lower conversion rate, including staff turnover among the IC teams who answer questions about studies.

- Mr. Baum recommended developing a patient alumni organization, similar to the Fellows alumni group that the FNIH recently announced. There are thousands of patients who could be ambassadors for CCRHB. Mr. Aiyelawo agreed that this is an opportunity. Mr. Leslie commented that volunteers relieve some of the burden for the CC and noted that some hospitals oppose having patients talking to each other; some training would be required to standardize what patient ambassadors can say.
- Ms. Royster suggested that content creators could help recruit healthy volunteers and patients with rare diseases.
- Dr. Devaskar was impressed by the use of artificial intelligence (AI) tools and asked about the OPR team's experience with social media. For example, has the team considered using influencers to counteract anti-science misinformation? Mr. Vasudevan noted that the OPR had its own social media accounts prior to the NIH communication consolidation; OPR messages are disseminated via the NIH account.
- Dr. Green commented on the need to find channels and new partners to increase awareness of the CC capabilities among patient and provider communities. The message needs to highlight what distinguishes the CC from others. There is much room to grow. The entire intramural program must be engaged.
- Mr. Baum suggested that the NIH website should have a section targeting the health care provider community, as opposed to the general public, or a section educating physicians about what NIH is and what it does that can benefit them and their patients. Dr. Green agreed that this was a good idea.

New Clinical Center Electronic Health Record Status Update

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

Dr. McKeeby provided an update on the CC EHR modernization project. CRIS is more than an important tool for patient care; it is also a mission-critical engine for scientific discovery.

Current System Status

Dr. McKeeby described the current state of the EHR system. Since its implementation in August 2004, more than 550,000 patients have relied on the system. With 74,000 patient portal accounts, expectations for fast, reliable access are growing, and the CC's 4,000 telehealth visits each year demand modern, secure tools for virtual care. Over 1,400 active protocols strain an aging EHR system, making complex designs, drug tracking, and clinical research workflows harder to manage.

Delays in the current system slow the translation of discoveries into diagnostics, treatments, and prevention strategies. Scientific integrity relies on high-quality, reliable data, and critical research in chronic disease demands faster, cleaner data capture.

New EHRs now are very integrated with clinical information and other services. The CC has more than 15 major clinical information systems (e.g., separate systems for lab, radiology, surgery, and nutrition) and more than 280 interfaces that move data between these separate systems and CRIS. This lack of integration reduces efficiency.

Goals for the New EHR System

Goals for the new EHR system include streamlining patient throughput and clinical workflow to provide the patient story in a concise manner while reducing complexity to support system security patching, configuration, and customization. The new system will be designed to improve:

- Patient safety, experience, and engagement
- Quality of clinical care delivery
- Decision-making and communication across clinical and research care roles
- System availability

Critical Milestones and the Way Forward

The NIH CC Governing Board approved the project on May 18, 2023, and the MITRE Corporation was engaged to assist with Performance Work Statement development in 2023, while NIH and the Department of Health and Human Services reviewed funding options. In 2024, the EHR Modernization Executive Steering Committee (ESC) was formed, with 22 members representing CC clinical departments and administrative areas, NIH ICs, clinical care, and clinical research.

During 2026, a contract to complete the remaining models will be developed, the final acquisition documents and RFI will be prepared, market research will be conducted, and then a contract will be developed. Funding is being sought to complete the EHR acquisition.

Ms. Wehrlen detailed the ESC's role, provided an overview of a survey that was sent to CRIS users, and described the clinical workflow modeling process. This is a Complex Organizational Project with IT Components. Project success will require participation from NIH leadership, clinical leadership, prescribers, principal investigators, CC clinical departments, technicians, technical staff, and all CRIS users.

The ESC provides strategic oversight and leadership and makes executive-level decisions affecting how EHR modernization is achieved. These decisions affect the scope of the EHR modernization initiative, funding and acquisitions, organizational change management, risk identification and mitigation, and engagement with key partners and stakeholders, among other aspects. The ESC is accountable for program results and provides strategic guidance supporting the modernization initiative's goal to improve the health status of the NIH–CC patient partners while supporting sound clinical research.

In 2024, a 1,400-item survey was sent to 3,400 CRIS users; 10% responded and provided more than 700 comments on specific items. Clinical workflow modeling began in 2025, and the first 50 models were completed. Each model maps every step of every process and decision point in every staff member interaction with the EHR. Work was divided into three pillars: clinical, clinical research, and administrative. Initially, 50 models were prioritized, but the workflow modeling effort expanded to include other NIH components that will be using the EHR, such as NIDDK Phoenix, the National Institute on Drug Abuse facility in Baltimore, and the National Institute of Environmental Health Sciences facility in Research Triangle Park. Of the first 50 models, 37 have completed quality reviews and have been approved by the ESC.

Dr. McKeeby noted that CRIS is a complex, fragile organizational risk that requires a high number of skilled staff.

Discussion

The following discussion ensued:

- Mr. Baum asked whether new hires would have the skillsets needed to manage the new system. Dr. McKeeby responded that some of the positions require a year to train.
- Dr. Chin agreed that legacy systems like CRIS are resource- and people-intensive, and EHRs are often mentioned as a contributing factor to physician burnout. He asked whether the new EHR system will include AI ambient listening. Dr. McKeeby responded that some of the ICs are using it and the telehealth system has that function. However, users have been asked to stop until processes and policies are in place for it. The requirements include AI, machine learning, predictive modeling, and clinical decision support.
- Ms. Reel questioned whether creating and getting broad consensus on exhaustive requirements might be expending more time and energy than necessary. Dr. McKeeby replied that the process must comply with government procurement standards and broad buy-in will be key to implementation.
- Mr. Baum asked for more details about the procurement strategy (e.g., lowest cost or best value, negotiated or sealed bid). Mr. Aiyelawo responded that sensitive aspects of procurement cannot be discussed in a public forum. Dr. McKeeby added that the team had visited other institutions, such as Johns Hopkins and Mayo, and met all the government players.
- Dr. Devaskar asked whether the new system will be able to communicate with external institutions. Dr. McKeeby responded that continuity of care is part of the EHR requirements.
- Dr. Green acknowledged the incredible effort that has gone into keeping CRIS alive and the EHR modernization initiative.

Overview of the NIH Gene Therapy Task Force

James L. Gulley, M.D., Ph.D., Co-Director, Center for Immuno-Oncology, Center for Cancer Research, and Clinical Director, NCI

Dr. Gulley presented the history of the task force and the case for an in-house gene therapy vector production facility.

The task force was established to coordinate intramural gene therapy efforts across institutes and eliminate bottlenecks in advancing gene therapies in clinical trials at NIH. All 27 ICs participate, allowing the task force to operate across the Intramural Research Program (IRP).

For the past few years, vectors have been produced at outside entities, including a leading cell and gene therapy contract development and manufacturing organization (CDMO) based in Philadelphia, the Center for Breakthrough Medicines. Two vectors are currently advancing to clinical trials: one clinical-grade lentivirus vector and one research-grade vector earlier in development.

These experiences have demonstrated the increasing need for an in-house vector production facility. Fortunately, a facility already exists at the CC that could be repurposed for this: the T10 Terrace facility.

The Financial Case for an In-House Vector Production Facility

An in-house vector production facility is a prudent investment. The current process is too expensive and too slow. Production of one adenoviral (AAV) vector costs about $15 million, and time to establish contracts and scheduling at the external facility have delayed clinical trials for 12–24 months. Many CDMOs prioritize larger clinical trials that require more vectors, bumping smaller batches multiple times. Vector production for rare or ultra-rare trials does not fit large-lot economics.

An in-house facility would allow transparent and open discussions about how the manufacturing takes place, which will help accelerate similar efforts elsewhere, boost innovation, and ultimately reduce costs for users. Lessons learned while developing a gene therapy for one disease are directly applicable to similar efforts for other diseases.

The infrastructure in place in T10 offers significant advantages. The facility is complete and qualified, and its four independent suites permit powerful parallel manufacturing operations. Over the next 6 months, the facility will be used for gene and cell therapy manufacturing; after that, it could be available for vector manufacturing. Center for Cellular Engineering leadership and quality assurance/control infrastructure are already in place in the Department of Transfusion Medicine.

The task force proposes manufacturing a range of gene therapy and gene-related products for internal efforts, including AAV, lentiviral, and retroviral vectors; antisense oligonucleotides; and lipid nanoparticles. These would be small-batch productions for first-in-human studies, which is ideal for rare diseases.

The cost of gene therapy is often beyond what a single investigator or laboratory can afford. A centralized facility would create opportunities for advancing brilliant ideas from the lab into the clinic.

Start-up would be approximately $25 million over 5 years, including $3 million per year for FY27–28 and $4 million per year for FY27–31, plus $3 million in upgrades.

Leveraging Unique Opportunities

No other place in the U.S. has all the elements needed to build a gene therapy pipeline to help people with rare diseases. The IRP is unique in this regard. An in-house facility would allow the CC to conduct small studies for patients with rare genetic diseases, cancers, and neurological diseases at an affordable scale, while using taxpayer dollars more efficiently and giving investigators greater flexibility.

Discussion

The following discussion ensued:

- Dr. Chin noted that financial return may be understated and asked whether the proposal has been approved. Dr. Gulley replied that the infrastructure is largely in place. Additional personnel with expertise in vector production will need to be hired; those costs were included in the estimates. Assessment studies are under way for operational feasibility. This is a win for the IRP. Mr. Aiyelawo noted that there is more work to be done.

- Dr. Devaskar asked whether the facility would be available to extramural investigators. Dr. Gulley responded that the plan is to use it internally first, and if there is extra bandwidth, there might be opportunities to use it for select collaborative intramural/extramural projects. One idea being discussed by NCI is to bring in the best ideas from the extramural community to run intramural clinical trials.
- Mr. Baum asked whether additional regulatory bodies might require inspections of the T10 facility. Dr. Colleen Hadigan responded that T10 is already an aseptic processing facility, and some products being used may be adjusted, but the regulatory bodies reviewing it would not change.
- Dr. Gulley commented that staff have the physical space to do all the cell therapy manufacturing for the foreseeable future. The vector production would not slow down those other efforts.

Final Discussion

- Ms. Royster suggested having persons with disabilities tour the SRLM to identify potential accessibility concerns. Mr. Aiyelawo noted that this is being worked on.
- Dr. Green reported that Mr. Leslie had left the meeting early due to his father's death.

Closing Remarks and Adjournment

Dr. Green thanked CCRHB members and presenters and adjourned the meeting at 12:26 p.m. EDT.

_____/s/_____ _August 21, 2026_

Mr. Jack Leslie

Chair, NIH Clinical Center Research Hospital Board

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

Definitions of Abbreviations and Acronyms

AAV	adenoviral
AI	artificial intelligence
CC	Clinical Center
CCRHB	Clinical Center Research Hospital Board
CDMO	contract development and manufacturing organization
CEO	chief executive officer
CIO	chief information officer
COO	chief operating officer
CRIS	Clinical Research Information System
EHR	electronic health record
ESC	EHR Modernization Executive Steering Committee
EVP	executive vice president
FNIH	Foundation for the National Institutes of Health
FY	fiscal year
GME	Graduate Medical Education
GPT	generative pre-trained transformer
ICs	Institutes and Centers
ICU	intensive care unit
IRP	Intramural Research Program
NCI	National Cancer Institute
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
OCPL	Office of Communications and Public Liaison
OPR	Office of Patient Recruitment
OPSQC	Office of Patient Safety and Quality Care
RFI	Request for Information
SCSU	Special Clinical Studies Unit
SRLM	Surgery, Radiology, and Laboratory Medicine
UCLA	University of California, Los Angeles